



are not required to participate in the Medicaid program. Rather, participation is voluntary and drug manufacturers must affirmatively elect to participate by signing a contract with the federal government. By doing so, a drug manufacturer is entitled to have its drugs reimbursed by state Medicaid programs. Since at least 1993, Sandoz has chosen voluntarily to participate in Medicaid, thereby requiring the Wisconsin Medicaid program to reimburse providers (primarily retail pharmacies) who dispense Sandoz's drugs.

Both federal and Wisconsin law limit the amount that the Wisconsin Medicaid program may reimburse providers for drugs dispensed to Medicaid beneficiaries to the providers' "estimated acquisition cost" ("EAC") plus a dispensing fee. The EAC is defined as the "best estimate of the price generally and currently paid by providers." Because of the large number of drug manufacturers that have chosen to participate in the Medicaid program, there are thousands of drugs that may be dispensed by a provider to a Medicaid beneficiary. In order to estimate the acquisition cost of these thousands of drugs efficiently and in an automated manner, the Wisconsin Medicaid program has relied on pricing information published by First DataBank, the largest electronic source of drug pricing information. During the relevant time period, the Wisconsin Medicaid program has estimated the acquisition cost of prescription drugs through formulae that rely on the average wholesale prices ("AWPs") published by First DataBank, ranging from AWP minus 10% to the present AWP minus 13%.

Sandoz does not dispute that it sets and controls the AWPs for its drugs that are published by First DataBank and upon which the Wisconsin Medicaid program relies in estimating provider acquisition cost. Nor does Sandoz dispute that the AWPs it reports and causes First DataBank to publish are not the true average prices charged by wholesalers. In fact, Sandoz admits that its AWPs are not prices that any purchasers pay for Sandoz's drugs. In addition,

Sandoz admits that it sets and controls the wholesale acquisition costs (WACs) for its drugs that are published by First DataBank. Sandoz further admits that the WACs it reports and causes First DataBank to publish are not the true net prices paid by wholesalers to Sandoz to acquire Sandoz's drugs. Rather, Sandoz admits that its WACs are simply the prices that appear on invoices sent by Sandoz to wholesalers, but do not reflect rebates, discounts, chargebacks, and similar items that reduce the wholesalers' true cost to purchase Sandoz's drugs. Sandoz keeps these rebates and discounts secret and requires those who receive the benefit of such rebates and discounts to keep them secret as well. These rebates, discounts, and other items reduce the true price of Sandoz's drugs by as much as 90% below WAC.

Sandoz has violated Wis. Stat. 100.18(1), which prohibits any representation with the intent to sell that contains any assertion that is untrue, deceptive or misleading. Indeed, it is well-established that it is unlawful to publish a price of any kind, regardless of the name attributed to the price, where no significant sales are made at that price. Because Sandoz admits that no purchaser pays the published AWP for Sandoz's drugs, Sandoz has violated Section 100.18(1).

Sandoz has also violated Wis. Stat. 100.18(10)(b), which declares it unlawful to represent a price as a "wholesale" price when retailers are in fact paying less. Sandoz's conduct violates Section 100.18(10)(b) because retail pharmacies pay substantially less than the published AWPs for Sandoz's drug.

By keeping secret the discounts and rebates it pays to purchasers and requiring those purchasers to keep the discounts and rebates secret as well, Sandoz has also violated Wis. Stat. 133.05(1), which prohibits the "secret payment or allowance of rebates, refunds, commissions or unearned discounts . . ."

Finally, by reporting and causing to be published false and inflated AWP's that the Wisconsin Medicaid program has relied on in determining how much to reimburse providers, Sandoz has violated the Wisconsin Medicaid Fraud Act, Wis. Stat. 49.49(4m)(a)(2), which prohibits the making of "any false statement or representation of a material fact for use in determining rights to a benefit or payment" in connection with medical assistance.

Notwithstanding these clear violations of law, the State expects Sandoz to argue that liability cannot be established because Wisconsin employees knew or should have known that discounts were being given to providers, resulting in average acquisition costs that were less than the published AWP's. This argument fails for several reasons. First, liability under the relevant statutes exists upon the publication of a false price. No more needs to be proven, and nothing else is relevant to the determination of liability. None of the elements of these claims examines the knowledge, beliefs, action, or inaction, of the State. Second, Sandoz's argument is an estoppel argument that is not available to Sandoz as a matter of law. Third, Sandoz's argument misplaces the burdens and duties. The State has no duty to modify its Medicaid program to account for Sandoz's misconduct. Rather, Sandoz has a duty to be honest and truthful with the State where, as here, Sandoz knows that the AWP's it sets, controls, and causes to be published will determine the amount of taxpayer dollars spent by the Wisconsin Medicaid program for Sandoz's drugs.

## **II. CLAIMS**

Wisconsin seeks summary judgment on liability as to Counts I through IV of its Second Amended Complaint.<sup>1</sup>

### **A. Count I - Wis. Stat. 100.18(1)**

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<sup>1</sup> The State is not at this time moving for summary judgment on Count V of the Second Amended Complaint, the unjust enrichment claim.

This statute provides:

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

- Elements:
- (1) an advertisement, announcement, statement or representation
  - (2) containing a statement that is untrue, deceptive or misleading
  - (3) with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase, sale, hire, use or lease of any real estate, merchandise, securities, employment or service

The statement need not be made with knowledge as to its falsity or with an intent to defraud or deceive.

Sources:

*State v. American TV & Applicant of Madison, Inc.*, 146 Wis.2d 292, 300 (1988)  
Wisconsin Pattern Jury Instructions, Civil § 2418

**B. Count II - Wis. Stat. 100.18(10)(b)**

This statute states: "It is deceptive to represent the price of any merchandise as a manufacturer's or wholesaler's price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise."

- Elements:
- (1) a representation
  - (2) that the price of any merchandise is a wholesale price

- (3) when retailers regularly pay less than the wholesale price for the merchandise

Sources: Plaintiff has been unable to locate any case law or Wisconsin pattern jury instruction that identifies the elements of this claim. The elements are evident from the plain language of the statute.

**C. Count III - Wis. Stat. 133.05(1)**

This statute provides in pertinent part:

The secret payment or allowance of rebates, refunds, commissions or unearned discounts, whether in the form of money or otherwise, or the secret extension to certain purchasers of special services or privileges not extended to all purchasers purchasing upon like terms and conditions, such payment, allowance or extension injuring or tending to injure a competitor or destroying or tending to destroy competition, is an unfair trade practice and is prohibited.

Elements:

- (1) the payment or receipt of secret rebates, refunds, commissions or unearned discounts
- (2) that had or tended to have an injurious effect on a Wisconsin competitor, OR that destroyed or tended to destroy competition in Wisconsin.

Sources: Plaintiff has been unable to locate any case law or Wisconsin pattern jury instruction that identifies the elements of this claim. The elements are evident from the plain language of the statute.

**D. Count IV - Wis. Stat. 49.49(4m)(a)2**

This statute provides in pertinent part: “No person, in connection with medical assistance, may . . . 2. Knowingly make or cause to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment.”

Elements:

- (1) knowingly making or causing to be made a false statement or representation
- (2) of a material fact

- (3) for use in determining rights to a benefit or payment
- (4) in connection with medical assistance.

Sources: Plaintiff has been unable to locate any case law or Wisconsin pattern jury instruction that identifies the elements of this claim. The elements are evident from the plain language of the statute.

### III. PROPOSED UNDISPUTED FACTS

1. Medicaid is a joint program between the federal government and participating States that provides medical assistance, including prescription drug benefits, to the poor, elderly, disabled, and blind. 42 U.S.C. § 1396, *et seq.*; Transcript of January 25, 2007 deposition of Sandoz corporate designee Ronald Hartmann, Director of Government Affairs (“Hartmann Tr.”), at 28-29.<sup>2</sup>

2. Since 1991, the State of Wisconsin has participated in the Medicaid program and provided a prescription drug benefit to program participants. Hartmann Tr. at 29.

3. Drug manufacturers are not required to participate in the Medicaid program; rather, they must elect to participate. Hartmann Tr. at 29-30.

4. Drug manufacturers who wish to participate in the Medicaid program and have their prescription drugs reimbursed by participating state Medicaid programs must sign a written contract with the federal government known as a rebate agreement. 42 U.S.C. § 1396r-8, *et seq.*; Hartmann Tr. at 32-33.

5. If a drug manufacturer chooses to participate in the Medicaid program by signing a rebate agreement with the federal government, the Wisconsin Medicaid program is required to reimburse pharmacies for any drug covered by the program. *See Exhibit 3 - Pharmacy Handbook – Covered Services and Reimbursement, July 2001, at 9.*

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<sup>2</sup> Excerpts of the deposition of Ronald Hartmann are attached hereto as Exhibit 1.

6. Most of the large drug manufacturers have elected to participate in Wisconsin's Medicaid program. *See* Exhibit 4, Manufacturer Table (listing the drug manufacturers who have signed federal rebate agreements).

7. Sandoz Inc. ("Sandoz") is a manufacturer of generic drugs. Hartmann Tr. at 25.

8. A generic drug is the chemical equivalent to a brand named drug. Hartmann Tr. at 25-26.

9. Prior to 2002, Sandoz was known as Geneva Pharmaceuticals Inc. ("Geneva"). Hartmann Tr. at 24-25; Transcript of January 25, 2007 deposition of Sandoz corporate designee Hector Armando Kellum, Manager of Trade Pricing and Analysis ("Kellum Tr."), at 49-50.<sup>3</sup>

10. Since 1993, Sandoz has chosen voluntarily to participate in the Medicaid program. Hartmann Tr. at 30.

11. Sandoz believes that as a corporate citizen it has a duty to know everything about the Medicaid program. Hartmann Tr. at 36-37.

12. For a general description of the Wisconsin Medicaid program's coverage, including eligibility requirements, *see* Pharmacy Handbook - Claims Submission Section, July 2001 (Exhibit 5 at 3, *et. seq.*) and Wisconsin Medicaid Program, 2006 (Exhibit 6 at 2-3, 6).

13. A retail pharmacy is a public pharmacy with a physical "brick and mortar" location such as Walgreens, CVS, or Wal-Mart that is open to anyone who has a prescription. Hartmann Tr. at 41-42.

14. The Wisconsin Medicaid program reimburses providers such as retail pharmacies for prescription drugs in the following manner:

15. A Medicaid patient obtains a prescription from a doctor and takes the prescription to a pharmacy that participates in the Medicaid program to be filled. Hartmann Tr. at 41.

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<sup>3</sup> Excerpts of the deposition of Hector Armando Kellum are attached hereto as Exhibit 2.

16. There are thousands of prescription drugs for which a Medicaid patient might obtain a prescription from a doctor. Hartmann Tr. at 43-44.

17. The pharmacy fills the prescription and electronically sends information regarding the prescription to the Wisconsin Medicaid program. Hartmann Tr. at 42-43.

18. The Wisconsin Medicaid program makes a payment, known as reimbursement, to the pharmacy for the prescription. Hartmann Tr. at 43.

19. Both federal and Wisconsin law limit the amount that the Wisconsin Medicaid program may reimburse a provider for a prescription drug.

20. For generic (also known as multiple source) drugs, such as those manufactured and sold by Sandoz, the federal government may set a specific limit, known as a Federal Upper Limit (“FUL”) when there are at least three suppliers of the drug. The FUL is equal to “150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.” 42 C.F.R. § 447.332.

21. Where an FUL has been established, federal law prohibits a state Medicaid agency from paying more than the FUL plus a reasonable dispensing fee. 42 C.F.R. § 447.332.

22. Where no FUL has been established, federal law provides that a state Medicaid agency may pay no more than the lower of: (1) the estimated acquisition cost plus a reasonable dispensing fee established by the state Medicaid agency, or (2) the provider’s usual and customary charge to the general public. 42 C.F.R. § 447.331.

23. Federal law defines “estimated acquisition cost” as the state Medicaid agency’s “best estimate of the price generally and currently paid by providers for a drug marketed or sold

by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.” 42 C.F.R. § 447.301.

24. Sandoz understands “estimated acquisition cost” as used in 42 C.F.R. § 447.301 to mean the price a retail pharmacy paid to acquire a drug. Hartmann Tr. at 47-48.

25. Wisconsin law provides that the Wisconsin Medicaid program shall reimburse a Medicaid provider such as a retail pharmacy the lowest of: (1) estimated acquisition cost; (2) the provider’s usual and customary charge to the general public; (3) the FUL if one has been established; and (4) the state Maximum Allowable Cost. *See* Exhibit 7, Wisconsin Department of Healthcare and Family Services, Pharmacy Terms of Reimbursement.

26. Wisconsin determines estimated acquisition cost based on the Department of Healthcare and Family Services’ best estimate of prices currently and generally paid for pharmaceuticals” using “either Maximum Allowable Costs (MAC) or discounted published average wholesale prices” Exhibit 7.

27. From 1990 to the present, Wisconsin has estimated the acquisition cost of prescription drugs through formulac that rely on the published average wholesale price (“AWP”) ranging from AWP minus 10% to the present AWP minus 13%. *See, e.g.*, Exhibits 8 and 9 (showing the reimbursement formula in different years).

28. The Wisconsin Medicaid program’s source for the AWP’s it uses to estimate acquisition cost is First DataBank, with whom it contracts to provide current AWP’s electronically. Exhibit 6, at 4, 40.

29. First DataBank has on more than one occasion informed its subscribers that its published AWP’s are averages of actual prices paid by retailers. For example, in 1991, First

DataBank stated that “AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.” Exhibit 11.

30. In 1999, First DataBank stated: “As you know, AWP represents the average wholesale price; the average price a wholesaler would charge a customer for a particular product.” Exhibit 12.

31. The Wisconsin Medicaid program processes claims for reimbursement from Medicaid providers in the following manner:

32. At the time a prescription is presented to a pharmacy, the pharmacy electronically submits a real-time claim to EDS (the fiscal intermediary with whom the Wisconsin Medicaid contracts) through a Point-of-Sale (POS) claims processing system. Upon receipt, the POS system monitors the reimbursement claim for eligibility, covered drugs, Medicaid cost containment policies, and pricing. EDS then sends a real time response which includes the authorized payment and any patient liability (such as a co-payment). Thereafter EDS sends Remittance and Status Reports (R&S) to Medicaid certified providers for paid claims. Exhibit 5 at 5-7.

33. First DataBank sends its current average wholesale prices (AWPs) for the thousands of drugs listed in its database (each of which is identified by a unique 11-digit number known as a National Drug Code or “NDC”) to EDS on a weekly basis and this information is entered into EDS’s claims processing system. These prices become the basis for Wisconsin’s determination of estimated acquisition cost. Exhibit 3 at 17; Exhibit 10 - “At-A-Glance” Summary of Most of 2007 Financial Eligibility/Rates in Long Term Support, at 7.

34. Sandoz sets an AWP (Average Wholesale Price) and a WAC (Wholesale Acquisition Cost) for its drugs. Kellum Tr. at 75.

35. Since January 1, 1993, Sandoz has reported the AWP's and WACs that it sets for each of its drugs to price reporting services including First DataBank and the Red Book. Kellum Tr. at 37-38; 53-54.

36. Since January 1, 1993, Sandoz has reported the same AWP's and WACs to First DataBank and the Red Book. Kellum Tr. at 57.

37. Sandoz reports AWP's and WACs to First DataBank because its customers expect it. These customers include retail pharmacies that are reimbursed by the Wisconsin Medicaid program. Kellum Tr. at 42-47.

38. Hector Armando Kellum, Sandoz's corporate designee, testified at deposition:

Q: So, back to that, one of the reasons that Sandoz has chosen to report AWP's and WAC's, to the pricing publications like First Data Bank is because Sandoz's customers expect and want Sandoz to do that; is that correct?

A: That is correct.

Q: And that is because those prices affect the reimbursement of those customers; is that correct?

A: I believe that's correct, yes.

Q: And the reimbursement -- these customers by the way are reimbursed by among other entities, state Medicaid programs; is that correct?

A: That's my understanding, that some of our customers are reimbursed by state Medicaid programs, yes.

Kellum Tr. at 46-47.

39. When Sandoz reports AWP's and WACs to First DataBank, Sandoz intends for First DataBank to publish the identical AWP's and WACs. Kellum Tr. at 55.

40. First DataBank publishes the identical AWP's and WACs that Sandoz sets and reports to First DataBank. Kellum Tr. at 75-76.

41. Sandoz knows that First Data Bank takes the AWP's and WACs that Sandoz reports to it and publishes those identical AWP's and WACs. Kellum Tr. at 55-56.

42. In each of the few instances where First DataBank did not publish the identical AWP or WAC that Sandoz reported to First DataBank for a Sandoz drug, Sandoz advised First DataBank of this fact and First DataBank published the corrected AWP or WAC as requested by Sandoz. Kellum Tr. at 56-57.

43. In addition, First DataBank has asked Sandoz to verify the AWPs and WACs that First DataBank intends to publish for Sandoz's drugs. Kellum Tr. at 57-58.

44. When First DataBank has asked Sandoz to verify the AWPs and WACs that First DataBank intends to publish for Sandoz's drugs, Sandoz has in fact verified them. Kellum Tr. at 58.

45. In some instances, Sandoz determined that corrections needed to be made to the AWPs or WACs that First DataBank had asked Sandoz to verify. In each of those instances, Sandoz reported the corrected AWPs or WACs to First DataBank and First DataBank published the corrected AWPs or WACs reported by Sandoz. Other than these instances, Sandoz has never taken any action to stop, object to, or otherwise oppose the publication of the AWP or WAC for any of its drugs by First DataBank or two other price reporting compendia -- Red Book and Medispan. Kellum Tr. at 58, 73, 76-77.

46. Sandoz knows the AWPs and WACs for its drugs that First DataBank publishes because Sandoz purchases a product called Analysource from First DataBank which includes the AWPs and WACs for Sandoz's drugs. Kellum Tr. at 59-60.

47. Sandoz understands that state Medicaid programs purchase electronic pricing information from First DataBank, including AWPs and WACs. Hartmann Tr. at 60-61, 66-67.

48. Sandoz believes that First DataBank is the largest repository of electronic pricing information for prescription drugs. Kellum Tr. at 68.

49. When Sandoz sends price proposals or bids to potential customers regarding Sandoz's drugs, Sandoz provides not only the proposed bid or contract price, but also the AWP for the drugs. Sandoz does this because it knows that at least in some instances, reimbursement for Sandoz's drugs is based on AWP. Kellum Tr. at 210-212.

50. The AWP for Sandoz's drugs that Sandoz reports to First DataBank and that are published by First DataBank are not the average prices at which wholesalers sell Sandoz's drugs. Kellum Tr. at 90-91.

51. Hector Armando Kellum, Sandoz's corporate designee, testified at deposition:

Q: . . . Would you agree that the average wholesale prices that Sandoz reports and the First Data Bank publishes for the Sandoz drugs, is in fact, more than what retailers regularly pay for Sandoz drugs?

MR. GALLAGHER: Objection to the form.

A: My understanding is that you know, based on data that I have looked at, that typically, retailers pay less than the generic AWP, that we have listed with First Data Bank.

Kellum Tr. at 193.

52. Sandoz has no information showing that any of its drugs were purchased by retail pharmacies at a price equal to or greater than the then current AWP published by First DataBank or Redbook since 1993. Kellum Tr. at 102.

53. In those instances in which Sandoz sells its drugs directly to retail pharmacies, it knows that retail pharmacies have paid less than the AWP for the drugs that Sandoz reports to First DataBank and that First DataBank publishes because WAC is the highest contract price paid by a retail pharmacy that buys directly from Sandoz and WAC is always lower than AWP. Kellum Tr. at 109-111.

54. In those instances in which Sandoz sells its drugs indirectly to retail pharmacies through wholesalers and there is a contract between Sandoz and the retail pharmacy that establishes the price to be paid by the retail pharmacy, the contract price paid by the retail pharmacy is typically lower than the WAC, which is always lower than the AWP for the drugs reported by Sandoz to First DataBank and published by First DataBank. Kellum Tr. at 115-116.

55. Because the AWP for a Sandoz drug is always higher than the WAC for that drug, Sandoz knows that when it sells its drugs to retail pharmacies through wholesalers, the retail pharmacy is paying less than the AWP for the drug. Kellum Tr. at 123-124.

56. Sandoz defines WAC as the price on the invoice to a wholesaler. Kellum Tr. at 91, 259-260.

57. WACs that Sandoz reports and causes First DataBank to publish do not include various discounts, rebates, and chargebacks. Kellum Tr. at 91-98. Accordingly, the WACs that Sandoz reports and causes First DataBank to publish for Sandoz's drugs are not the true net prices paid by wholesalers to Sandoz.

58. As Mr. Kellum testified at deposition:

Q: Can you explain what a charge-back is?

A: Sure. Going through our sale to the wholesaler we sell to a wholesaler at WAC. At that point in time we don't know exactly where that product will eventually be distributed to. So he could sell it at WAC. He could sell it at a contracted price to or at a price to his source program or he could sell it to one of our customers at our contracted price with the customer. When he does that, that contracted price is typically below WAC. So, he is actually selling it to them at below his original acquisition costs. And that charge back is an accounting mechanism to make him whole for selling it at that price.

Q: And these charge backs or rather the contract price that is honored that results in the charge-back, those are not reflected in the WAC's that Sandoz reports to First Data Bank; is that correct?

A: No, they are not.

Kellum Tr. at 163-164.

59. Amerisource Bergen is a national drug wholesaler. Kellum Tr. at 98-99.

60. Sandoz offers numerous rebates and discounts to drugs wholesalers such as Amerisource Bergen. One document produced by Sandoz in discovery identifies potential rebates of up to 33.9% that Amerisource Bergen could earn in 2004. Exhibit 13 (2004 AmerisourceBergen ProGenerics RFP Offering). These rebates and discounts are deducted from WAC but are not reflected in the WACs that Sandoz reports to First DataBank and that First DataBank publishes. Kellum Tr. at 94-95, 98-101.

61. In those instances in which Sandoz sells its drugs indirectly to a retail pharmacy through a wholesaler and there is a contract in place between Sandoz and the retail pharmacy that sets the price, that contract price is always lower than WAC. The contract price could be as much as 90% below WAC. Kellum Tr. at 115-116.

62. Sandoz sets a WAC and AWP for its generic drugs at the time that it launches, or introduces, a new generic product into the market. The rule of thumb that Sandoz uses to set its AWP at the time it launches a new product is to set the AWP at 10% below the published AWP for the brand name drug to which the Sandoz generic drug is equivalent. Sandoz then sets the WAC for its generic drug at 20% below the AWP for the generic drug. Kellum Tr. at 77-78.

63. As time passes and competition increases, the WAC and the true contract prices for Sandoz's drugs fall. Although Sandoz reports a lower WAC as the contract price falls, it does not report a lower AWP. Accordingly, the spreads between the true contract prices and the published AWP's can be thousands of percents. Kellum Tr. at 81, 126-127.

64. As an example, in October 2002, Sandoz reported and caused to be published an AWP for the drug atenolol (NDC 00781-1507-10) of \$1,188.93 and a WAC of \$154.57. Kellum Tr. at 124-125; Exhibit 14 (Redbook Product Listing Verification dated October 21, 2002).

65. Sandoz cannot explain why it reported and caused to be published an AWP for atenolol (NDC 00781-1507-10) of \$1,188.93 in October 2002 when it knew that the true market price for the drug was less than \$154.57. Kellum Tr. at 128-129.

66. As another example, in April 2004, Sandoz reported and caused to be published an AWP for atenolol (NDC 00781-1506-10) of \$792.49 even though the price to retail chain drug stores such as Walgreens and CVS was \$36.15. Kellum Tr. at 141-153; Exhibit 15 (Sandoz Price List Updated April 26, 2004).

67. Exhibits 14-15 contains numerous examples of drugs for which Sandoz reported and caused to be published AWP's that were hundreds, and in some instances, thousands of percents higher than the true average prices paid by retail pharmacies for the drugs. Exhibits 14-15.

68. Sandoz has no policy requiring it to lower the AWP or WAC for any of its drugs when the market price for any of its drugs drops. Kellum Tr. at 88-89.

69. Sandoz has no policy prohibiting it from raising the AWP or WAC for any of its drugs when the market price for any of its drugs has not changed. Kellum Tr. at 89.

70. Sandoz cannot identify any business reason for raising the AWP or WAC of any of its drugs when the Sandoz contract price for the drug has not changed. Kellum Tr. at 132.

71. In January 2003, Sandoz increased the AWP and WAC for two forms of the drug cefadroxil (NDCs 59772-727103 and 59972-727104) even though the contract price for these drugs had not changed. Kellum Tr. at 134-136; Exhibit 16 (January 16, 2003 e-mail from Kevin Galownia to Kimberly Lembo).

72. Sandoz goes to great lengths to keep secret the prices it charges for its drugs. Kellum Tr. at 180-181.

73. There is a standard provision in all contracts between Sandoz and wholesalers or retail pharmacies requiring that they keep confidential the true net prices they pay. Kellum Tr. at 181-182.

#### **IV. ARGUMENT**

##### **SUMMARY JUDGMENT ON LIABILITY SHOULD BE GRANTED FOR THE STATE OF WISCONSIN.**

The Medicaid program was well intentioned and well designed. It was intended to help the neediest in society obtain basic health care, and it was designed to do so at the lowest cost to the taxpayers by limiting the payment to providers to no more than their acquisition cost plus a dispensing fee. The Wisconsin Medicaid program estimates acquisition cost by relying on pricing information supplied by First DataBank, the largest source of electronic pricing information, which obtains its pricing information directly from the drug manufacturers. As a result, Wisconsin's drug reimbursement system has been, and remains, almost completely dependent on drug manufacturers' reported prices. Sandoz has taken advantage of this fact. Sandoz admits that it sets and controls the AWP's that are published by First DataBank. Sandoz further admits that its AWP's are not the true average prices charged by wholesalers. These admissions establish liability as a matter of law under Counts I through IV of the State's Second Amended Complaint.

##### **A. Factual Background Regarding the Medicaid Program.**

Medicaid is a joint program between the federal government and participating states to provide medical assistance, including prescription drug benefits, to the neediest and most vulnerable populations in society – the poor, elderly, disabled, and blind. PUF 1. The program is voluntary rather than mandatory. Drug manufacturers must affirmatively elect to participate. PUF 3. Since at least 1993, Sandoz has elected to participate in the Medicaid program, thereby

requiring the Wisconsin Medicaid program to reimburse providers for Sandoz's drugs. PUF 10. By electing voluntarily to participate in Medicaid, Sandoz must comply with certain rules. The first of these is the general rule applicable to all businesses benefiting from public expenditures:

Justice Holmes wrote: 'Men must turn square corners when they deal with the government.' *Rock Island, A. & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). This observation has its greatest force when a private party seeks to spend the Government's money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.

*Heckler v. Community Health Servs.*, 467 U.S. 51, 63 (1984).

Under federal law, for generic drugs for which there is no Federal Upper Limit, the rule provides that the state Medicaid program must pay no more than the lower of the "estimated acquisition cost" plus a reasonable dispensing or the providers' usual and customary charges to the general public. PUF 22; 42 C.F.R. § 447.331(b). For generic drugs for which there is a Federal Upper Limit, Wisconsin law provides the rule: the state Medicaid program must pay the lower of estimated acquisition cost, the FUL, the state Maximum Allowable Cost, or the provider's usual and customary charge. PUF 25. Federal law defines "estimated acquisition cost" as the state Medicaid agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." PUF 23; 42 C.F.R. § 447.301. Sandoz understands "estimated acquisition cost" as used in 42 C.F.R. § 447.301 to mean the price a retail pharmacy paid to acquire a drug. PUF 24. Not only is Sandoz expected to be aware of these rules, *Heckler*, 467 U.S. at 63, Sandoz admits that as a corporate citizen, it has a duty to be familiar with these rules. PUF 11.

Because of the large number of drug manufacturers that have chosen to participate in the Medicaid program, there are thousands of drugs that may be dispensed by a provider to a Medicaid beneficiary. PUF 16. In order to estimate the acquisition cost of these thousands of drugs efficiently and in an automated manner, the Wisconsin Medicaid program has relied on pricing information published by First DataBank, the largest electronic source of drug pricing information. PUF 27-28, 48. First DataBank purports to provide Wisconsin with truthful average wholesale prices (“AWPs”). As it explained in 1999, “As you know, AWP represents the average wholesale price; the average price a wholesaler would charge a customer for a particular product.” PUF 30; Exhibit 12. During the relevant time period, the Wisconsin Medicaid program has estimated the acquisition cost of prescription drugs through formulae that rely on the average wholesale prices (“AWPs”) published by First DataBank, ranging from AWP minus 10% to the present AWP minus 13%. PUF 27.

#### **B. Sandoz’s Unlawful Conduct**

Sandoz does not dispute that it sets and controls the AWP for its drugs that are published by First DataBank and upon which the Wisconsin Medicaid program relies in estimating provider acquisition cost. PUF 34-35, 39-47. Nor does Sandoz dispute that the AWP it reports and causes First DataBank to publish are not the true average prices charged by wholesalers. PUF 50-51. Rather, Sandoz admits that the AWP it reports and causes First DataBank to publish are far above the true average prices charged by wholesalers. PUF 50-55. Stated differently, Sandoz admits that retail pharmacies pay far less than AWP to acquire Sandoz’s drugs. As an example, in October 2002, Sandoz reported and caused to be published an AWP for the drug atenolol (NDC 00781-1507-10) of \$1,188.93 when it knew that the true market price for the drug was less than \$154.57. PUF 64, Exhibit 14. This means that the AWP was more

than seven times the true price. Sandoz cannot provide any business reason for this. PUF 65. As another example, in April 2004, Sandoz reported and caused to be published an AWP for atenolol (NDC 00781-1506-10) of \$792.49 even though the price to retail chain drug stores such as Walgreens and CVS was \$36.15. PUF 66. This means that the AWP was nearly 22 times the true price. Exhibits 14-15 contain numerous examples of additional drugs for which Sandoz reported and caused to be published AWP's that were hundreds, and in some instances, thousands of percents higher than the true average prices paid by retail pharmacies for the drugs. PUF 67.

Moreover, although Sandoz cannot identify any business reason for raising the AWP or WAC of any of its drugs when the Sandoz contract price for the drug has not changed, PUF 70, Sandoz did just that in January 2003, increasing the AWP and WAC for two forms of the drug cefadroxil (NDCs 59772-727103 and 59972-727104) even though the contract price for these drugs had not changed. PUF 71.

In addition, Sandoz admits that it sets and controls the wholesale acquisition costs ("WACs") for its drugs that are published by First DataBank. PUF 33-35, 39-47. Sandoz further admits that the WACs it reports and causes First DataBank to publish are not the true net prices paid by wholesalers to Sandoz to acquire Sandoz's drugs. Rather, Sandoz admits that its WACs are simply the prices that appear on invoices sent by Sandoz to wholesalers, but do not reflect rebates, discounts, chargebacks, and similar items that reduce the wholesalers' true cost to purchase the drugs from Sandoz. PUF 56-60. Sandoz keeps these rebates and discounts secret and requires those who receive the benefit of such rebates and discounts to keep them secret as well. PUF 72-73. These rebates, discounts, and other items reduce the true price of Sandoz's drugs by as much as 90% below WAC. PUF 61.

### **C. Sandoz's Conduct Violates Wisconsin Law**

1. Sandoz's Conduct Violates Wis. Stat. § 100.18(1).

a. Sandoz's Reporting and Publication of False Prices is Unlawful.

Wis. Stat. § 100.18(1) prohibits any representation with the intent to sell, distribute, or increase the consumption of merchandise when the representation contains any assertion, representation, or statement of fact that is untrue, deceptive or misleading. Sandoz's reporting and publication of false AWP's and WAC's clearly violate this statute. As the Wisconsin Supreme Court held almost twenty years ago, there are only two elements to this claim: (1) an advertisement or announcement must exist; and (2) the advertisement must contain a statement which is "untrue, deceptive or misleading." It is not necessary to prove that the statement was made with knowledge as to its falsity or with an intent to deceive or defraud. *State v. American TV & Appliance of Madison, Inc.*, 146 Wis.2d 292, 300 (1988); *see also* Wisconsin Pattern Jury Instructions, Civil § 2418. Rather, the only intent that must be demonstrated is the intent to sell, distribute or increase the consumption of the merchandise. The two required elements are easily established here.

As to the first element, Sandoz made an advertisement or announcement each time it reported and caused First DataBank to publish AWP's and WAC's for Sandoz's drugs. Sandoz reports and causes First DataBank to publish AWP's and WAC's for Sandoz's drugs because Sandoz's customers expect it. PUF 37-38. That is, Sandoz knows that third party payers, including state Medicaid programs such as Wisconsin's, rely on the published AWP's in determining how much to reimburse for Sandoz's drugs. PUF 38. In addition, Sandoz made an advertisement or announcement each time it sent a price proposal or bid to a potential customer which contained the AWP for a Sandoz drug. PUF 49.

As to the second element, each time Sandoz reported and caused First DataBank to publish AWP's and WACs for Sandoz's drugs, Sandoz made a "statement" that was "untrue, deceptive, or misleading." In fact, each statement was untrue, deceptive, and misleading.

Sandoz's statements were clearly untrue. The starting point for this analysis is the plain meaning of the term "average wholesale price." When faced with this question, Judge Saris of the United States District Court for the District of Massachusetts, who is presiding over the multidistrict litigation entitled *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 (D.Mass.), turned to her dictionary and determined that "average wholesale price" means exactly what it says: the average price paid for goods for resale. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277, 287-88 (D.Mass. 2006); *id.* at 278 ("the Court construes the statutory term according to its plain meaning and holds that AWP means the average price at which wholesalers sell drugs to their customers."). Other courts have defined the term "wholesale price" in a similar fashion. *E.g.*, *Federated Nationwide Wholesalers Service v. Federal Trade Commission*, 398 F.2d 253, 257 n.3 (2d Cir. 1968) ("[t]he term 'wholesale price' is generally defined as the price which a retailer pays to its source of supply when purchasing goods for resale to the ultimate consumer."); *Guess v. Montague*, 51 F.Supp. 61, 65 (E.D.S.Car. 1942) ("a wholesale price is that price which the retailer pays in the expectation of obtaining a higher price by way of profit from the ultimate consumer"). Where a term is undefined, Wisconsin courts also turn to the dictionary. *Jauquet Lumber Co. v. Kolbe & Kolbe Millwork Co.*, 164 Wis.2d 689, 698, 476 N.W.2d 305, 308 (Ct. App. 1991). Any dictionary the court chooses confirms Judge Saris' definition of the plain meaning of "average wholesale price."

A statement is “untrue” within the meaning of Wis. Stat. 100.18(1) when it “does not express things exactly as they are.” *Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis.2d 56, 65 n.3, 416 N.W.2d 670, 673 n.3 (Ct. App. 1987); *see also* Wisconsin Pattern Jury Instructions - Civil § 2418 (1998) (a statement is untrue “if it is false, erroneous, or does not state or represent things as they are.”). Importantly, what the public, the State, or any other purchaser understood about Sandoz’s AWP’s is irrelevant to the determination of truthfulness under the statute. *Tim Torres Enterprises*, 142 Wis.2d at 66; 416 N.W.2d at 674 (“When a statement is actually false, relief can be granted on the court’s own findings without reference to the reaction of the product’s buyers or consumers.”) (citing *American Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir.1978)); *see also Quaker State Oil Refining Corp. v. Burmah-Castrol, Inc.*, 504 F.Supp. 178, 182 (S.D.N.Y. 1980) (if advertising is false on its face, preliminary injunction may be granted without demonstrating that consumers were actually misled). Because Sandoz admits that the AWP’s it reports and causes First DataBank to publish are not the true average prices charged by wholesalers to retailers (PUF 50-51), Sandoz statements are “untrue” and violate Wis. Stat. 100.18(1).<sup>4</sup>

Sandoz’s statements were also “deceptive” and “misleading” within the meaning of Wis. Stat. 100.18(1). In construing its consumer protection statutes, Wisconsin looks to federal law interpreting the Federal Trade Commission Act, 15 U.S.C. § 45(a). *Tim Torres, Inc.*, 142 Wis.2d at 66-67, 416 N.W.2d at 674. That Act gives the Federal Trade Commission the power to bring suit to enjoin the dissemination “unfair” and “deceptive” acts or practices. To implement “the prophylactic purpose of the statute” it is not necessary to show that the misleading or deceptive statement was relied upon for there to be a violation of the law. *Tim Torres, Inc.*, 142 Wis.2d at

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<sup>4</sup> For the same reason, Sandoz’s conduct in reporting and publication of wholesale acquisition costs that Sandoz admits are not the true net prices paid by wholesalers to acquire drugs from Sandoz also violates the statute.

66-67; 416 N.W.2d at 674 (citing *Federal Trade Commission v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir.1963)). Rather, “[i]t is enough to show that the ‘representations made have a capacity or tendency to deceive, *i.e.*, when there is a likelihood or fair probability that the reader will be misled.’” *Id.*

Pricing information is material as a matter of law. *Federal Trade Commission v. Crescent Publ’g Group, Inc.*, 129 F.Supp.2d 311, 321 (S.D.N.Y. 2001) (“The materiality of [pricing] information cannot be denied. Information concerning prices or charges for goods or services is material, as it is “likely to affect a consumer’s choice of or conduct regarding a product.”) *Id.* (citing *In re Thompson Medical Co.*, 104 F.T.C. 648, 816 (1984), *aff’d*, 791 F.2d 189 (D.C.Cir. 1986)). As a consequence, it has been the law for over forty years that it is unlawful to publish a price, regardless of the name attributed to the price, where that price does not truly represent a price at which significant sales are made. This principle even applies to characterizations of prices as “suggested,” “suggested list,” or “manufacturer’s list” prices. For example, in *Giant Food, Inc. v. Federal Trade Commission*, 322 F.2d 977 (D.C.Cir. 1963), the D.C. Circuit affirmed the Federal Trade Commission’s determination that the use of the term “manufacturer’s list price” represented to the public that that was the price at which the product was usually and customarily sold by other stores in the area. Because this was not the case, Giant Food violated the Federal Trade Commission Act:

The Commission here has determined that the use of the term ‘manufacturer’s list price’ represents to the public that that was the price at which the product was usually and customarily sold by other stores in the area. This determination was within its power, unless it was ‘arbitrary or clearly wrong.’ \* \* \* If a manufacturer can be prevented from placing a deceptive price on its product, we see no reason to permit a retailer to make reference to a deceptive *suggested price*.

977 F.2d at 981-982 (emphasis added).<sup>5</sup> Numerous decisions of the Federal Trade Commission and federal courts are in accord. *E.g.*, *In re Regina Corporation*, 61 F.T.C. 983, 1962 WL 75514 (F.T.C. 1962) (dissemination of “suggested list prices” for products which were not the usual and customary prices at which the products were sold violated the Federal Trade Commission Act); *Regina Corp. v. Federal Trade Commission*, 322 F.2d 765 (3d Cir. 1963); *In re George’s Radio and Television Company, Inc.* 62 F.T.C. 179, 1962 WL 75744 (F.T.C. 1962) (finding it unlawful to advertise “manufacturer’s suggested list prices,” which conveys the impression that merchandise was usually and customarily sold at retail at such prices, where no substantial sales were made at that price).

Subsequent to these decisions, the Federal Trade Commission revised its pricing guidelines to provide that if a “list price” is significantly in excess of the highest price at which substantial sales in the trade area are made, there is a clear and serious danger of the consumer being misled by an advertised reduction from this price. FTC Guides Against Deceptive Pricing, 16 C.F.R. § 233.3(d). In *Helbros Watch Co. v. Federal Trade Commission*, 319 F.2d 868, 870 n.4 (D.C. Cir. 1962), the D.C. Circuit affirmed a determination by the Federal Trade Commission that where 40% of all sales of respondent’s products were made at prices substantially less than the preticketed price, this was sufficient to establish “fictitious pricing” in violation of the Federal Trade Commission Act.

Liability against Sandoz is even more compelling than in the above cases, because Sandoz did not report its prices as “suggested” or “list” prices. Rather, Sandoz repeated and consistently stated that its prices were “average wholesale prices,” without any qualifying

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<sup>5</sup> To the extent that Sandoz argues that its AWP’s are akin to an automobile “sticker prices,” *Giant Food* explains why automobile manufacturers can attach a “manufacturer’s suggested retail price” to their cars regardless of whether substantial sales are made at that price -- they are required to do so by a specific federal statute, 15 U.S.C. § 1231, *et seq.* *Giant Food*, 322 F.3d at 982. The pharmaceutical industry enjoys no similar protection.

language. PUF 35. Yet Sandoz knew that these were not the average prices charged by wholesalers to retailers. PUF 50-55. Because the undisputed facts establish that Sandoz (1) made advertisements or announcements containing (2) statements that were false, misleading, or deceptive, it has violated Wis. Stat. § 100.18(1).<sup>6</sup>

Wisconsin need not demonstrate that Sandoz acted with an intent to deceive or defraud. The only intent that must be demonstrated is an intent to sell, distribute, or increase the consumption of merchandise. Such intent is amply demonstrated here, where Sandoz has admitted that it reported and caused First DataBank to publish its AWP because Sandoz's customers, including retail pharmacies that are reimbursed by the Wisconsin Medicaid program, expect it, as they know that third party reimbursement depends on publication of Sandoz's AWP. PUF 37-38. Sandoz provides its AWP directly to potential purchasers (along with its proposed contract or bid price) for the same reason. PUF 49. These facts are sufficient to demonstrate the requisite intent under the statute.

b. Sandoz Cannot Escape Liability by Blaming First DataBank.

Sandoz cannot escape liability by attempting to shift responsibility to First DataBank. As an initial matter, Sandoz admits that it sets and controls the AWP and WACs that First DataBank publishes. PUF 34-35, 39-46. Indeed, in every instance in which First DataBank published an AWP or WAC that was different than the AWP or WAC that Sandoz had reported to it, Sandoz brought this to First DataBank's attention and requested that the AWP or WAC be changed. In every instance, First DataBank did what Sandoz asked it to do. PUF 42-45.

Second, the fact that First DataBank, rather than Sandoz, published the pricing information is irrelevant as a matter of law. "[D]irect participation in the fraudulent practices is

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<sup>6</sup> Although Sandoz's statements are only susceptible to one meaning, even where a statement is capable of two meanings, one of which is false, it is unlawful. See *Giant Food*, 322 F.2d at 981.

not a requirement for liability. Awareness of fraudulent practices and failure to act within one's authority to control such practices is sufficient to establish liability." *Federal Trade Commission v. Windward Marketing, Ltd.*, 1997 WL 33642380 at 13 (N.D.Ga. 1997) (citing *Federal Trade Commission v. Atlantex Assocs.*, No. 87-45, 1987 WL 20384, at \*9 (S.D.Fla. Nov.25, 1987), *aff'd*, 872 F.2d 966 (11th Cir. 1989)). Moreover, "[i]t is settled law that 'one who places in the hands of another a means of consummating a fraud or competing unfairly in violation of the Federal Trade Commission Act is himself guilty of a violation of the Act. . .'" *In re Coro, Inc.*, 63 F.T.C. 1164, 1963 WL 66825 (1963) (citing *C. Howard Hunt Pen Co. v. Federal Trade Commission*, 197 F.2d 273, 281 (3d Cir. 1952)); *see also Federal Trade Commission v. Winsted Hosiery Co.*, 258 U.S. 483, 494 (1922) ("That a person is a wrongdoer who so furnishes another with the means of consummating a fraud has long been a part of the law of unfair competition."); *Coca Cola Co. v. Gay-Ola Co.*, 200 F. 720 (6th Cir. 1912) (finding liability where defendant "deliberately furnished to the dealers the material for practicing the fraud"); *Von Mumm v. Frash*, 56 F. 830 (2d Cir. 1893) (finding liability where "defendants knowingly put into the hands of the retail dealers an article of the defendants' manufacture, so dressed up that, in the hands of the retail dealers, it is an effective means of deceiving the ultimate purchaser . . ."); *Idaho v. Master Distributors, Inc.*, 101 Idaho 447, 458 (1980) (finding liability where defendant created and furnished the sales program, participated in the hiring and training of sales personnel, and was involved on a nearly daily basis with the ongoing operation of the sales program that was unfair or deceptive).

For this reason, a defendant may be liable where it provides the means by which a false, deceptive, or misleading act or practice may be carried out. For instance, in *Baltimore Luggage Company v. Federal Trade Commission*, 296 F.2d 608 (4th Cir. 1961), respondent preticketed its

luggage with prices that the retailers were free to retain or remove. These prices were higher than the prices at which the luggage was actually being sold. As the court explained:

Although Baltimore's pretickets were sometimes removed by the retailers who sold the luggage at less than the preticketed price when the luggage was put on sale, generally the retailers left Baltimore's tickets on the luggage. Some stores also exhibited cards furnished by Baltimore showing the same price as that printed on Baltimore's tickets. The hearing examiner found, and the Commissioner adopted his findings, that by preticketing its luggage, and in some instances also by furnishing customers with display cards showing retail prices, Baltimore represented that the prices on the tickets and cards were the usual and regular retail prices, for its luggage, and that this representation was false in those trade areas where the luggage was usually and regularly sold at retail at approximately \$2.00 less.

*Id.* at 609. The court had no difficulty affirming the Federal Trade Commission's determination that this conduct was unlawful. *See also Clinton Watch Co. v. Federal Trade Commission*, 291 F.2d 838, 840 (7th Cir. 1961) ("[P]etitioners' practice [of preticketing] places a means of misleading the public into the hands of those who ultimately deal with the consumer. Notwithstanding the prevalence of these practices and the familiarity therewith among members of the trade, these activities are proscribed to protect the interest of the public.")

Similarly, in *In re Regina*, the Federal Trade Commission squarely rejected respondent Regina's argument that its conduct was lawful because it merely furnished suggested list prices to distributors and retailers but did not make any representations directly to the purchasing public:

Respondent Regina furnished its said suggested list prices to distributors and to retailers. In the period covered by the complaint it did not make any representations as to customary and usual prices directly to the purchasing public. Regina, however, placed in the hands of retailers and others the means and instrumentalities by and through which they may mislead the purchasing public as to the usual and customary prices for Regina [products].

61 F.T.C. 983, 1962 WL 75514; *see also Regina Corporation*, 322 F.2d at 768 ("With respect to those instances where petitioner did not contribute to the cost of misleading advertising, it is

settled that ‘One who places in the hands of another a means of consummating a fraud or competing unfairly in violation of the Federal Trade Commission Act is himself guilty of a violation of the Act.’ . . . Proof of petitioner’s intention to deceive is not a prerequisite to a finding of a violation . . . ; it is sufficient that deception is possible.’”) (citations omitted).<sup>7</sup>

The principles set forth in the above case law have special resonance here. As Justice Holmes long ago made clear, by electing voluntarily to participate in the Medicaid program, Sandoz subjected itself to a greater standard of care than if it were operating in the private marketplace. “Men must turn square corners when they deal with the Government.” *Rock Island, A & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). No matter how Sandoz seeks to spin its conduct, supplying false prices to First DataBank knowing that First DataBank would not only publish these prices, but provide them to state Medicaid agencies for use in estimating acquisition cost, is not “turning square corners” with the government.

2. Sandoz’s Conduct Violates Wis. Stat. § 100.18(10)(b).

Wis. Stat. § 100.18(10)(b) provides a specific example of conduct that is *per se* deceptive. The statute states: “It is deceptive to represent the price of any merchandise as a manufacturer’s or wholesaler’s price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise.” Although the State has not located any case law or pattern jury instruction that articulates the elements of a claim under this section, the elements are evident from the plain language of the statute:

- (1) a representation

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<sup>7</sup> See also Restatement of Tort, Sections 876, which provides, in relevant part:

For harm resulting to a third person from the tortious conduct of another, a person is liable if he:

(b) knows that the other’s conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or

(c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person.

- (2) that the price of any merchandise is a wholesale price
- (3) when retailers regularly pay less than the wholesale price for the merchandise

As to the first element, as demonstrated earlier, each time Sandoz reported and caused First DataBank to publish average wholesale prices for its drugs, Sandoz made a “representation.” Similarly, Sandoz made a “representation” each time it provided an actual or potential customer with an average wholesale price for a Sandoz drug. The second element is easily satisfied because Sandoz uses the word “wholesale” in its reporting of “average wholesale prices.” Finally, the third element is undisputed. As Hector Armando Kellum, Sandoz’s corporate designee, testified at deposition:

Q: Would you agree that the average wholesale prices that Sandoz reports and the First Data Bank publishes for the Sandoz drugs, is in fact, more than what retailers regularly pay for Sandoz drugs?

MR. GALLAGHER: Objection to the form.

A: My understanding is that you know, based on data that I have looked at, that typically, retailers pay less than the generic AWP, that we have listed with First Data Bank.

PUF 51.

Section 100.18(10)(b) is consistent with Federal Trade Commission law. *Federated Nationwide Wholesalers Service v. Federal Trade Commission*, 398 F.2d 253, 256-57 (2d Cir. 1968) (finding that it was deceptive to call a price a wholesale price “where the price actually charged exceeds what retailers in the area normally pay their sources of supply for the same item.”); *see also L. & C. Mayers Co. v. Federal Trade Commission*, 97 F.2d 365 (2d Cir. 1938) (finding it to be a deceptive practice to represent prices as wholesale prices when those prices are higher than the usual and customary prices charged by wholesalers).

3. Sandoz’s Conduct Violates Wis. Stat. § 133.05(1)

Section 133.05(1) provides:

The secret payment or allowance of rebates, refunds, commissions or unearned discounts, whether in the form of money or otherwise, or the secret extension to certain purchasers of special services or privileges not extended to all purchasers purchasing upon like terms and conditions, such payment, allowance or extension injuring or tending to injure a competitor or destroying or tending to destroy competition, is an unfair trade practice and is prohibited.

Although the State has not located any case law or pattern jury instructions that identify the elements of this claim, they are evident from the plain language of the statute:

- (1) the payment or receipt of secret rebates, refunds, commissions or unearned discounts
- (2) that had or tended to have an injurious effect on a Wisconsin competitor, OR that destroyed or tended to destroy competition in Wisconsin.

The Wisconsin courts have construed the term “secret” to mean “kept from knowledge or view; concealed, hidden.” *Jauquet Lumber Co.*, 164 Wis.2d at 698-699.

The first element is clearly established, as Sandoz admits that it has paid a variety of rebates, discounts, chargebacks, and similar items to wholesalers and to pharmacies, none of which are reflected in either the WACs or AWP that Sandoz sets, reports, and causes First DataBank to publish. PUF 56-60. Moreover, such rebates, discounts, and chargebacks are “secret” within the meaning of Section 133.05(1) as Sandoz keeps them concealed and hidden from the State of Wisconsin. Sandoz goes to great lengths to keep these price concessions secret and confidential, requiring each purchaser with whom it does business to keep them secret. Indeed, Sandoz has a standard clause in all of its contracts requiring that these items be kept secret. PUF 72-73.

*Obstetrical & Gynecological Associates of Neenah, S.C. v. Landig*, 129 Wis.2d 362, 384 N.W.2d 719 (Ct. App. 1986), makes clear that Wisconsin has established the second element of the statute. In *Landig*, the interior decorator for the plaintiff obtained rebates from her suppliers which she did not report or pass on to the plaintiff. Instead, she collected her fee based on the

undiscounted price. The court held that the plaintiff stated a cause of action, rejecting the defense that because the decorator was not a competitor of the plaintiff, the plaintiff could not show the type of direct injury contemplated by the statute:

There is no need to make the direct-indirect distinction under our statute. Section 133.18(1), Stats., explicitly allows any person injured directly *or indirectly* to sue upon this statute. Similar language is not found in the federal law. *See* 15 U.S.C.A. § 15 (1973). This, coupled with the legislature's instruction that we give the most liberal construction to achieve the aim of competition, compels us to the conclusion that an ultimate consumer who pays a higher price for goods and services indirectly due to a secret rebate comes within the ambit of the statute. In addition to the clear wording of the statute, we perceive a valid policy reason for our holding. By encouraging ultimate consumers (tertiary level) to bring lawsuits for violation of this section, the perpetrators will evaluate risk differently. They may decide that it is not worth the risk because of the chance of having to pay treble damages under sec. 133.18(1). *OB-GYN*, we conclude, has standing.

*Id.* at 371-72, 384 N.W.2d at 723-24.

The only difference between *Landig* and the instant case is that here the State is suing the party responsible for the hidden discounts and rebates (Sandoz), not the parties who received the benefits of such discounts and rebates (wholesalers and retail pharmacies). This distinction makes the instant case stronger than *Landig*. *Landig* allowed a claim against the party that received the benefit of the secret discount, but the statute is specifically directed at the party that provides the secret discount. The statute says: "The secret payment or allowance of rebates, refunds, commissions or unearned discounts, whether in the form of money or otherwise....is an unfair trade practice and is prohibited." Sandoz's reporting and publication of false and inflated AWP's and WAC's while at the same time either selling these drugs to pharmacies directly (or indirectly through wholesalers) at prices which are secretly and substantially discounted from the published prices, is exactly what the Act precludes. This result is consistent with the application of Federal Trade Commission law over many decades:

Preticketing at fictitious and excessive prices must be deemed to have the tendency of deceiving the public as to the savings afforded by the purchase of a product thus tagged as well as to the value of the product acquired. Petitioners' practice places a means of misleading the public into the hands of those who ultimately deal with the consumer. Notwithstanding the prevalence of these practices and the familiarity therewith among members of the trade, these activities are proscribed to protect the interest of the public.

Misrepresentation as to the retail value of merchandise by means of an attached, fictitious price and deception as to savings afforded by the purchase of the product at a substantially lower price than that indicated thereon constitute unfair methods of competition.

*Clinton Watch Co. v. Federal Trade Com.*, 291 F.2d 838, 840 (7th Cir. 1961).

The publication of false prices is especially noxious in the context of the Medicaid program. It reduces the funds available to help society's neediest citizens, and creates an incentive for providers to prescribe or dispense the drug with the largest profit margin instead of the drug that is most efficacious or inexpensive.

4. Sandoz's Conduct Violates Wis. Stat. § 49.49(4m)(a).

Wis. Stat. § 49.49(4m)(a) provides in relevant part: "No person, in connection with medical assistance, may . . . 2. Knowingly make or cause to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment." Although plaintiff has been unable to locate any case law or Wisconsin pattern jury instruction that identifies the elements of this claim, they are evident from the plain language of the statute:

- (1) knowingly making or causing to be made a false statement or representation
- (2) of a material fact
- (3) for use in determining rights to a benefit or payment
- (4) in connection with a medical assistance program.

The undisputed facts establish all four elements. Sandoz sets, controls, reports, and causes First DataBank to publish average wholesale prices. PUF 33-35, 39-47. These prices are false, *i.e.*, they do not represent the true average prices charged by wholesalers. PUF 50-55. As

demonstrated above, price is a material fact as a matter of law. And the false AWP's that Sandoz reports and causes to be published are used by the Wisconsin Medicaid program to estimate provider acquisition cost and determine the "payment" to Medicaid providers. PUF 27-28, 31-33. Accordingly, plaintiff is entitled to summary judgment on liability as to this claim.

**C. Sandoz Has No Defense as a Matter of Law To Plaintiff's Motion.**

The State expects Sandoz to oppose the instant motion by arguing that liability cannot be established because certain Wisconsin employees connected with the Medicaid program knew or should have known that First DataBank's published average wholesale prices for at least some drugs were being discounted to pharmacies and doctors. That is, Sandoz is likely to argue that certain Wisconsin employees knew or should have known that Sandoz's average wholesale prices were false. Moreover, Sandoz will likely argue that these employees failed adequately to amend or modify the Medicaid program's reimbursement formula for prescription drugs to account fully for such discounting, thereby permitting, through negligence, inadvertence, or design, reimbursement to providers above their actual acquisition cost. This argument fails for several reasons.

1. Knowledge or Belief of State Employees is Legally Irrelevant to Liability

As shown above, liability under the statutes invoked by the State is established by virtue of Sandoz's conduct. What State employees knew, should have known, or could have discovered is simply irrelevant to the question of liability.

First, in connection with three of the statutes which Sandoz is accused of violating, liability is established by virtue of Sandoz's admissions that it published average wholesale prices and wholesale acquisition costs that were false. No more needs to be proven, and nothing else is relevant to the determination of liability. Thus, Wis. Stat. § 100.18(1) makes it unlawful

to publish a false statement – period. Similarly, Section 100.18(10)(b) provides that representing a price as a wholesale price when retailers regularly pay less than that price is a *per se* deceptive act. Wis. Stat. § 49.49(4m)(a)2 prohibits a person from making or causing to be made a false statement or representation of a material fact for use in determining rights to a benefit or payment in connection with a medical assistance program.<sup>8</sup> None of the elements of these claims examines the knowledge, belief, action, or inaction, of the State or any individual state employees. They do not even require knowledge by Sandoz of the falsity of the statements (although if required, such knowledge is established here).<sup>9</sup>

A different analysis is required in connection with plaintiff’s claim under Wis. Stat. §133.05(1), but the result is the same. That statute prohibits the payment of secret rebates or discounts that tend to destroy competition. This statute requires a showing beyond the conduct of Sandoz -- an injury to competition. But this element is present as a matter of law pursuant to *Obstetrical & Gynecological Associates of Neenah, S.C. v. Landig*, 129 Wis.2d 362, 384 N.W.2d 719 (Ct.App. 1986).

In sum, liability under these statutes depends solely and exclusively on the conduct of Sandoz. Any efforts by Sandoz to shift the focus of the court’s inquiry to the knowledge, belief, or actions of the State is improper.

## 2. Sandoz’s Estoppel Argument is Unavailable as a Matter of Law

Sandoz’s attempt to shift the focus from its own misconduct to the knowledge, belief, action, or inaction of Wisconsin employees is also improper because it is an estoppel argument

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<sup>8</sup> This Medicaid Fraud Act further holds that any person violating the statute may be required to forfeit not less than \$100 nor more than \$15,000 for each false statement. Wis. Stat. § 49.49(4m)(b).

<sup>9</sup> In contrast, Section 100.18(12)(b) shields real estate brokers from liability unless they have “knowledge that the assertion, representation, or statement of fact is untrue, deceptive or misleading.”).

that is not available to Sandoz as a matter of law. Even assuming that certain state Medicaid employees negligently or purposely looked the other way as Sandoz violated the law, such conduct cannot estop Wisconsin from establishing liability against Sandoz in this civil law enforcement action.

It is well-established that a defendant who breaks the law cannot excuse its conduct by pointing to negligent, misleading or intentional misconduct on the part of state employees. The United States Supreme Court articulated this principle in *Heckler v. Community Health Services*, 467 U.S. 51, 63 (1984):

Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.

*Heckler* is consistent with a well-established line of authority holding that a defendant may not excuse its unlawful conduct by blaming a government employee when a public right is involved. *See, e.g., Nevada v. United States*, 463 U.S. 110, 141 (1983) (“As a general rule laches or neglect of duty on the part of officers of the government is no defense to a suit by it to enforce a public right or protect a public interest.”); *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384 (1947) (“Whatever the form in which the Government functions, anyone entering into an arrangement with the Government takes the risk of having accurately ascertained that he who purports to act for the Government stays within the bounds of his authority. The scope of this authority may be explicitly defined by Congress or be limited by delegated legislation, properly exercised through the rule-making power. And this is so even though, as here, the agent himself may have been unaware of the limitations upon his authority.”); *United States v. Socony-Vacuum Oil Co.*, 310 US 150, 226 (1940) (“Though employees of the government may have known of those

(unlawful) programs and winked at them or tacitly approved them, no immunity would have thereby been obtained.”); *Utah Power & Light Co. v. United States*, 243 U.S. 389, 409 (1917) (“As a general rule, laches or neglect of duty on the part of officers of the government is no defense to a suit by it to enforce a public right or protect a public interest”); *U.S. v. Aging Care Home Health, Inc.*, 2006 WL 2915674 (W.D.La. 2006) (“The defense of estoppel is unavailable where the government’s recovery of public money is concerned.”) (citing *Rosas v. United States*, 964 F.2d 351, 360 (5th Cir.1992)); *Federal Trade Commission v. Crescent Publ’g Group, Inc.*, 129 F.Supp.2d 311, 324 (S.D.N.Y. 2001) (“As presenting another ground of estoppel it is said that the agents in the forestry service and other officers and employees of the Government, with knowledge of what the defendants were doing, not only did not object thereto but impliedly acquiesced therein until after the works were completed and put in operation. This ground also must fail. As a general rule laches or neglect of duty on the part of officers of the government is no defense to a suit by it to enforce a public right or protect a public interest.”).

This doctrine dates back to the earliest days of the Supreme Court. See *United States v. Kirkpatrick*, 22 U.S. 720, 735 (1824); *United States v. Insley*, 130 U.S. 263, 266 (1889) (“The principle that the United States are not bound by any statute of limitations nor barred by any laches of their officers, however gross, in a suit brought by them as a sovereign government to enforce a public right or to assert a public interest, is established past all controversy or doubt.”).

Wisconsin adopted these principles in the seminal case of *Wisconsin v. City of Green Bay*, 96 Wis.2d 195, 291 N.W.2d 508 (1980). There the court stated:

We have not allowed estoppel to be invoked against the government when the application of the doctrine interferes with the police power for the protection of the public health, safety or general welfare. *State of Chippewa Cable Co.*, 21 Wis.2d 598, 608, 609, 124 N.W.2d 616 (1963); *Park Bldg. Corp. v. Ind. Comm.*, 9 Wis.2d 78, 87, 88, 100 N.W.2d 571 (1960); *Town of Richmond v. Murdock*, 70 Wis.2d 642, 653, 654, 235 N.W.2d 497 (1975); *McKenna v. State Highway*

*Comm.*, 28 Wis.2d 179, 186, 135 N.W.2d 827 (1965); *Milwaukee v. Milwaukee Amusement, Inc.*, 22 Wis.2d 240, 252-53, 125 N.W.2d 625 (1964).

*City of Green Bay*, 96 Wis.2d at 201-202, 291 N.W.2d at 511. In this case, the Wisconsin Attorney General is acting for the “public health, safety [and] general welfare.” The State is seeking to enforce a “public right” and recover “public money.” Accordingly, estoppel is unavailable to Sandoz. *See also Westgate Hotel, Inc. v. E.R. Krumbiegel*, 39 Wis.2d 108, 113, 158 N.W.2d 362, 364 (1968) (rejecting the argument that because the City of Milwaukee had not enforced an ordinance for nine years, the defendant had been lulled into thinking that it was in full compliance with the ordinance and that the City was therefore estopped from enforcing the ordinance).

### 3. Sandoz’s Argument Misplaces the Duties of the Parties

Finally, Sandoz’s argument misplaces the burdens and duties of the parties.

Sandoz has a duty to be honest and truthful with the State where, as here, it knows that the AWP’s it sets, controls, reports, and causes First DataBank to publish will determine the amount of taxpayer dollars spent by the Wisconsin Medicaid program on Sandoz’s drugs. *Heckler*, 467 U.S. at 63. In contrast, the State had no duty to sue Sandoz earlier or to modify its Medicaid program to account for Sandoz’s misconduct. Rather, the reverse is true. Wisconsin is permitted to sue to enforce its laws at any time to recover public funds that were lost due to Sandoz’s misconduct. *Aging Care Home Health, Inc.*, 2006 WL 2915674 at \*1 (defendants’ argument that the government was at fault in not discovering defendants’ wrongdoing earlier was irrelevant); *see also Westgate Hotel*, 39 Wis.2d at 114, 158 N.W.2d at 365 (where government failed to enforce ordinance for nine years, “the most that can be said for the plaintiff’s position is that he had been violating the law for a number of years and had got away with it”); *id.* (“It, however, is

axiomatic that a law-enforcing body, when faced with the practical difficulties of enforcing all of its regulations at once, is not thereby barred from future enforcement of the law.”).

**V. RELIEF SOUGHT**

Wisconsin requests the court grant its motion for summary judgment and enter a finding of liability against Sandoz on Counts I through IV of plaintiff’s Second Amended Complaint. Wisconsin further requests that the court enjoin Sandoz from reporting and causing to be published false average wholesale prices and wholesale acquisition costs.

Dated this 7th day of June, 2007.



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