

vulnerable populations in society – the poor, elderly, disabled, and blind. Drug manufacturers are not required to participate in the Medicaid program. Rather, participation is voluntary and drug manufacturers must affirmatively elect to participate. Since 1991, AstraZeneca has chosen voluntarily to participate in the Medicaid program.

AstraZeneca does not dispute that it sets and controls two different prices for its drugs – an average wholesale price (“AWP”) and a wholesale acquisition cost (“WAC”) – and that it reports and causes these prices to be published by various pricing compendia, including First DataBank. Nor does AstraZeneca dispute that it knows that state Medicaid programs obtain and rely on this pricing information from First DataBank in determining how much to pay providers (such as retail pharmacies) for AstraZeneca’s drugs. Most importantly, AstraZeneca admits that the AWP’s it reports and causes First DataBank to publish are not the true average prices charged by wholesalers. In fact, AstraZeneca admits that its AWP’s are not prices that any purchasers pay for AstraZeneca’s drugs. AstraZeneca further admits that the WAC’s it reports and causes First DataBank to publish are not the true prices paid by wholesalers to AstraZeneca to acquire AstraZeneca’s drugs. Rather, AstraZeneca admits that its WAC’s do not reflect rebates, discounts, chargebacks, and similar items that reduce the wholesalers’ true cost to purchase AstraZeneca’s drugs.

AstraZeneca 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 AstraZeneca admits that no purchaser pays the published AWP for AstraZeneca’s drugs, AstraZeneca has violated Section 100.18(1).

AstraZeneca 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. AstraZeneca’s conduct violates Section 100.18(10)(b) because retail pharmacies pay substantially less than the published AWP for AstraZeneca’s drug.

Notwithstanding these clear violations of law, the State expects AstraZeneca 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. 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 or any individual state employee. Second, AstraZeneca’s argument is an estoppel argument that is not available to AstraZeneca as a matter of law. Third, AstraZeneca’s argument misplaces the burdens and duties. The State has no duty to modify its Medicaid program to account for AstraZeneca’s misconduct. Rather, AstraZeneca has a duty to be honest and truthful with the State where, as here, AstraZeneca knows that the Wisconsin’s Medicaid program obtains and relies on AstraZeneca’s AWP and WACs from First DataBank.

II. CLAIMS

Wisconsin seeks summary judgment on liability as to Counts I and II of its Second Amended Complaint.¹

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

This statute provides:

¹ The State is not at this time moving for summary judgment on Counts III and V of the Second Amended Complaint.

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.

III. PROPOSED UNDISPUTED FACTS

1. AstraZeneca manufactures and sells branded drugs. Transcript of May 14, 2007 deposition of AstraZeneca corporate designee Christine McHenry, Director of Government Operations (“McHenry Tr.”), p. 36;² Transcript of May 15, 2007 deposition of AstraZeneca corporate designee Roger Hyde, Vice President of Global Commercial Effectiveness (“Hyde Tr.”), p. 51.³

2. A branded drug is a product that has a new drug application associated with it and that has patent protection, meaning that the manufacturer is allowed to sell the drug exclusively for the life of the patent and no competitors may manufacture the equivalent chemical compound. McHenry Tr. at 37; Hyde Tr. at 51-52.

3. AstraZeneca manufactures and sells both “self-administered” and “physician-administered” branded drugs. McHenry Tr. at 38.

4. A self-administered drug is a tablet or capsule that a physician prescribes and that a person swallows or takes himself. McHenry Tr. at 38.

5. A physician-administered drug is one that needs to be injected or administered through equipment in a physician’s office. McHenry Tr. at 39.

6. 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. McHenry Tr. at 58-59; Hyde Tr. at 75.

² Excerpts of the deposition of Christine McHenry are attached hereto as Exhibit 1.

³ Excerpts of the deposition of Roger Hyde are attached hereto as Exhibit 2.

7. AstraZeneca knows that every state, including Wisconsin, has chosen to participate in the Medicaid program. McHenry Tr. at 59; Hyde Tr. at 75-76.

8. Drug manufacturers are not required to participate in the Medicaid program; rather, they must elect to participate. McHenry Tr. at 59-60.

9. 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.*; McHenry Tr. at 61.

10. Since 1991, AstraZeneca has chosen voluntarily to participate in the Medicaid program. McHenry Tr. at 60, 216-217.

11. Among the reasons AstraZeneca has chosen voluntarily to participate in the Medicaid program is so that its drugs can be reimbursed by state Medicaid programs and so that AstraZeneca can realize greater revenues and greater profits. Hyde Tr. at 77-78.

12. In 2000, AstraZeneca's gross annual sales for its drugs in the United States was approximately \$11 billion. Hyde Tr. at 71-72.

13. In 2000, reimbursement by state Medicaid programs for AstraZeneca's drugs represented approximately 17.3% of AstraZeneca's gross annual sales (or approximately \$1.9 billion). Hyde Tr. at 72.

14. AstraZeneca believes that by choosing voluntarily to participate in the Medicaid program it has a duty to familiarize itself with the laws, rules, and regulations that govern the Medicaid program. McHenry Tr. at 62; Hyde Tr. at 79-80.

15. AstraZeneca believes that by choosing voluntarily to participate in the Medicaid program, it has a duty and obligation to be honest and truthful in its dealings with the Medicaid

program as a whole and the individual Medicaid programs of each state. McHenry Tr. at 62-63; Hyde Tr. at 80.

16. AstraZeneca believes that it is responsible for knowing the laws that govern its conduct in each state that participates in the Medicaid program. McHenry Tr. at 63.

17. A retail pharmacy is a pharmacy with a physical “brick and mortar” location that is licensed to dispense drugs such as Walgreens, CVS, or Wal-Mart. McHenry Tr. at 76; Hyde Tr. at 82-83.

18. AstraZeneca knows that state Medicaid programs make payments to providers such as retail pharmacies for AstraZeneca’s drugs. Hyde Tr. at 66.

19. Prilosec, a capsule that is taken orally, is an AstraZeneca branded drug that treats acid reflux. McHenry Tr. at 75.

20. The manner in which the Wisconsin Medicaid program reimburses a pharmacy for an AstraZeneca branded drug such as Prilosec is as follows. A person who is eligible for the Wisconsin Medicaid program would get a prescription from a doctor and take it to a retail pharmacy such as Walgreens, CVS, or Wal-Mart to be filled. McHenry Tr. at 75-76.

21. The retail pharmacy would fill the Prilosec prescription, but because the person was eligible for Wisconsin’s Medicaid program, the person would not pay for the drug. McHenry Tr. at 76.

22. To receive payment, the retail pharmacy would provide information electronically to the Wisconsin Medicaid program about the prescription. McHenry Tr. at 76-77.

23. The Wisconsin Medicaid program has thousands of individuals who are eligible for the program and receive drug benefits. McHenry Tr. at 77.

24. Retail pharmacies in Wisconsin fill thousands of prescriptions each day for Wisconsin Medicaid patients. McHenry Tr. at 78.

25. After the Wisconsin Medicaid program receives information from the retail pharmacy about the Prilosec prescription, it makes a payment to the pharmacy. McHenry Tr. at 78.

26. There are two portions to that payment – (1) the ingredient cost, and (2) the dispensing fee. McHenry Tr. at 78-79.

27. The ingredient cost pays for the drug itself. McHenry Tr. at 79.

28. The dispensing fee pays for the pharmacy’s cost of filling the prescription. McHenry Tr. at 79.

29. Federal regulations tell the Wisconsin Medicaid program that with respect to the ingredient cost of the Prilosec prescription, it can pay no more than the lesser of the “estimated acquisition cost” or the pharmacy’s “usual and customary charge.” McHenry Tr. at 80-83; 42 C.F.R. § 447.331(b).

30. Federal regulations define “estimated acquisition cost” as the Wisconsin 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.” McHenry Tr. at 83-84; 42 C.F.R. § 447.301.

31. In other words, the “estimated acquisition cost” means the price the retail pharmacy paid to acquire the drug from whomever it purchased it from. McHenry Tr. at 84-85.

32. Since January 1, 1991, AstraZeneca has known that many state Medicaid programs rely on the average wholesale price (“AWP”) of AstraZeneca’s drugs published by First DataBank in their formulas for determining the amount of the payment or reimbursement

made by the state Medicaid programs to a provider such as a retail pharmacy. McHenry Tr. at 92, 98; Hyde Tr. at 108-109, 188-191, 360-361.

33. AstraZeneca knows that there is publicly available information showing the reimbursement formulas for prescription drugs used by each state Medicaid program. McHenry Tr. at 95.

34. AstraZeneca knows that the reimbursement formulas of state Medicaid programs are efforts at estimating the acquisition cost to pharmacies for covered drugs, including those manufactured by AstraZeneca. Hyde Tr. at 190.

35. First DataBank is a company that reports a variety of pharmaceutical pricing information about AstraZeneca's drugs and other manufacturers' drugs. McHenry Tr. at 98; Hyde Tr. at 101-102.

36. AstraZeneca believes that First DataBank is the largest repository of electronic pricing information for prescription drugs. Hyde Tr. at 103.

37. Red Book and MediSpan are also companies that report a variety of pharmaceutical pricing information about AstraZeneca's drugs and other manufacturers' drugs. Hyde Tr. at 101-102.

38. Since January 1, 1991, AstraZeneca has known that those state Medicaid programs that use the average wholesale price ("AWP") of drugs in their formulas for determining the amount of the payment or reimbursement made by the state to a Medicaid provider such as a retail pharmacy use the AWP that is published by either First DataBank or Red Book. McHenry Tr. at 111-112.

39. AstraZeneca initially reports a WAC and an AWP for a drug to First DataBank, Red Book, and MediSpan at the time it launches, or introduces the drug, into the market. Hyde Tr. at 132.

40. AstraZeneca defines WAC as the price at which AstraZeneca sells its drugs to wholesalers. McHenry Tr. at 121-123.

41. AstraZeneca's WACs do not include rebates, discounts, or similar items that might at a later date be applied and thereby reduce the net cost to the purchaser of the drug. McHenry Tr. at 121-123; Hyde Tr. at 111-112.

42. AstraZeneca defines AWP as a benchmark that is derived through a simple mathematical calculation of multiplying the WAC times 1.2 or 1.25. Hyde Tr. at 112-113.

43. Between January 1991 and 2002, AstraZeneca reported to First DataBank, Red Book, and Medispan, both a WAC and an AWP for each of AstraZeneca's drugs. Hyde Tr. at 104-105.

44. From 2002 to the present, AstraZeneca has reported to First DataBank, Red Book and Medispan only the WAC for each of AstraZeneca's drugs. Hyde Tr. at 104-105.

45. AstraZeneca stopped reporting AWPs to First DataBank, Red Book and Medispan for each of AstraZeneca's drugs in 2002 based on the advice of counsel. Hyde Tr. at 105-106.

46. Since January 1, 1991, when AstraZeneca has reported a WAC or AWP for its drugs to First DataBank, Red Book, or Medispan, it reports the identical WACs and AWPs to all three companies. Hyde Tr. at 194.

47. Since 1991, AstraZeneca has not been required by any law or regulation to report any pricing information to First DataBank, Red Book, or MediSpan. Hyde Tr. at 106-107.

48. AstraZeneca has chosen voluntarily to report WAC and AWP for its drugs from January 1991 to 2002 and WAC after 2002 to First DataBank, Red Book, and MediSpan. Hyde Tr. at 107.

49. AstraZeneca has chosen voluntarily to report WAC and AWP for its drugs to First DataBank, Red Book, and Medispan because it wants the prices of its products to be accurately reflected in these publications and because it wants its customers to have ready access to the prices of its products. Hyde Tr. at 107, 136.

50. During the time that AstraZeneca reported both a WAC and an AWP for its drugs to First DataBank, Red Book, and MediSpan, AstraZeneca understood that those companies would publish the identical WACs and AWP's provided by AstraZeneca. Hyde Tr. at 184.

51. During the time that AstraZeneca reported both a WAC and an AWP for its drugs to First DataBank, Red Book, and MediSpan, AstraZeneca intended for those companies to publish the identical WACs and AWP's provided by AstraZeneca. Hyde Tr. at 184.

52. After 2002, when AstraZeneca only reported a WAC for its drugs to First DataBank, Red Book, and MediSpan, AstraZeneca knew and understood that First DataBank would take the WAC provided by AstraZeneca and multiply the WAC by a markup factor of either 20% or 25% to calculate an AWP that it would publish. Hyde Tr. at 184-185.

53. AstraZeneca knows the WACs and AWP's for its drugs that are published by First DataBank because AstraZeneca purchases pricing information from First DataBank regarding AstraZeneca's drugs and the drugs of AstraZeneca's competitors. This pricing information includes WAC and AWP. Hyde Tr. at 103-104.

54. In addition, First DataBank has asked AstraZeneca to verify the AWP's and WACs that First DataBank intends to publish for AstraZeneca's drugs. Hyde Tr. at 195-196.

55. In some instances, AstraZeneca determined that corrections needed to be made to the WACs that First DataBank had published for some AstraZeneca products. In each of those instances, AstraZeneca reported the corrected WAC to First DataBank and First DataBank published the corrected WAC as reported by AstraZeneca. Hyde Tr. at 210.

56. In some instances, AstraZeneca determined that corrections needed to be made to the AWP's that First DataBank had published for some AstraZeneca products. In 1994 or 1995, AstraZeneca requested that First DataBank change the AWP's for products in connection with the spinoff of Astra-Merck from Merck. First DataBank agreed to change the AWP's as requested by AstraZeneca. Hyde Tr. at 211-214

57. In approximately 2000 or 2001, in connection with the merger of Astra and Zeneca, AstraZeneca learned that First DataBank had lowered the AWP's for the AstraZeneca drug Zomig from 25% above WAC to 20% above WAC. AstraZeneca requested that First DataBank change the AWP's for Zomig to 25% above WAC. First DataBank denied this request and AstraZeneca took no further action to stop, object to, or otherwise oppose the publication of the AWP's for Zomig that were 25% above WAC. Hyde Tr. at 211-215.

58. AstraZeneca has known and understood since January 1, 1991 through the present that its AWP are not the actual average prices that wholesalers charge for AstraZeneca's products. As Roger Hyde, AstraZeneca's corporate designee, testified at deposition:

Q: Well, would you -- would you mind just answering my question directly, which is whether AstraZeneca has known and understood since January 1 of 1991 through to the present that AWP is not the actual average price that wholesalers charge for AstraZeneca's products; is that correct?

A: It's my understanding, yes.

Q: When you say your understanding, I want to make sure that it's clear that you're testifying here today as a designee on behalf of AstraZeneca, so I don't want you to limit your answer to your personal knowledge but any knowledge you obtained in preparing to testify today about this subject, about the meaning of AWP.

A: Broadly, I think that's the understanding within AstraZeneca, yes.

Hyde Tr. at 262.

59. Since January 1, 1991, with two exceptions, retail pharmacies generally did not purchase AstraZeneca's drugs directly from AstraZeneca. The two exceptions were a regional chain drug store called Happy Harry's with locations in Maryland, Delaware, and Pennsylvania, and a chain drug store in Ohio called Medina Drugs. Hyde Tr. at 91-92.

60. When AstraZeneca sold its drugs directly to Happy Harry's and Medina Drugs, those customers paid no more than AstraZeneca's WAC for the drugs. Because AstraZeneca's AWP's were always at least 20% higher than AstraZeneca's WACs, these customers never paid a price equal to or greater than AWP for AstraZeneca's drugs. Hyde Tr. at 288-289.

61. Since January 1, 1991, other than Happy Harry's and Medina Drugs, retail pharmacies typically would buy or acquire AstraZeneca's drugs through wholesalers. Hyde Tr. at 92.

62. A wholesaler is an intermediary in a purchasing process that buys a product and then turns around and sells it to somebody else. Hyde Tr. at 92-93.

63. AstraZeneca believes that when retail pharmacies such as Walgreens, CVS, Wal-Mart, Target, Rite Aid, and Albertsons purchase AstraZeneca's drugs from wholesalers, the most they pay is AstraZeneca's WAC for those drugs. Hyde Tr. at 258-260.

64. The WACs that AstraZeneca reports and causes First DataBank to publish do not include various discounts, rebates, and chargebacks. Accordingly, the WACs that AstraZeneca reports and causes First DataBank to publish for AstraZeneca's drugs are not the true wholesale acquisition costs. Hyde Tr. at 344-345, 370-371.

65. In 2000 or 2001, AstraZeneca was informed by First DataBank that with respect to those AstraZeneca's drugs with an AWP that was 20% above the WAC, First DataBank

intended to increase the AWP to 25% above the WAC in order to standardize the markup factors above WAC for all branded drugs to 25%. Hyde Tr. at 224-227.

66. In response to this information, AstraZeneca tried to assess the impact of this change. Among other things, AstraZeneca directed that a “white paper” be prepared for internal AstraZeneca employees. Hyde Tr. at 225-230.

67. AstraZeneca knew that the 5% increase of the AWP for AstraZeneca’s drugs would result in payers that reimburse retail pharmacies and other providers based on AWP paying 5% more for AstraZeneca’s drugs. This would include state Medicaid programs that use AWP in their drug reimbursement formulas. Hyde Tr. at 236-238, 268-269.

68. At the time that AstraZeneca learned that First DataBank intended to increase the AWP for certain AstraZeneca drugs by 5%, AstraZeneca did not believe that wholesalers had increased the prices they charged to retail pharmacies by 5%. As Roger Hyde testified at deposition:

Q: I’ll define it for you, then. At the time this was taking place, AstraZeneca -- that is, in 2002, when AstraZeneca learned that First DataBank was going to raise the AWP spread from 20 to 25%, AstraZeneca did not believe that wholesalers had increased their prices charged to retail pharmacies by 5%; is that correct?

A: That is correct.

Hyde Tr. at 238-239.

69. AstraZeneca was not aware of any public statement or public disclosures made by First DataBank explaining that it was increasing the AWP-to-WAC spread from 20% to 25% for certain branded drugs, including AstraZeneca’s branded drugs, solely to achieve consistency, rather than because wholesalers had begun charging their customers 5% more. Hyde Tr. at 245-246.

70. AstraZeneca never communicated to any state Medicaid program, including the Wisconsin Medicaid program, that First DataBank was increasing the AWP-to-WAC spreads from 20 to 25% for AstraZeneca's branded products solely to achieve consistency in the marketplace rather than because wholesalers had begun to charge their customers 5% more for AstraZeneca's products. Hyde Tr. at 246-247, 277-278.

71. Nor did AstraZeneca take any other steps to assist state Medicaid programs in learning the reason for First DataBank's increase in the AWP to WAC spread from 20% to 25% for AstraZeneca's products. Hyde Tr. at 253-254.

72. AstraZeneca never communicated to First DataBank that First DataBank should advise state Medicaid programs that the increase in the AWP to WAC spread by 5% for AstraZeneca's products was not attributable to any increase in the real prices wholesalers were charging to retail pharmacies and that state Medicaid programs that rely on AWP in their drug reimbursement formulas would wind up paying 5% more for AstraZeneca's drugs, or words to that effect. Hyde Tr. at 255.

73. AstraZeneca believed that state Medicaid programs would eventually figure out what was happening and ratchet down their reimbursement to pharmacies by 5%. Hyde Tr. at 268-269.

74. AstraZeneca believed that it would take state Medicaid programs about 1 or 2 years after the AWP to WAC spread was increased from 20% to 25% to adjust their reimbursement to pharmacies to account for this spread increase. Hyde Tr. at 269.

75. AstraZeneca knew that during this 1 or 2 year period of time, state Medicaid programs would pay an additional 5% for AstraZeneca's drugs even though the prices charged by wholesalers to pharmacies had not in fact increased. As Roger Hyde testified at deposition:

Q: But for the year or two that it would take government payers, such as the state Medicaid programs, to make that adjustment, they'd be paying an additional 5% for AstraZeneca's drugs even though the prices charged by wholesalers to pharmacies had not, in fact, increased; is that correct?

MR. FLYNN: Objection to the form.

THE WITNESS: Yeah, I think that's somewhat consistent with the understanding, yes.

Hyde Tr. at 271.

76. In light of AstraZeneca's gross annual sales and the percentage of those sales attributable to reimbursement by state Medicaid programs in the year 2000, AstraZeneca understood that the AWP to WAC spread increase from 20% to 25% would have resulted in state Medicaid programs paying an additional \$95 million for AstraZeneca's drugs in the first year after the spread increase and \$190 million in the first two years after the spread increase. Hyde Tr. at 271-275.

77. In June 2003, AstraZeneca pled guilty to federal criminal charges of violating the Prescription Drug Marketing Act in connection with its sales and marketing practices for the drug Zoladex, a physician-administered drug. Hyde Tr. at 43-44; Exhibit 3 (Transcript of June 20, 2003 guilty plea in the United States District Court for the District of Massachusetts).

78. During the June 20, 2003 guilty plea proceedings, the following colloquy occurred between United States District Judge Joseph Farnan, Jr. and Glenn Engelmann, who at the time was chief counsel for AstraZeneca's United States business:

COURT: Now, in this information, there are certain elements that I am interested in understanding, that AstraZeneca knows that it committed a crime by committing these elements, which, when considered as a whole, constitute the offense that you are charged with. Can you tell me in your own words what AstraZeneca did that makes you believe it's guilty of the offense charged in the information?

MR. ENGELMANN: Beginning in or about 1993 and continuing at least until July 1996, some Zeneca employees provided free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer samples

to their patients and thereafter seek and receive reimbursement in violation of the Pharmaceutical Drug Marketing Act. When this was done, one of the objectives was to induce the physicians to order Zoladex. It was an objective of the physicians to bill for the free samples in order to increase their income.

Hyde Tr. at 48-49; Exhibit 3, at 7-8

79. In addition, Mr. Engelmann agreed with the following proffer made by Assistant United States Attorney Beth Moskow-Schnoll::

MS. MOSKOW-SCHNOLL: . . . From 1990 until the present, sold a drug called Zoladex, which was subject to the requirements of the federal Food, Drug and Cosmetic Act. During the relevant time period, Zeneca had approval to distribute Zoladex for the treatment of prostate cancer and the drug was marketed at least in the – starting in the early 1990s, it was marketed, sold, and provided to urologists across the country for the treatment of prostate cancer. In fact, the drug was sold directly to urologists by the company.

Beginning in or about 1993 and continuing at least until July 1996, the defendant, which is called Zeneca here, through its employees, provided thousands of free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer those drug samples to their patients and thereafter seek and receive reimbursement for the free samples.

The objective for Zeneca was to obtain money from the increased sales of Zoladex, while the objective for the physicians was to obtain money for reimbursement for the samples of Zoladex. Therefore, it was an objective of Zeneca in this conspiracy to provide free samples of Zoladex to induce the urologists to order Zoladex. And it was an objective of some of the physicians participating in the conspiracy to bill for the free samples in order to increase their income.

Exhibit 3, pp. 9-10.

80. In connection with this guilty plea, AstraZeneca paid a criminal fine of \$64 million. Hyde Tr. at 45; Exhibit 3 at 11.

81. Incorporated into the guilty plea was a civil settlement agreement between AstraZeneca and the United States Department of Justice, the United States Department of Health and Human Services Office of Inspector General and numerous state Medicaid programs

in which AstraZeneca paid approximately \$291 million to the United States and the state Medicaid programs. Hyde Tr. at 49-50.

82. The total of the criminal fines and the payments under the civil settlement agreement paid by AstraZeneca was approximately \$355 million. Hyde Tr. at 50-51; Exhibit 3 at 13.

IV. ARGUMENT

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

AstraZeneca admits that it sets and controls the AWP and WACs that are published by First DataBank. AstraZeneca further admits that its AWP is not the true average price charged by wholesalers and that its WAC is not the true wholesaler acquisition cost for AstraZeneca's drugs. These admissions establish liability as a matter of law under Counts I, II, and 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 6. The program is voluntary rather than mandatory. Drug manufacturers must affirmatively elect to participate. PUF 8. Since at least 1993, AstraZeneca has elected to participate in the Medicaid program. PUF 10. By electing voluntarily to participate in Medicaid, AstraZeneca must comply with certain rules. Among 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).

B. AstraZeneca's Unlawful Conduct.

AstraZeneca does not dispute that it sets and controls the AWP for its drugs that are published by First DataBank and which state Medicaid programs purchase. PUF 39-57. Nor does AstraZeneca dispute that the AWP it reports and causes First DataBank to publish are not the true average prices charged by wholesalers. PUF 58-63. Rather, AstraZeneca admits that the AWP it reports and causes First DataBank to publish are at least 20-25% above the true average prices charged by wholesalers. *Id.* Stated differently, AstraZeneca admits that retail pharmacies pay far less than AWP to acquire AstraZeneca's drugs.

In addition, AstraZeneca admits that it sets and controls the wholesale acquisition costs ("WACs") for its drugs that are published by First DataBank. PUF 39-57. AstraZeneca further admits that the WACs it reports and causes First DataBank to publish are not the wholesaler acquisition costs for AstraZeneca's drugs. Rather, AstraZeneca admits that its WACs do not reflect rebates, discounts, chargebacks, and similar items that reduce the wholesalers' true cost to purchase the drugs from AstraZeneca. PUF 64.

C. AstraZeneca's Conduct Violates Wisconsin Law.

1. AstraZeneca's Conduct Violates Wis. Stat. § 100.18(1).
 - a. AstraZeneca'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. AstraZeneca'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, AstraZeneca made an advertisement or announcement each time it reported and caused First DataBank to publish AWP's and WAC's for AstraZeneca's drugs. AstraZeneca reports and causes First DataBank to publish AWP's and WAC's for AstraZeneca's drugs because it wants the prices of its products to be accurately reflected in these publications and because it wants its customers to have ready access to the prices of its products. PUF 47-49. AstraZeneca knows that third party payers, including state Medicaid programs such as Wisconsin's, rely on the AWP's published by First DataBank in determining how much to reimburse providers for AstraZeneca's drugs. PUF 32-34, 38.

As to the second element, each time AstraZeneca reported and caused First DataBank to publish AWP's and WAC's for AstraZeneca's drugs, AstraZeneca made a "statement" that was

“untrue, deceptive, or misleading.” In fact, each statement was untrue, deceptive, and misleading.

AstraZeneca’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 AstraZeneca’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 AstraZeneca 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 58-63), AstraZeneca’s statements are “untrue” and violate Wis. State. 100.18(1).⁴

AstraZeneca’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 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

⁴ For the same reason, AstraZeneca’s reporting and publication of wholesale acquisition costs that AstraZeneca admits are not the true wholesaler acquisition costs also violates the statute.

‘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).⁵ 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 AstraZeneca is even more compelling than in the above cases, because AstraZeneca did not report its prices as “suggested” or “list” prices. Rather, AstraZeneca repeated and consistently stated that its prices were “average wholesale prices,” without any

⁵ To the extent that AstraZeneca argues that its AWP’s are akin to 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.

qualifying language. Yet AstraZeneca knew that these were not the average prices charged by wholesalers to retailers. PUF 58-63. Because the undisputed facts establish that AstraZeneca (1) made advertisements or announcements containing (2) statements that were untrue, deceptive, or misleading, it has violated Wis. Stat. § 100.18(1).⁶

Wisconsin need not demonstrate that AstraZeneca 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 AstraZeneca has admitted that it reported and caused First DataBank to publish its AWP because AstraZeneca wanted its customers to have this information, and it knows that state Medicaid rely on these AWP in determining how much to reimburse providers for AstraZeneca's drugs and it has chosen voluntarily to participate in the Medicaid program in order to so that it can realize greater revenues and greater profits. PUF 47-49. These facts are sufficient to demonstrate the requisite intent under the statute.

b. AstraZeneca Cannot Escape Liability by Blaming First DataBank.

AstraZeneca cannot escape liability by attempting to shift responsibility to First DataBank. As an initial matter, AstraZeneca admits that it sets and controls the AWP and WACs that First DataBank publishes. PUF 39-57. Indeed, with only one exception, in every instance in which First DataBank published an AWP or WAC that was different than the AWP or WAC that AstraZeneca had reported to it, AstraZeneca brought this to First DataBank's attention and requested that the AWP or WAC be changed. PUF 54-57.

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

⁶ Although AstraZeneca'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).⁷

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, AstraZeneca 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 AstraZeneca 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, is not “turning square corners” with the government.

The fact that AstraZeneca only reported WACs to First DataBank and the other pricing compendia after 2002 on advice of counsel is of no moment. Because AstraZeneca expected, indeed knew, that First DataBank would apply a standard markup to its WACs to derive an AWP (PUF 52), it effectively controlled the AWPs published by First DataBank. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 2007 WL 1774644 *4 & *29 (D.Mass., June 21, 2007) (rejecting Bristol-Myers Squibb’s argument that because it only reported a “Wholesale List Price” (its name for WAC) for its drugs, it was not responsible for First DataBank’s publication of AWPs for those drugs).

⁷ 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. AstraZeneca'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
- (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 AstraZeneca reported and caused First DataBank to publish average wholesale prices for its drugs, AstraZeneca made a "representation." The second element is easily satisfied because AstraZeneca uses the word "wholesale" in its reporting of "average wholesale prices." Finally, the third element is undisputed. As Roger Hyde, AstraZeneca's corporate designee, testified at deposition:

Q: Well, would you -- would you mind just answering my question directly, which is whether AstraZeneca has known and understood since January 1 of 1991 through to the present that AWP is not the actual average price that wholesalers charge for AstraZeneca's products; is that correct?

A: It's my understanding, yes.

Q: When you say your understanding, I want to make sure that it's clear that you're testifying here today as a designee on behalf of AstraZeneca, so I don't want you to limit your answer to your personal knowledge but any knowledge you obtained in preparing to testify today about this subject, about the meaning of AWP.

A: Broadly, I think that's the understanding within AstraZeneca, yes.

PUF 58.

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).

C. AstraZeneca Has No Defense as a Matter of Law To Plaintiff’s Motion.

The State expects AstraZeneca 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, AstraZeneca is likely to argue that certain Wisconsin employees knew or should have known that AstraZeneca’s average wholesale prices were false. Moreover, AstraZeneca 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 AstraZeneca’s conduct. What State employees knew, should have known, or could have discovered is simply irrelevant to the question of liability.

In connection with the statutes at issue in this motion, liability is established by virtue of AstraZeneca’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. 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 AstraZeneca of the falsity of the statements (although if required, such knowledge is established here).⁸ In sum, liability under these statutes depends solely and exclusively on the conduct of AstraZeneca. Any efforts by AstraZeneca to shift the focus of the court’s inquiry to the knowledge, belief, or actions of the State is improper.

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

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

⁸ 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.”).

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 AstraZeneca. *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. AstraZeneca's Argument Misplaces the Duties of the Parties.

Finally, AstraZeneca's argument misplaces the burdens and duties of the parties.

AstraZeneca 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 AstraZeneca's drugs. *Heckler*, 467 U.S. at 63. In contrast, the State had no duty to sue AstraZeneca earlier or to modify its Medicaid program to account for AstraZeneca'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 AstraZeneca'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 AstraZeneca on Counts I and II of plaintiff's Second Amended Complaint. Wisconsin further requests that the court enjoin AstraZeneca from reporting and causing to be published false average wholesale prices and wholesale acquisition costs.

Dated this 30th day of August, 2007.



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STATE OF WISCONSIN

CIRCUIT COURT DANE COUNTY
Branch 9

STATE OF WISCONSIN,)	
)	
Plaintiff,)	
)	
v.)	Case No. 04-CV-1709
)	Unclassified – Civil: 30703
AMGEN INC., et al.,)	
)	
Defendants.)	

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of **MOTION FOR PARTIAL SUMMARY JUDGMENT ON LIABILITY AGAINST DEFENDANTS ASTRAZENECA LP AND ASTRAZENECA PHARMACEUTICALS LP WITH RESPECT TO COUNTS I AND II OF WISCONSIN’S SECOND AMENDED COMPLAINT AND SUPPORTING MEMORANDUM FILED BY PLAINTIFF STATE OF WISCONSIN**, the Declaration of Charles Barnhill, and Appendix to be served on counsel of record by transmission to LNFS pursuant to Order of the Circuit Court of Dane County, Branch 7, Case Number 04-CV-1709, dated December 20th, 2005.

Dated this 30th day of August, 2007.



Charles Barnhill