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GLOSSARY OF TERMS

AMP.....	Average Manufacturer Price
ASP.....	Average Sales Price
AWP.....	Average Wholesale Price
BHCF.....	Bureau of Health Care Financing
CMS.....	Centers for Medicaid and Medicare Services
Complaint/Compl.....	State of Wisconsin's Second Amended Complaint
DHCF.....	Division of Health Care Financing
DHFS.....	Wisconsin Department of Health and Family Services
DOA.....	Department of Administration
EAC.....	Estimated Acquisition Cost
EDS.....	Electronic Data Systems
FDB.....	First DataBank
HCFA.....	U.S. Health Care Financing Administration
HHS.....	U.S. Health and Human Services
JCF.....	Joint Committee on Finance
DAPUF.....	Defendants' Additional Proposed Undisputed Fact
LFB.....	Wisconsin Legislative Fiscal Bureau
MAC.....	Maximum Allowable Cost
NDC.....	National Drug Code
OIG.....	Office of Inspector General
PSW.....	Pharmacy Society of Wisconsin
WAC.....	Wholesale Acquisition Cost

I. INTRODUCTION

In its separate Motions for Partial Summary Judgment Against Johnson & Johnson, AstraZeneca, Novartis, and Sandoz (“Motions”), the State of Wisconsin (“Plaintiff” or the “State”) seeks summary judgment on its § 100.18(1) and § 100.18(10)(b) claims.¹ These Motions should be denied because they are premised on statutory provisions that do not apply and allegations that find no support in the undisputed factual record.

Plaintiff has brought this lawsuit alleging that Wisconsin Medicaid over-reimbursed providers for pharmaceuticals, asserting that the State was deceived because it believed that certain prices, called AWP, which the State obtained from a third-party publisher, First DataBank, were representative of actual averages of wholesale prices. Plaintiff has failed, however, to come forward with any evidence in support of the notion that it was somehow deceived into believing AWP represent actual averages of wholesale prices. To the contrary, the undisputed facts demonstrate that the State’s allegations are, as one State Medicaid employee put it, “[REDACTED]

[REDACTED]” Other facts, such as State Medicaid officials referring to AWP as “ain’t what’s paid” and observing that AWP “rarely reflect the market,” lend support to the conclusion that the State’s historical understanding of AWP is completely at odds with Plaintiff’s allegations.

The undisputed facts show that the State was neither misled into believing that AWP represented an actual average of wholesale prices, nor actually believed this to be the case.

¹ This response is filed on behalf of all Defendants who do not have Motions currently pending against them except to the extent those Defendants expressly join in this response. As previously discussed with the Court, Defendants who are not the subject of the State’s Motions file this response due to concerns regarding potential issue preclusion. See *In re Estate Rille ex rel. Rille*, 2007 WI 36, ¶¶ 36-105, 300 Wis.2d 1, ¶¶ 36-105; 728 N.W.2d 693, ¶¶ 36-105; *Daughtry v. MPC Systems, Inc.*, 2004 WI App. 70, ¶¶ 36-43, 272 Wis.2d 260, ¶¶ 36-43, 679 N.W.2d 808, ¶¶ 36-43; *Precision Erecting, Inc. v. M&I Marshall & Ilsley Bank*, 224 Wis. 2d 228, 300-311; 592 N.W.2d 5, 11-15 (Wis. App. 1998).

Even though the State had access to providers' actual acquisition costs through a variety of sources (including providers, wholesalers, State agencies that purchased drugs directly and drug manufacturers) and notwithstanding that, for many years, the State's analysts have informed it that AWP "does not reflect the actual cost of acquiring the drug," the State has repeatedly and affirmatively elected to retain AWP as part of its reimbursement formula to providers dispensing brand-name and certain generic pharmaceuticals to Medicaid beneficiaries (the "Reimbursement Rate"). The State has done this to further policy goals, electing to use AWP (less some percentage) in order to assure a level of reimbursement to providers in excess of their actual acquisition costs in order to compensate for low dispensing fees, in an effort to foster providers' continued participation in the Medicaid program and to placate an aggressive pharmacists' lobby. Plaintiff's summary judgment Motions should be denied.

First, this case, without a doubt, implicates reimbursement under Wisconsin's Medicaid program, and involves complex issues involving important State budgetary and healthcare policy considerations that are properly left to the legislative and executive branches. The Court, therefore, should abstain from adjudicating this matter on the merits in accordance with long-standing separation of powers principles.

Second, even if the Court does choose to entertain the merits of the State's Motions, they fail as a matter of law. The State's claims were wrongly asserted under § 100.18 given the existence of a separate statutory provision, Wis. Stat. § 100.182, that was intended to specifically govern conduct related to drugs. Just as the Wisconsin Court of Appeals found § 100.183 and other state regulation of the food industry prevents the application of § 100.18 to alleged misrepresentations related to food,² any claims concerning alleged

² *Gallego v. Wal-Mart Stores East, Inc.*, 2005 WI App. 244, 288 Wis. 2d 229, 707 N.W. 2d 539, review granted, 289 Wis. 2d 9 (2006).

misrepresentations related to drugs can only be properly brought under § 100.182 and not § 100.18. The State has asserted no claim under § 100.182. Moreover, just as with food, representations regarding drugs are not governed by § 100.18 because neither “drugs” nor “pharmaceuticals” are specifically identified in that provision and they are not considered “merchandise” as that term is used in the statute.

Third, § 100.18(1) is inapplicable to the conduct alleged here. This provision was intended to protect consumers from being induced into an obligation by false or deceptive representations. The State does not provide evidence that it was induced by AWP into any obligation whatsoever, and *none* of the potential obligations that the State *may* have been induced into making, fits with the statutory language.

Fourth, the State’s Motions also fail to set forth undisputed material facts showing that any Defendant violated § 100.18. The State, for instance, does not set forth material facts demonstrating: (1) that Defendants made untrue, deceptive or misleading representations, as the facts show that AWP for Defendants’ drugs were consistent with the State’s own understanding of the term AWP; (2) that AWP materially induced the State to act differently than it would have otherwise acted; or (3) that Defendants affirmatively represented that the AWP were something other than the industry’s, and the State’s, understanding of them. The same holds true with respect to the State’s claims concerning Defendants’ “wholesale acquisition costs” or “WACs,” which the State has never used for reimbursement purposes.

Fifth, the State’s § 100.18(10)(b) claim fails because § 100.18(10)(b) does not create a separate cause of action, but merely defines conduct that would be deceptive under § 100.18(1). Additionally, the State has failed to set forth undisputed material facts showing that a representation was made that AWP was a “wholesaler’s price” as required under § 100.18(10)(b).

In light of these compelling facts, in addition to responding to Plaintiff's Motions, Defendants cross-move for summary judgment on all of the State's claims. The Court should dismiss all claims on the separation of powers grounds. The Court should also grant Defendants' cross-motion on the State's § 100.18(1) and § 100.18(10)(b) claims because those claims fail as a matter of law for the same reasons described in Defendants' response to Plaintiff's Motions. In addition, the Court should grant Defendants' cross-motion on the State's remaining claims – §§ 133.05 and 49.49, and unjust enrichment – because the undisputed factual record demonstrates that those claims are time-barred by the applicable six year statutes of limitations.³

II. RESPONSE TO CLAIMS

A. Count I – Wis. Stat. § 100.18(1).

Plaintiff's misstate the elements of Wis. Stat. § 100.18(1). The Wisconsin Supreme Court ruled that Wis. Stat. § 100.18(1) requires proof of the following elements:

1. “[W]ith the intent to induce an obligation, the defendant made a representation to ‘the public.’” *K&S Tool & Die Corp. v. Perfection Machinery Sales, Inc.*, 2007 WI 70, ¶ 19; 301 Wis.2d 109, ¶ 19, 732 N.W.2d 792, ¶ 19.
2. “[T]he representation was untrue, deceptive or misleading.” *Id.*
3. “[T]he representation caused the plaintiff a pecuniary loss.” *Id.* To prove causation, the plaintiff must show that the representation “materially induced” it to act differently. *Id.* at ¶ 35.

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

Defendants do not dispute that Plaintiff has accurately quoted the text of Wis. Stat. § 100.18(10)(b), but do dispute Plaintiff's characterization of Wis. Stat. §100.18(10)(b) as a separate cause of action. Subsection (10)(b) merely provides a statutorily defined example of

³ The Defendants are cross moving at this time only on these grounds but reserve the right to move on other grounds in the future, if necessary.

one type of conduct that the Legislature has deemed “deceptive” under Wis. Stat. § 100.18(1), and therefore there are no separate “elements” of this claim as set forth in Plaintiff’s Motions.

III. ELEMENTS OF DEFENSES

A. Separation of Powers.

The Court should not decide the merits of this case because it presents a non-justiciable political issue. *Baker v. Carr*, 369 U.S. 186, 210 (1962).⁴ “The nonjusticiability of a political question is primarily a function of the separation of powers.” *Id.* An issue is non-justiciable if:

1. the Court lacks “judicially discoverable and manageable standards for resolving [the issues],” *Id.* at 217; or
2. there is an “impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion.” *Id.*

B. The State’s § 100.18 Claims Fail because § 100.182, and not § 100.18, Applies to Conduct Relating to Drugs.

No analysis of the elements is necessary to this defense.

C. Statutes of Limitations.

1) **Wis. Stat. § 49.49 fraud claim.**

“The following actions shall be commenced within 6 years after the cause of action accrues or be barred...An action for relief on the ground of fraud.” Wis. Stat. § 893.93(1)(b).

2) **Wis. Stat. § 133.05 claim.**

“A civil action for damages or recovery of payments under this chapter is barred unless commenced within 6 years after the cause of action accrued.” Wis. Stat. § 133.18(2).

⁴ This case is frequently cited by Wisconsin Courts addressing separation of powers principles and the political question doctrine. *See, e.g. In the Matter of a John Doe Proceeding*, 2004 WI 65, ¶¶ 25-28, 272 Wis.2d 208, ¶¶ 25-28, 680 N.W.2d 792, ¶¶ 25-28 (concerning whether a subpoena for legislative documents intruded into a “core zone” of legislative power violating an area constitutionally reserved to the Legislature); *Vincent v. Voight*, 2000 WI 93, ¶¶ 192-93, 236 Wis.2d 588, ¶¶ 192-93, 614 N.W.2d 388, ¶¶ 192-93 (Sykes J., concurring in part, dissenting in part); *State v. Jensen*, 2004 WI App 89, ¶ 48, 272 Wis.2d 707, ¶ 48, 681 N.W.2d 230, ¶ 48.

3) **Unjust enrichment claim.**

An action to recover for unjust enrichment must be filed within six years from the date the claim accrues. *Boldt v. State*, 101 Wis. 2d 566, 578, 305 N.W.2d 133, 141 (Wis. 1981), *cert. denied*, 454 U.S. 973 (1981) (applying contract limitations period found in Wis. Stat. § 893.43 to unjust enrichment claim).

IV. **DEFENDANTS' ADDITIONAL PROPOSED UNDISPUTED FACTS (DAPUF)**

A. **Throughout the Relevant Period the Reimbursement Community Has Understood AWP Is a Benchmark Price That Does Not Represent Actual Provider Cost.**

1) **It has been common knowledge for decades that AWP represents a benchmark or reference price, rather than actual average of wholesale drug prices.**

1. AWP is not defined in any Wisconsin or federal Medicaid statute or regulation. Transcript of Deposition of James J. Vavra ("Vavra Tr.") at 159, 210 (Aug. 16, Sept. 26-27, 2007) (excerpts attached as Ex. 1); Transcript of Deposition of Thomas A. Scully ("Scully Tr.") at 311-12 (May 15, July 13, 2007) (excerpts attached as Ex. 2).

2. AWP has been defined as a "[REDACTED]" Deposition of Christopher J. Decker ("Decker Tr.") at 111 (Dec. 11, 2006) (excerpts attached as Ex. 3).

3. Christopher Decker, the Executive Vice President and Chief Executive Officer of the Pharmacy Society of Wisconsin ("PSW"), testified that:

[REDACTED] Decker Tr. at 111 (Ex. 3).

4. The Manager of Editorial Services of First DataBank, Patricia Kay Morgan, who was responsible for the database containing drug pricing information that Wisconsin received, testified that AWP is a "benchmark" or "reference" price and that it was no "secret" in the industry that "contract prices" were lower than AWP. Transcript of

Deposition of Patricia Kay Morgan ("Morgan Tr.") at 27:21-29:8, 35:15-36:13 (Aug. 27, 2007) (excerpts attached as Ex. 4).

5. Robert F. Helms, chairman of a federal task force appointed to study state Medicaid reimbursement, has stated:

In the 1980s, it was well known among federal policy makers at [Health & Human Services] and among state Medicaid agencies that AWP did not reflect actual sales prices for drugs from wholesalers to pharmacies. Rather, AWP was a misnomer and actual prices paid by pharmacists to wholesalers were substantially below AWP. This was well understood and accounted for in Medicaid reimbursement practices." Affidavit of Robert F. Helms ("Helms Aff.") ¶ 3 (Jan. 9, 2008) (attached as Ex. 5).

6. Numerous CMS officials have testified that the federal government was well aware that AWP exceeded the actual acquisition costs of providers and, with this knowledge, approved state plans which used AWP-based reimbursement methodologies. For example:

- Former HCFA Administrator, Bruce Vladeck testified that HCFA was not "fooled" into believing that AWP represented actual acquisition costs. Transcript of Deposition of Bruce C. Vladeck ("Vladeck Tr.") at 139-41, 189-93, 382, 473 (May 4, June 21, 2007) (excerpts attached as Ex. 6).
- Former CMS Administrator Thomas Scully testified that he knew that as far back as 1990, AWP was substantially in excess of the price at which wholesalers could actually acquire drugs, that AWP was referred to as a "sticker price" or a "list price" which was not reflective of the price paid by purchasers, that if AWP was really an average cost, most people probably wouldn't be discounting it, and that AWP does not have much functional meaning as it is a number that "nobody really pays." Scully Tr. at 39-40, 216-17, 489, 516-17, 596-97, 846-47 (Ex. 2).
- CMS Director in the Division of Pharmacy, Larry Reed, testified that, since 1990, he understood that AWP exceeded the provider's acquisition costs and heard AWP referred to as both a "sticker price" and "ain't what's paid". Transcript of Deposition of Larry Reed ("Reed Tr.") at 258-61, 371, 520 (Sept. 26-27, 2007) (excerpts attached as Ex. 7) (also testifying that the difference between AWP and acquisition costs was significantly greater for generic drugs as opposed to branded drugs).

7. Federal government reports as far back as at least 1984 have concluded that AWP does not represent, and does not purport to represent, the wholesaler's actual selling price to the retail pharmacy, or an average of the wholesaler's actual selling prices to retail

pharmacies. For example:

- In 1984, the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) issued a report stating that “pharmacies do not purchase drugs at the AWP published in the “Bluebook,” “Redbook or similar publications. Thus, AWP cannot be the best--or even an adequate--estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists’ invoices.” OIG Report, *Changes to the Medicaid Prescription Drug Program Could Save Millions* (“1984 OIG Report”) at 22 (Sept. 1, 1984) (attached as Ex. 8).
- In 1997, OIG issued a report indicating that “the invoice price for brand name drugs was a national average of 18.3 percent below AWP.” OIG Report, *Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs* at WI-Prod-AWP-104244 (Apr. 10, 1997) (attached as Ex. 9).
- In 2001, OIG issued a report finding that the actual acquisition cost for brand name drugs was an average of 21.84 percent below AWP. OIG Report, *Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products* at WI-Prod-AWP-104255 (Aug. 10, 2001) (attached as Ex. 10).
- In 2001, GAO issued a report noting that AWP “is often described as a ‘list price,’ ‘sticker price,’ or ‘suggested retail price,’ reflecting the fact that AWP is not necessarily the price paid by a purchaser or a consistently low or ‘wholesale’ price.” The report further noted that AWP “may be neither an average nor what wholesalers charge[.]” GAO Report to Congressional Committees, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers’ Cost* at 9 (Sept. 2001) (attached as Ex. 11).⁵

⁵ See also OIG Report, *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program* at 7 (Oct. 3, 1989) (attached as Ex. 12) (“We continue to believe that AWP is not a reliable price to be used as a basis for reimbursements for either the Medicaid or Medicare programs.”); OIG Report, *Physicians’ Costs for Chemotherapy Drugs* at 5 (Nov. 1992) (attached as Ex. 13) (“Red Book officials confirmed that AWP is not designed to reflect physicians’ costs.”); HCFA Report to Congress, “Pharmacy Reimbursement Rates: Their Adequacy and Impact on Medicaid Beneficiaries” at 4 (June 1994)(excerpt attached as Ex. 14) (AWP “is not . . . a direct measure of true acquisition costs” but rather a “suggested wholesale price to the pharmacy. . . [W]holesalers compete with each other by offering pharmacies discounts from [AWP]. . . . Estimates of the range of discounts from AWP available to pharmacies include 10-18 percent.”); OIG Report, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products* at WI-Prod-AWP-106038 (Aug. 4, 1997) (attached as Ex. 15) (“pharmacies pay an average of 42.5 percent less than AWP for [generic] drugs sold to Medicaid beneficiaries.”); 2001 OIG Report, *Medicare Reimbursement of Prescription Drugs* at ii (Jan. 2001) (attached as Ex. 16) (stating that “the published AWP’s . . . bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers.”); OIG Report, *Medicaid’s Use of Revised Average Wholesale Prices* (Sept. 2001) (attached as Ex. 17); GAO

8. Numerous other publicly available studies reviewed by the State, including some Wisconsin-specific studies, confirmed that AWP did not represent an actual average of wholesale drug prices. For example, a 1998 Minority Staff Report by the U.S. House of Representatives, Committee on Government Reform and Oversight, found that the published AWP for the ten most commonly used drugs by seniors were 18% higher than prices available from one drug wholesaler. Minority Staff Report, Committee on Government Reform and Oversight, U.S. House of Representatives, *Prescription Drug Pricing in the Fifth Congressional District in Wisconsin: Drug Companies Profit at the Expense of Older Americans* at 9 (Oct. 9, 1998) (attached as Ex. 23).⁶

Testimony Before the Subcommittee on Health, Committee on Finance, U.S. Senate, *Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices* at 5 (Mar. 14, 2002) (attached as Ex. 18) (AWP “is neither ‘average’ nor ‘wholesale;’ it is simply a number assigned by the product’s manufacturer. The AWP is often described as a ‘list price,’ ‘sticker price,’ or ‘suggested retail price,’ reflecting that it is not necessarily the price paid by a purchaser or a consistently low or ‘wholesale’ price.”); OIG Report, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products* at WI-Prod-AWP-112295 (Mar. 14, 2002) (attached as Ex. 19) (finding that the actual acquisition cost for generic drugs was a national average of 65.93 percent below AWP); OIG Report, *Medicaid Pharmacy - Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products* at 4 (Sept. 16, 2002) (attached as Ex. 20) (finding that pharmacies purchased single source innovator drugs at 17.2 percent below AWP; drugs without FULs at 27.2 percent below AWP; multiple source drugs without FULs at 44.2 percent below AWP; and multiple source drugs with FULs at 72.1 percent below AWP, and recommending that, if a state must use AWP as a basis for reimbursement, it should adopt a four-tiered reimbursement system to bring pharmacy reimbursement more in line with the actual acquisition costs); Medicare Prescription Drug and Modernization Act of 2003, H.R. Rep. 108-178(II), at 197 (July 15, 2003) (excerpt attached as Ex. 21) (“Congress has long recognized AWP is a list price and not a measure of actual prices.”); OIG Report, *State Strategies to Contain Medicaid Drug Costs* at 8-9 (Oct. 2003) (attached as Ex. 22) (finding that “AWP overstated pharmacy acquisition costs for brand name drugs by 22% and overstated acquisition costs for generic drugs by 66%[,]” and that “OIG audits have also suggested that WAC is unreliable.”)

⁶ See, also, David Kreling, *Assessing Potential Prescription Reimbursement Changes: Estimated Acquisition Costs in Wisconsin*, Health Care Financing Review, Vol. 10, No. 3 at 67 (Spring, 1989) (attached as Ex. 24) (Wisconsin specific-study finding that, “[b]ecause it is apparent that AWP is not the best estimates of pharmacists’ purchase costs, there has been an interest in changing reimbursement formulas to improve the accuracy of prescription ingredient cost reimbursement. Several different policies have been proposed.”); Kaiser Family Foundation Report, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit* at 20 (Jan. 2000) (attached as Ex. 25) (“Rebates are usually negotiated as a percentage of the list price (that is the average wholesale price, AWP) since this is the key published price. However, no purchaser actually pays the list price—which is only a suggested

2) The State historically understood AWP did not represent actual provider cost.

9. Since the mid-1970s, Wisconsin has understood that AWP did not reflect an actual average of wholesale prices, and that AWP-based reimbursement exceeds the acquisition costs providers typically pay for drugs. See Draft Medicaid Pharmacy Task Force Report (“1976 Task Force Report”) at 3 (Jan. 16, 1976) (attached as Ex. 29).

10. Numerous documents produced by the State of Wisconsin demonstrate that all branches of Wisconsin Government involved in setting Medicaid reimbursement have known since at least the mid-1970s that pharmacies are able to purchase drugs well below published AWPs. For example:

- A 1975 Memorandum from Dale Cattnach, Director of the Legislative Fiscal Bureau (LFB) to the Joint Committee on Finance, states that “the policy of the Department of Health and Social Services has been to reimburse at the listed wholesale price plus \$2 dispensing fee. Many observers believe that this method of reimbursement is not economical since it fails to take into account state variations from the national wholesale price list or discounts obtained through bulk purchasing.” Memorandum from Dale Cattnach to the Joint Committee on Finance, *Health and Social Services—Medical Assistance Cost Controls and Sum Sufficient Reestimate* (“1975 Cattnach Memorandum”) at 4 (Apr. 25, 1975) (attached as Ex. 30).
- In 1976, the Governor’s Task Force on Medicaid Pharmacy Reimbursement (the “Task Force”) concluded “that the Blue Book prices overstate actual drug costs.”

price.”); David Kreling, et al., Kaiser Family Foundation Report, *Prescription Drug Trends, A Chartbook Update* at 49 (Nov. 2001) (attached as Ex. 26) (defining AWP as “a national average of list prices charged by wholesalers to pharmacies. With few exceptions, the AWP is the manufacturer’s suggested list price for a wholesaler to charge a pharmacy for a drug. It typically is higher than the pharmacy’s actual acquisition cost”); George Washington University, National Health Policy Forum, Issue Brief No. 775: *Average Whole Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?* at 3 (June 7, 2002) (attached as Ex. 27) (“AWP is not an accurate reflection of actual market prices for drugs . . . There are no requirements or conventions that the AWP reflect the price of any actual sale of drugs by a manufacturer, or that it be updated at established intervals. It is not defined in law or regulation, and it fails to account for the deep discounts available to various payers, including federal agencies, providers, and large purchasers, such as HMOs.”); The Medicaid Commission, Report to the Honorable Secretary Michael O. Leavitt, DHHS, and the United States Congress at WI-PROD-PDF-012512 (Sept. 1, 2005) (attached as Ex. 28) (“There is a widespread acceptance that AWP is inflated and does not reflect a valid benchmark for pricing. A different reference price should be established and made available to the states that more accurately reflects the actual price for drugs. The Average Manufacturer Price (AMP) should be used for this purpose.”).

The Task Force recommended that Wisconsin reimburse Medicaid providers at actual acquisition costs, defined as “invoice cost minus bulk purchasing discounts plus billed warehouse costs.” 1976 Task Force Report at 3, 5 (Ex. 29).

- A DHFS Budget Issue Paper dated June 2, 1998 states that AWP “represents more than cost[,]” and that “Wisconsin MA’s current drug payment methodology over-compensates pharmacy providers for their cost of drugs.” DHFS 1999-2001 Biennial Budget Issue Paper, *Cost of Drugs* at 1 (June 2, 1998) (attached as Ex. 31).
- An LFB paper dated June 1, 1999 states that “AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to the ‘sticker price’ of a car. It does not reflect the actual cost of acquiring the drug.” LFB, Joint Committee on Finance, *Drug Reimbursement*, Paper #479 (“1999 LFB Paper”) at 3 (June 1, 1999) (attached as Ex. 32).

11. Since 1984, DHFS has received, reviewed, and distributed at least a dozen federal reports concluding that AWP does not represent an actual average of wholesale prices. Vavra Tr. at 474-515 (Ex. 1).⁷

12. DHFS specifically relied on a number of these reports in proposing reductions in the Reimbursement Rate. Vavra Tr. at 483-87, 491-94, 509-10 (Ex. 1).⁸

13. [REDACTED]

[REDACTED]

[REDACTED] Decker Tr. at 77-82 (Ex. 3).

14. [REDACTED]

[REDACTED]

[REDACTED] Decker Tr. at

119-20, 160-61 (Ex. 3).

15. [REDACTED]

⁷ See also documents cited *supra*, DAPUF ¶ 7.

⁸ See, e.g., DHFS 2005-07 Biennial Budget Issue Paper, *Topic: Pharmacy Reimbursement* at 2 (Jan. 25, 2005) (attached as Ex. 33); Letter from Helene Nelson, Secretary, DHFS to Representative Dean Kaufert and Senator Alberta Darling, Co-Chairs, Joint Committee on Finance at 1-2 (Mar. 25, 2003) (attached as Ex. 34); LFB, Joint Committee on Finance, *Reimbursement Rates for Prescription Drugs*, Paper #474 (“2001 LFB Paper”) at 3-4 (June 4, 2001) (attached as Ex. 35).

[REDACTED]

[REDACTED] Decker Tr. at 164 (Ex. 3).

16. In 1995, Wisconsin's Department of Agriculture, Trade and Consumer Protection concluded that: "Wholesalers often start their price negotiations with retailers at the Average Wholesale Price (AWP). The AWP is the manufacturer's suggested selling price for wholesalers to use. The 'Actual Acquisition Cost' is the true cost that retailers pay. *This amount may, and does, differ significantly from the AWP.*" Wisconsin Department of Agriculture, Trade and Consumer Protection, *Wholesale Pricing of Prescription Drugs in Wisconsin* ("1995 Report") at 21 (July 28, 1995) (attached as Ex. 36) (emphasis added).

17. The State's designee confirmed that this was DHFS's understanding of AWP. Vavra Tr. at 188-89 (Ex. 1).

18. From at least February 1998, Wisconsin Medicaid has commonly referred to AWP as "ain't what's paid." Transcript of Deposition of Theodore M. Collins ("Collins Tr.") at 165-66 (Oct. 30, 2007) (excerpts attached as Ex. 37).⁹

19. In September 1998, Wisconsin Medicaid sent EDS (Wisconsin's fiscal agent) a document stating that AWP's reported by First DataBank do not accurately represent average prices some wholesalers charge providers. Transcript of Deposition of Mark L. Gajewski ("Gajewski Tr.") at 287-88 (Dec. 19, 2007) (excerpts attached as Ex. 39).

20. Since the late 1990s, Wisconsin has been informed by numerous Defendants that the AWP's published by First DataBank do not represent actual prices for drugs. See Transcript of Deposition of Mary Roma Rowlands ("Rowlands Tr.") at 111-118, 124-133

⁹ See also E-mail from Ted Collins to Alan S. White (Feb. 24, 1998) (attached as Ex. 38) ("AWP (i.e. ain't what's paid) prices rarely reflect the market...").

(Nov. 1, 2007) (excerpts attached as Ex. 40).¹⁰ For example:

- On August 10, 1999, Dey wrote to all State Medicaid Administrators, including Wisconsin, informing them that: “As you also know, the Average Wholesale Price (or “AWP”) per unit listed above does *not* represent actual wholesale prices which will be charged or paid for this product. . . We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.” Letter from Dey to State Medicaid Administrator (Aug. 10, 1999) (attached as Ex. 47).
- In 2002, Baxter notified Wisconsin that First DataBank’s AWP’s for Baxter’s drugs were inaccurate. Memorandum from Peggy Handrich to Mark Gajewski at WI-Prod-AWP-099898 (Dec. 13, 2002) (Ex. 45).

21. A 2002 study commissioned by Wisconsin to investigate pharmacy reimbursement concluded that AWP exceeded actual acquisition costs by 17.52 to 17.58% for brand name drugs, and 74.44 to 76.16% for generics. David Kreling, *Draft Pharmacy Cost of Dispensing/Acquisition Cost Study Final Report* (“2002 Kreling Report”) at 2-3 (Mar. 6, 2002) (attached as Ex. 48); Vavra Tr. at 30 (Ex. 1) (confirming that the draft report accurately reflects the main conclusions of the final report).

22. In a 2004 letter responding to a private attorney’s solicitation for AWP litigation business, which outlined the alleged facts underlying a potential fraud claim against drug manufacturers, DHFS Administrator Mark Moody wrote:

The issue you present is one of which we have been aware for several years. In 1997, and again in 2001, Wisconsin was one of the eight states that the Department of Health and Human Services’ Office of the Inspector General included in its survey of Medicaid Coverage of Prescription Drugs. That survey indicated that pharmacists could obtain brand name prescription drugs at 21.84 percent below the average wholesale price, while Medicaid reimbursement for those drugs averaged around 10-12 percent below the average wholesale price. We have been discussing this issue with the

¹⁰ See e.g., Letter from Schering Plough to Roma Rowlands (Oct. 3, 2002) (attached as Ex. 41); Letter from Bristol Myers Squibb to Roma Rowlands (Mar. 14, 2000) (attached as Ex. 42); Letter from Amgen to Roma Rowlands (Mar. 28, 2002) (attached as Ex. 43); Letter from Zeneca Pharmaceuticals to Medicaid Pharmacy Program Administrator (Jan. 23, 1998) (attached as Ex. 44); Memorandum from Peggy Handrich to Mark Gajewski, EDS (Dec. 13, 2002) (attached as Ex. 45) (enclosing letters from Genzyme and Baxter expressing “concerns related to the determination of Average Wholesale Pricing (AWP) from FDB”); Ivax Product Bulletin (June 13, 2005) (attached as Ex. 46).

Wisconsin Department of Justice for some time.... Letter from Mark B. Moody to Gary F. Franke at WI-Prod-AWP-126686 (Mar. 17, 2004) (attached as Ex. 49).

23. On January 6, 2005, Neil Gebhart, in-house counsel for DHFS, sent an email to Robert Blaine, employee at the Department of Administration, [REDACTED] Mr. Gebhart stated in his e-mail:

[REDACTED] E-mail from Neil Gebhart to Robert Blaine (Jan. 6, 2005 12:34 pm) (attached as Ex. 50).

3) For over 25 years, the State has had access to actual acquisition cost information for both generic and brand name drugs.

24. Since at least 1979, the State, through its pharmacy consultants, has had access to actual acquisition costs for both generic and brand name drugs from numerous sources, including wholesalers, internet-based pharmacy buying groups, multi-state purchasing organizations, provider invoices and prices paid by other Wisconsin governmental entities. Transcript of Deposition of Carrie L. Gray ("Gray Tr.") at 53, 54-63, 82-84 (Sept. 27, 2007) (excerpts attached as Ex. 51); Collins Tr. at 16-17, 43-45, 81-83 (Ex. 37).¹¹

25. Specifically, the State, through its pharmacy consultants, has had access to the following sources for actual acquisition costs for both generic and brand name drugs:

¹¹ See also E-mail from Ted Collins, Wisconsin's Pharmacy Consultant, to Alan S. White, DHFS (Feb. 24, 1998) (attached as Ex. 52) (indicating that F. Dohmen was selling a particular drug at "a small fraction of the AWP"); E-mail from Ted Collins to Carrie Gray (Aug. 28, 2000, 4:55 pm) (attached as Ex. 53) (indicating that the WAC price for a particular drug was "seven times the IPC price," and that DHFS had access to pricing data from McKesson); E-mail from Ted Collins to Carol Neeno, DHFS (Dec. 16, 2004) (attached as Ex. 54) ("If Mary Durkin hasn't gotten you access to Cardinal, take the Accupril prices AWP-13% price and subtract another 20%."); E-mail from Ted Collins to Carrie Gray (May 26, 2000) (attached as Ex. 55) (indicating that DHFS had access to numerous sources of actual acquisition costs for various drugs, including Multim, McKesson, IPC and various pharmacy invoices).

- *Wholesalers:* From 1999 until the present, except for a brief period, DHFS had access to actual pricing data provided by either F. Dohman or Cardinal, two major drugs wholesalers in Wisconsin. Collins Tr. at 16-17, 61-62 (Ex. 37); Gray Tr. at 53-54 (Ex. 51). McKesson sells brand name and generic prescription drugs to retail pharmacies in Wisconsin. Transcript of Deposition of Susan L. Sutter (“Sutter Tr.”) at 46-47 (Dec. 12, 2007) (excerpts attached as Ex. 56); Collins at 137 (Ex. 37). At various points from at least 2000 to the present, the State has had access to pricing data from McKesson, another major national wholesaler. Gray Tr. at 57-59, 84 (Ex. 51); Collins Tr. at 136-37, 141-42 (Ex. 37).
- *Internet Pricing Sources:* At various times between 1985 and the present, Wisconsin Medicaid has had access to prices from IPC, an internet-based pharmacy buying group. Collins Tr. at 151 (Ex. 37); Transcript of Deposition of Michael C. Boushon (“Boushon Tr.”) at 194-96 (Nov. 5, 2007) (excerpts attached as Ex. 57). In the past, the State had access to Vet Net, another internet-based source showing actual acquisition costs for drugs. Collins Tr. at 17 (Ex. 37); Gray Tr. at 82-83 (Ex. 51) (indicating that Wisconsin had access to Vet Net prices from 2000 to 2003).
- *State Entity Purchase Prices:* Between 1979 and 1984, the Department of Administration arranged for Wisconsin state entities, such as the University of Wisconsin hospitals and the Department of Corrections, to purchase prescription drugs directly from wholesalers or manufacturers. DHFS had access to the prices at which these entities could purchase prescription drugs. Collins Tr. at 43-45 (Ex. 37); Vavra Tr. at 178-79 (Ex. 1). Between 1985 to 1995 and 1999 to 2006, Wisconsin Medicaid had access to the prices at which Wisconsin state entities, and similar entities of other states, were able to purchase prescription drugs through a group purchasing organization, the Minnesota Multi-State Contracting Alliance for Pharmacy (“MMCAP”). Collins Tr. at 57-59, 64, 157-58 (Ex. 37);¹² Boushon Tr. at 194-96 (Ex. 57). State entities were able to purchase both brand name and generic prescription drugs through MMCAP. Boushon Tr. at 67 (Ex. 57).
- *Invoices:* Since 1979, Wisconsin Medicaid has received wholesaler invoices when pharmacies have protested that the Maximum Allowable Cost (“MAC”) price for a drug was below their acquisition cost. Collins Tr. at 81-82 (Ex. 37); Gray Tr. at 54-55, 59-60 (Ex. 51). Wisconsin pharmacies have repeatedly protested MAC prices by submitting wholesaler invoices to Wisconsin Medicaid. Boushon Tr. at 195 (Ex. 57); Transcript of Deposition of Kimberly A. Hodgkinson (“Hodgkinson Tr.”) at 60-66 (Nov. 19, 2007) (excerpts attached as Ex. 58); Transcript of Deposition of Russell J. Jensen (“Jensen Tr.”) at 146-49 (Aug. 3, 2007) (excerpt attached as Ex. 59); Transcript of Deposition of Gary A. Donaldson (“Donaldson Tr.”) at 42-44 (Nov. 27, 2007) (excerpt attached as Ex. 60). As shown on these wholesaler invoices, the unit prices of prescription drugs were lower than their listed AWP. Hodgkinson Tr. at 66-67 (Ex. 58); Donaldson Tr. at 42-46 (Ex. 60).

¹² Ted Collins cannot recall if there were any points between 1999 and 2006 during which he did *not* have access to such pricing information, and stated that “likely for most of the period I had access to it.” Collins Tr. at 158:19-21 (Ex. 37).

- *Other Prices:* Since 2001, the State has had access to Average Sales Price (“ASP”) information from some Defendants, information that is reported directly by Defendants to the federal government. Gray Tr. at 218 (Ex. 51).¹³ Wisconsin Medicaid also had access to AMPs, prices reported directly by manufacturers to the federal government. Collins Tr. 193, 199, 205-07 (Ex. 37). Wisconsin Medicaid has access to WAC prices for prescription drugs through First DataBank. Gray Tr. at 114-15 (Ex. 51).

26. Wisconsin used these sources in setting its “maximum allowable cost” or “MAC” price for generic drugs. Boushon Tr. at 194-96 (Ex. 57); Collins Tr. at 15-17 (Ex. 37); Gray Tr. at 62 (Ex. 51).

27. The State Medicaid Official responsible for setting MACs testified that he did not use AWP because he knew the selling price was lower:

Q. With regard to Cardinal, what field in the Cardinal pricing information did you rely on in setting the MAC?

A. I don't know how it was actually defined. Again, it was a field for selling price, for want of a better thing. I don't remember how it was actually defined. They also, I believe, had AWP.

Q. And WAC?

A. No, they didn't have WAC, to my knowledge.

Q. And you didn't rely on the Cardinal report of AWP because that selling field, in your experience, was lower?

A. Yes.

Collins Tr. at 184:22-185:14 (Ex. 37).

28. Wisconsin also had access to information showing what private third-party payors, such as insurance companies, were reimbursing for dispensing prescription drugs. In considering reimbursement changes, Wisconsin Medicaid has reviewed the reimbursement terms for all of the significant payors in the Madison area, including

¹³ See Plaintiff's Response to Defendant TAP Pharmaceutical Products Inc.'s First Set of Interrogatories and Requests for Production of Documents to the State of Wisconsin (“Plaintiff's TAP Response”) at 2 (July 11, 2007) (attached as Ex. 61); Plaintiff's Response to Defendants' Fourth Set of Interrogatories and to Defendants' Fourth Requests for Production of Documents (“Plaintiff's Fourth Response”) at 2 (Nov. 26, 2007) (attached as Ex. 62); 42 U.S.C. 1396r-8(b) (requiring all drug manufacturers to report ASPs since 2005); 42 U.S.C. § 1395w-3a(c) (setting out the methodology for calculating ASP).

Physicians Plus, Unit, Dean, and Navitus. Gray Tr. at 108-09 (Ex. 51).

29. The State used acquisition cost information in preparing and considering budget proposals involving changes to the Reimbursement Rate. *See, e.g.*, DHFS, 2005 – 2007 Biennial Budget Issue Paper, *Topic: Pharmacy Reimbursement* at 2 (Jan. 25, 2005) (Ex. 33) (noting that IPC lists prices that are on average 21% below AWP).

30. In addition, the State could have required, but did not require, providers to report and certify their actual acquisition costs on their claims forms submitted for reimbursement. Vavra Tr. at 387-88 (Ex. 1); Gray Tr. at 89 (Ex. 51).

B. Despite Knowing AWP is Merely a Benchmark Price, the State Chose to Use It as Part of Its Reimbursement Methodology Contrary to the Federal Government’s Recommendation and the Practice of Other States.

31. The State does not purchase drugs for Medicaid recipients. Vavra Tr. at 178 (Ex. 1); Wis. Admin. Reg. HFS 108.

32. Providers participating in the Medicaid program must enter into a contract with the State, pursuant to which the State agrees to reimburse properly submitted claims for drugs dispensed to Medicaid recipients. DHFS Wisconsin Medicaid Program Provider Agreement, Wisconsin Medicaid Pharmacy Certification Packet (excerpt attached as Ex. 63).

33. Federal law requires that reimbursement for brand name drugs not exceed, *in the aggregate*, the lower of: (1) the estimated acquisition costs (“EAC”) plus reasonable dispensing fees; or (2) the providers’ usual and customary charges to the general public. 42 C.F.R. § 447.512(b) (emphasis added).

34. Each state is given discretion to determine the appropriate level of reimbursement. Vavra Tr. at 68 (Ex. 1).

35. No federal statute or regulation requires the use of AWP by a state Medicaid

program, including Wisconsin. Vavra Tr. at 208 (Ex. 1).

36. Since at least 1984, the federal government has discouraged using AWP as a basis for Medicaid reimbursement because AWP is an inadequate estimate of the prices providers generally pay for drugs. *See* 1984 OIG Report at 22-23 (Ex.8).

37. In 1989, the federal government prohibited the use of undiscounted AWP as a basis for reimbursement. HCFA, Revised State Medicaid Manual (Aug. 1989) (attached as Ex. 64).

38. States that have chosen to base “estimated acquisition cost” on discounted AWP have applied different discounts to arrive at a reimbursement amount. For example, Alaska’s Medicaid program reimburses pharmacies at AWP-5%, whereas Rhode Island reimburses at AWP-16%. Memorandum from Christopher Decker, PSW, to Members of the Joint Committee on Finance, *Wisconsin Medicaid Pharmacy Reimbursement: Why Changes are Necessary* at PSW_00006123 (Apr. 30, 2005) (attached as Ex. 65-F).

39. Other States have chosen not to use AWP in their reimbursement formula under Medicaid. For example, Massachusetts reimburses based on the published “wholesale acquisition cost” (“WAC”) price plus 6%. Legislative Fiscal Bureau, Joint Committee on Finance, *Prescription Drug Reimbursement Rates*, Paper #371 (“2005 LFB Paper”) at 12 (May 26, 2005) (attached as Ex. 66). New York has chosen to reimburse physicians who administer drugs in the office at the “actual cost of drugs to the practitioners.” N.Y. Soc. Serv. L. § 367-a(9)(a).

40. From at least the late-1970s until June 1990, Wisconsin has reimbursed based on the lower of (1) EAC, which Wisconsin defined as the Direct Price charged by certain manufacturers, 100% AWP or MAC plus a reasonable dispensing fee; or (2) “usual and customary charge.” *See* State Plan Amendment No. 79-0032 at WI-Prod-AWP-022148 (Sept. 21, 1979) (attached as Ex. 67); State Plan Amendment No. 90-0006 at WI-Prod-AWP-

011366 (Apr. 17, 1990) (attached as Ex. 68); Vavra Tr. at 392-94 (Ex. 1).

41. Over the years, Wisconsin Medicaid changed its definition of EAC by increasing the percentage discount from AWP and dropping Direct Price¹⁴ but continued to reimburse at the lower of (1) EAC or MAC plus a reasonable dispensing fee, or (2) usual and customary charge. In July 1990, Wisconsin Medicaid changed its definition of EAC from 100% AWP to AWP-10%. Vavra Tr. at 394 (Ex. 1). In July 2001, it changed it to AWP-11.25%. Vavra Tr. at 97 (Ex. 1); State Plan Amendment No. 01-0009 at WI-Prod-AWP-027602 (July 1, 2001) (attached as Ex. 69). In 2003, it changed it to AWP-12%, and, in 2004, it changed it to AWP-13%, where it remains today. Vavra Tr. at 436, 452 (Ex. 1).

42. In October 2005, the State stopped reimbursing providers administering physician-administered drugs to Medicaid beneficiaries based on AWP and adopted an Average Sales Price (“ASP”) plus 6 percent reimbursement methodology. Vavra Tr. at 137-38 (Ex. 1).

43. To this day, Wisconsin continues to reimburse providers based on AWP for brand name drugs dispensed by a pharmacy. Vavra Tr. at 137 (Ex. 1).

44. The majority of generic drugs reimbursed by Wisconsin Medicaid are reimbursed based on the State’s MAC list prices, which are generally set by Wisconsin Medicaid at a markup of 10-25% above the lowest acquisition price at which Wisconsin Medicaid determined the product was available to retail pharmacies, based on information gathered from wholesalers, retail buying groups and other sources. Collins Tr. at 74-75 (Ex. 37). AWP and WAC were not used to set MACs. Collins Tr. at 160-61 (Ex. 37).

45. At no time has the State used “wholesale acquisition cost” or “WAC” to

¹⁴ Wisconsin understood that Direct Price was a list price for certain manufacturers for sales directly to retailers. Vavra Tr. 59-60, 126 (Ex. 1). In 2000, Wisconsin stopped using Direct Price as an alternative reimbursement price despite recognizing that using AWP-10% would increase the reimbursement rate for some manufacturers’ drugs. *Id.* at 59-60, 520.

reimburse for drugs under its Medicaid program. Vavra Tr. at 129 (Ex. 1).

46. Congress adopted the following definition of WAC in 2003: “The term ‘wholesale acquisition cost’ means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price” 42 U.S.C. § 1395w-3a(c)(6)(B).

47. According to Wisconsin’s Department of Agriculture, Trade and Consumer Protection, “wholesalers purchase from manufacturers at the Wholesale Acquisition Cost (WAC). Rebates or discounts from WAC, may be granted, such as those based on volume purchasing.” 1995 Report at 17 (Ex. 36).

48. The State’s designee testified that the definition of WAC referenced in ¶ 47 *supra* was consistent with Wisconsin’s understanding of WAC. Vavra Tr. at 133-34 (Ex. 1).

49. The federal government also knew that WAC was an undiscounted, list price and did not believe there was anything “wrong” with a drug manufacturer setting WAC at an undiscounted, list price. Scully Tr. at 642-43, 645-46, 652-53 (Ex. 2) (also testifying that WAC was generally lower than AWP).

C. The State’s Drug Reimbursement Methodology Under Medicaid is Set By the Legislative and Executive Branches After Considerable Deliberation and Compromise.

50. In Wisconsin, “the [Medicaid] reimbursement rate and the dispensing fee are both the product of a complex and interdependent legislative process that begins with the DHFS and ends at the end of the Governor’s veto pen.” Plaintiff’s Reply Brief in Support of Its Motion to Quash Defendants’ Notice of Deposition of Wisconsin Legislature’s Fiscal Bureau Budget Analysts Marlia Moore, Rachel Carabell, and Amie Goldman (“LFB Reply”)

at 12 (Nov. 12, 2007) (attached as Ex. 70).¹⁵

51. Every other year, DHFS submits a proposed budget to the Governor's office and Legislature. Plaintiff's LFB Reply at 2 (Ex. 70). Within this budget proposal, DHFS may recommend a change to the Reimbursement Rate. *Id.*

52. A few months later, the Governor submits to the Legislature his proposed budget, including any modifications to DHFS's budget proposal, along with the Executive Budget Book outlining program and policy changes from the previous year. *Id.* at 2-3.

53. The Governor's budget is then introduced by and referred to the Joint Committee on Finance ("JCF"). *Id.* at 3.

54. The JCF is staffed by the Legislative Fiscal Bureau ("LFB"), who in turn prepares a summary and analysis of the Governor's budget and proposed policy changes along with its own proposed changes, including analyses of the Medicaid reimbursement formula and potential reimbursement alternatives, for the JCF to consider. *Id.* at 3.

55. The JCF then votes on the proposed policy changes and submits its version of the budget to the full Legislature. Once the budget is passed by both the Assembly and the Senate, it is sent to the Governor for his signature. *Id.*

56. Once signed by the Governor, the reimbursement formula is published in the State's "state plan amendment," which is signed by a representative of the Governor's office and submitted to CMS for approval. Vavra Tr. at 31-32 (Ex. 1).

57. CMS must approve the proposed rate change before the State is entitled to any federal money for its Medicaid program. Vavra Tr. at 31-32 (Ex. 1).

58. The State admits that "[t]he budget cycles discussed above ... clearly

¹⁵ See also, Plaintiff's Response to Sandoz Inc.'s First Request for Production of Documents at 6-7 (Nov. 26, 2007) (attached as Ex. 71) ("The "decision" how to reimburse is made in Wisconsin through the legislative process, as proposed by the Legislature and as signed or modified by the Governor.").

demonstrate that “AWP” and the reimbursement formula and the dispensing fee are the product of the legislative process.” LFB Reply at 11 (Ex. 70).

59. The State’s reimbursement methodology and rates are not set forth in any statute or administrative rule. Vavra Tr. at 112 (Ex. 1).

60. In order to receive federal funds for its Medicaid program, Wisconsin is required to obtain federal approval for changes to its reimbursement methodology and rates, which are submitted to CMS in the form of state plan amendments. Vavra Tr. at 31-32 (Ex. 1).

61. State plan amendments are generally drafted by DHFS, and must be signed by a representative of the Governor’s office before transmittal to CMS. Vavra Tr. at 81-83 (Ex. 1).

62. Wisconsin is required to solicit public comments on each change to reimbursement before its effective date. Changes to reimbursement are generally published in newspapers or the State Register, and provider updates are sent to providers affected by the change. Vavra Tr. at 106-07, 110-12 (Ex. 1).

D. To Satisfy Certain Policy Goals, the State Used AWP Because it Represented More Than Providers’ Acquisition Costs.

1) The State chose to use AWP as a benchmark price after weighing its various policy goals.

63. Federal law requires Wisconsin to set its Medicaid reimbursement at an amount “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” 42 U.S.C. §1396a(a)(30)(A); *see also* Helms Aff. ¶ 21 (Ex. 5).

64. Wisconsin is responsible for establishing its reimbursement methodology based on its own determination of how best to achieve this goal of providing access to care.

Vavra Tr. at 43-45 (Ex. 1).

65. Wisconsin's reimbursement methodologies "are designed to enlist program participation by a sufficient number of providers so that MA recipients are assured that authorized medical care and services are available to the same extent those same services are available to the state's general population." Vavra Tr. at 43:10-19 (Ex. 1); State Plan Amendment No. 88-0003 at WI-Prod-AWP-016420 (Dec. 28, 1987) (attached as Ex. 72).

66. DHFS took this equal access requirement seriously. Vavra Tr. at 115 (Ex. 1).

67. DHFS was aware that providers may choose not to participate in the Medicaid program if Medicaid reimbursement did not cover their costs of providing drugs to Medicaid recipients. Vavra Tr. at 113-15 (Ex. 1).

68. Wisconsin was repeatedly lobbied and pressured by pharmacists' associations to reject proposals to reduce the Reimbursement Rate. Transcript of Deposition of Lorie L. Neumann ("Neumann Tr.") at 200-203, 216-217 (Oct. 31, 2007) (excerpts attached as Ex. 73); Jensen Tr. at 166-73 (Ex. 59).

69. Over the years, individual pharmacists also participated in opposing reductions in reimbursement by contacting their legislators and members of the Joint Finance Committee by phone, by mail or in person to discuss the effects of a reduction in reimbursement, or by meeting with or writing to the Governor. Jensen Tr. at 136-37, 166-173 (Ex. 59); Hodgkinson Tr. at 165-167, 169-171 (Ex. 58); Decker Tr. at 64-65, 90-95, 97-98 (Ex. 3); Neumann Tr. at 40-49, 153-58, 168-70, 195-97, 200-03 (Ex. 73); Sutter Tr. at 85-89 (Ex. 56).

70. Such lobbying was often accompanied by threats of withdrawal from participation in the Medicaid program and the resulting reduced access to care for Medicaid recipients. Jensen Tr. at 136-38, 167-70 (Ex. 59); Neumann Tr. at 43-49 (Ex. 73); Donaldson Tr. at 71-72 (Ex. 60); Transcript of Deposition of Nicole Y. Valentine ("Valentine

Tr.”) at 94-96 (July 19, 2007) (excerpts attached as Ex. 74).¹⁶

71. These lobbying efforts influenced Wisconsin’s decisions regarding proposed changes to the Reimbursement Rate. Hodgkinson Tr. at 174-79 (Ex. 58); Neumann Tr. at 203 (Ex. 73); Decker Tr. at 94-95, 98-101 (Ex. 3).

72. For example:

- In 1998, Governor Thompson told PSW: “Rest assured I remain committed to protecting the interests of pharmacies throughout the state of Wisconsin and will not approve this request to reduce the Medicaid pharmacist reimbursement in the 1999-2001 biennial budget.” Letter from Governor Thompson to Christopher Decker (Oct. 16, 1998) (attached as Ex. 65-C).
- In 2001, State Senator Dave Hansen issued a press release opposing a Reimbursement Rate cut, stating “I think there is a real risk of pharmacies closing, particularly in the smaller, more rural communities.

¹⁶ See also Letter from Wisconsin State Representative David A. Brandemuehl to Secretary Joe Lekan, DHFS (Oct. 15, 1998) (attached as Ex. 75) (stating that a change in reimbursement rate would have a “harsh” impact on many pharmacists in his district, some of which may be forced to close); PSW, Position Statement, *Pharmacy Medicaid Reimbursement Rate Reduction Included in the State Budget Bill [SB55 and AB 144]* at WI-Prod-AWP-117905 (2000) (attached as Ex. 76) (“Wisconsin has an obligation to assure its policies do not reduce the availability of important and necessary health care services. Reduction in pharmacy reimbursement will result in dramatic reductions in the quantity and quality of services provided to MA recipients.”); Memorandum from Tom Engels, PSW, to Governor McCallum (Aug. 1, 2001) (attached as Ex. 65-H) (asking Governor McCallum to veto legislation that would reduce the Medicaid reimbursement rate from AWP-10% to AWP-11.25%, because this reduction would have an impact on the ability of many Wisconsin pharmacies to participate in the Medicaid program); Letter from Jeffrey Fox, R.Ph, Walgreens, to Governor McCallum at PSW_00010591(Aug. 6, 2001) (attached as Ex. 65-B) (expressing concern and disappointment with the legislation reducing the Medicaid reimbursement rate for the 2001-2003 from AWP-10% to AWP-11.25%, explaining that the rate cut results in a reduction to gross profit of nearly 8%, and cautioning that a reduction will have detrimental effects on Wisconsin pharmacists and their patients); Letter from Christopher Decker, PSW, to Governor James Doyle (Feb. 24, 2003) (attached as Ex. 65-G) (expressing “grave concern” that budget proposals to reduce payments to pharmacy providers, “if adopted, will directly result in pharmacy practice closings statewide. Rural communities will be left without a pharmacy. ... Changing the state’s reimbursement formula to pay pharmacies less does nothing to reduce the cost of the drug, it only reduces the pharmacy’s margin.”); Memorandum from Tom Engels, PSW, to Members of the Joint Committee on Finance at PSW_00010095 (Mar. 13, 2003) (attached as Ex. 65-E) (“This proposal [changing reimbursement rate to AWP-15%] could result in pharmacies dropping the Medicaid program, the elimination of services, pharmacy closings, and employee layoffs. Worse yet will be the impact on patients who are served by these pharmacies.”); Memorandum from Tom Engels, PSW, to Wisconsin State Senator Ron Brown (2005) (attached as Ex. 77) (identifying pharmacies in the Senator’s district and the estimated financial impact resulting from the proposed DHFS reduction to pharmacy reimbursement rates).

I don't want anyone to be denied access to life- or health-saving prescriptions because the state forced their pharmacist out of business." Wisconsin State Senator Dave Hansen, Press Release, *Senator Dave Hansen Recommends that Wisconsin Not Cut Pharmacy Reimbursement* (Apr. 3, 2001) (attached as Ex. 78).

- In 2005, State Representative Albers wrote a letter to Thomas Raabe, a Wisconsin pharmacist, noting that the Legislature "saw the importance of maintaining reimbursement rates for pharmacists," recognized the inability of pharmacists to serve citizens enrolled in the MA program without "sufficient reimbursement rates," and restored \$17 million towards reimbursement rates that would have otherwise been cut. Letter from State Representative Sheryl K. Albers to Thomas Raabe (July 8, 2005) (attached as Ex. 65-D).
- Also, in 2005, State Senate Majority Leader Schultz wrote a letter stating that the JCF voted to restore the \$38 million Medicaid cut because the cut "would have jeopardized the level of service some pharmacies provide to patients that qualify for Medical Assistance." Letter from State Senate Majority Leader Dale W. Shultz to Thomas Raabe (July 7, 2005) (attached as Ex. 65-A).

73. CMS has known that states, like Wisconsin, set their reimbursement rates based, in part, on pressures from pharmacists. *See* Scully Tr. 656-657 (Ex. 2); Helms Aff. ¶¶ 22-23 (Ex. 5).

2) The State intentionally reimbursed at more than providers' actual costs to provide them a profit that would ensure their continued participation in the Medicaid program.

74. DHFS intended its AWP-based reimbursement system to cover providers' costs as well as provide some profit margin. *Vavra Tr.* at 77 (Ex. 1).

75. In 1975, the Governor's Office stated that pharmacists participating in Wisconsin Medicaid are entitled to a reasonable profit. Letter from Wisconsin Lt. Gov. Martin Schreiber to the Food and Drug Administration, Department of Health, Education and Welfare (Feb. 7, 1975) (attached as Ex. 79); *see also* 1976 Task Force Report at 3 (Ex. 29) (declaring "it was unconscionable for the State to require any person to provide a product at an out-of-pocket loss.")

76. In 2006, the Governor's Commission on Pharmacy Reimbursement (the "Governor's Commission") "sought to balance the interests of various stakeholders," including pharmacists' interest "to be provided with sufficient reimbursement to cover their costs of doing business, i.e., the cost of the drug (ingredient cost), and the costs of dispensing *and some profit margin.*" Governor's Commission on Pharmacy Reimbursement -- Final Report ("2006 Governor's Commission Report") at 7 (Mar. 30, 2006) (attached as Ex. 80) (emphasis added).

77. DHFS stated that under Wisconsin's reimbursement formula, pharmacies, on average, earn a margin on the ingredient cost of the drugs dispensed to Medicaid beneficiaries. Draft PSW Legislative Letter and Responses at WI-Prod-AWP-108023 (attached as Ex. 81).¹⁷

78. In response to a 1998 letter from PSW, DHFS wrote: "Because the difference between what pharmacists pay for [brand] drugs (WAC) and how [Medicaid] reimburses for drugs (AWP-10%), pharmacists often benefit from increases in drug costs. They profit from the difference between what they pay (WAC) and the higher ingredient costs reimbursed by [Medicaid] (AWP-10%)." Draft PSW Legislative Letter and Responses at WI-Prod-AWP-108023 (Ex. 81).

79. The Wisconsin Legislature, through its Legislative Fiscal Bureau, recognized that "[t]he difference between what pharmacist pay (WAC) [for brand drugs] and the higher ingredient costs reimbursed by MA (AWP – 10%) is profit for the pharmacist." OTC Drugs at WI-Prod-AWP-097610, attached to E-mail from Michael Bormett to Richard Chao and Marjorie Pifer at WI-Prod-AWP-097612 (Apr. 14, 1999) (attached as Ex. 83) (addressing the LFB's questions contained in the e-mail).

¹⁷ See also E-mail from Ted Collins to Carrie Gray (Feb. 26, 2003 4:25 pm) (attached as Ex. 82)(setting the MAC list price for Loratadine at \$.60, even though "the prices currently range from \$.37 to \$.49," specifically noting that "we let them make a few bucks.").

80. CMS permitted states, including Wisconsin, the flexibility to pay providers more than actual acquisition cost. Vladeck Tr. at 446 (Ex. 6). Former CMS Administrator Thomas Scully testified that, within reason, States could choose to pay a “spread” to providers, and that he never told state Medicaid officials that they should not pay a spread to providers. Scully Tr. at 595-96, 630-31, 632-33 (Ex. 2).

81. Linda Ragone, Deputy Regional Inspector General (“DRIG”) for the Office of Evaluation and Inspections (“OEI”) Region III office, testified that an appropriate amount of reimbursement includes an element of profit that is not included in reimbursement based on acquisition cost. Transcript of Deposition of Linda Ragone (“Ragone Tr.”) 377 (Apr. 17-18, 2007) (excerpts attached as Ex. 84).

3) The State intentionally reimbursed at more than providers’ ingredient costs for drugs to offset its inadequate dispensing fees.

a) Surveys show that Wisconsin’s dispensing fees do not cover providers’ costs.

82. According to studies commissioned by the State, Wisconsin’s dispensing fee has been inadequate to cover pharmacies’ actual dispensing costs since at least 1990. See Vavra Tr. at 295-97, 301-03 (Ex. 1); *Projecting a 1990 Cost of Dispensing a Prescription Drug* at WI-Prod-AWP-097969-71(1990) (attached as Ex. 85); 2002 Kreling Report at 2 (Ex. 48).

83. In 1979, Wisconsin commissioned a consulting firm, Hefner Associates, to perform a comprehensive survey of the cost of dispensing prescription drugs in Wisconsin. This study determined that the average cost of dispensing was \$3.02, yet Wisconsin only paid \$2.65. See Medical Assistance Provider Bulletin, *Cost of Dispensing Study* at WI-Prod-AWP-030353 (Oct. 31, 1980) (attached as Ex. 86); Letter from Martin Stanton, Regional Medicaid Director, to Donald Percy, DHSS at WI-Prod-AWP-022077

(Apr. 16, 1979) (attached as Ex. 87).

84. In response, Wisconsin increased its dispensing fee to \$3.10 in 1980. *Projecting a 1990 Cost of Dispensing a Prescription Drug* at WI-Prod-AWP-097969 (1990) (Ex. 85).

85. In 1990, Wisconsin used the Hefner Associates study data to project that the average cost of dispensing, in 1990, was \$5.28 per prescription. *Id.* at WI-Prod-AWP-097971.

86. Wisconsin did not increase its dispensing fee to \$5.28 in 1990. Instead, it paid \$3.83 per prescription until July 1990 when it increased its dispensing fee to \$4.69. Medical Assistance Provider Bulletin, *Pharmacy Policy and Billing Information* at WI-Prod-AWP-031330 (Dec. 15, 1989) (attached as Ex. 88); Memorandum from Christine Nye, Director, Bureau of Health Care Financing (“BHCF”), to Mark Gajewski, Executive Program Director, EDS (May 1, 1990) (attached as Ex. 89).

87. In 2000, Wisconsin commissioned David Kreling, Ph.D., of the University of Wisconsin School of Pharmacy, to perform, in part, a comprehensive survey of the cost of dispensing prescription drugs in Wisconsin. This study determined that the average cost of dispensing, in 2000, was \$6.60 per prescription. 2002 Kreling Report at 2 (Ex. 48).¹⁸

88. In 2000, Wisconsin did not increase its dispensing fee to \$6.60. Instead, it paid \$4.38 per prescription. *See* State Plan Amendment No. 01-0009 at WI-Prod-AWP-027605 (July 1, 2001) (Ex. 69).¹⁹

89. Dr. Kreling also projected that, by 2002, the dispensing cost had risen to

¹⁸ *See also* Legislative Fiscal Bureau, Joint Committee on Finance, *Prescription Drug Reimbursement Rates (DHFS – Health Care Financing – Payments, Services, and Eligibility)*, Paper # 389 (“2003 LFB Paper”) at 4 (May 21, 2003) (attached as Ex. 90) (citing Kreling’s findings).

¹⁹ While the dispensing fee was technically set at \$4.88, the 1995 \$.50 per-prescription reduction had the effect of reducing the dispensing fee to \$4.38. Vavra Tr. at 123, 142-43 (Ex. 1); 2003 LFB Paper at 1 (Ex. 90).

between \$7.03 and \$7.43 per prescription. 2002 Kreling Report at 2 (Ex. 48).

90. Wisconsin did not increase its dispensing fee. Instead, it continued paying \$4.38 per prescription. Vavra Tr. at 143 (Ex. 1).²⁰

91. In 2006, the Governor's Commission found the average cost of dispensing prescription drugs to be \$9.50. 2006 Governor's Commission Report at 4 (Ex. 80).

92. Despite this finding, Wisconsin continued to pay a dispensing fee of \$4.38 per prescription. Vavra Tr. at 279 (Ex. 1).²¹

93. In 2007, the average cost of dispensing a prescription to Medicaid patients in Wisconsin was between \$10 and \$11, but the dispensing fee remained \$4.38. Decker Tr. at 32, 33, 43 (Ex. 3); Vavra Tr. at 280 (Ex. 1).

94. On January 1, 2008, the State increased the dispensing fee, but only by \$.50. Hodgkinson Tr. at 178-79 (Ex. 58); Affidavit of Christopher Decker, RPh ("Decker Aff.") ¶¶ 12-13 (Jan. 10, 2008) (attached as Ex. 65).

b) *The State provides a margin on ingredient cost reimbursement to cross-subsidize for inadequate dispensing fees.*

95. Pharmacists have testified that Wisconsin's dispensing fees have been inadequate for decades. Hodgkinson Tr. at 95-97 (Ex. 58); Decker Tr. at 36 (Ex. 3); Sutter Tr. at 121-25 (Ex. 56); Jensen Tr. at 118 (Ex. 59).

96. Because the dispensing fee, on average, does not cover the full cost of dispensing drugs to Medicaid patients, Wisconsin pharmacies rely on the drug margin to make up for inadequate dispensing fees. Decker Tr. at 34-36, 54-55 (Ex. 3); Hodgkinson Tr. at 94-97 (Ex. 58); Jensen Tr. at 134-36 (Ex. 59); Neumann Tr. at 158-60 (Ex. 73); Donaldson

²⁰ See, *supra*, n. 19; see also 2003 LFB Paper at 1 (Ex. 90).

²¹ See, *supra*, n. 19.

Tr. at 61-62 (Ex. 60); Valentine Tr. at 77-78 (Ex. 74).²²

97. Wisconsin is aware of this and considers the drug margin together with dispensing fee to determine the adequacy of reimbursement. Decker Tr. at 54-55 (Ex. 3); Vavra Tr. at 331-37 (Ex. 1); Hodgkinson Tr. at 99-100, 106-107, 257-260 (Ex. 58); Neumann Tr. at 176 (Ex. 73).

98. In 1988, the Bureau of Health Care Financing (“BHCF”), the bureau responsible at the time for administering Medicaid, stated that: “It is generally accepted that [Wisconsin Medicaid’s] stated professional fee is lower than actual pharmacy overhead costs, but this discrepancy had previously been nullified by the difference between [Wisconsin Medicaid’s] payment for the drug and the actual new drug cost to the pharmacy. (A lower net cost can be due to ‘volume’ or early-pay discounts offered by wholesalers.)” Memorandum from Christine Nye, Director, Bureau of Health Care Financing to Roberta Kostrow, Director, Bureau of Budget at 3 (Nov. 22, 1988) (attached as Ex. 93).

99. In 1989 BHCF “acknowledge[d] that AWP is inflated, but argue[d] that total payments are not excessive because dispensing fees are artificially low and off-set the over allowance.” Memorandum from Christine Nye, Director, BHCF to George MacKenzie, Administrator, Division of Health at 2 (June 26, 1989) (attached as Ex. 94).²³

²² See also National Association of Chain Drug Stores, *Issue Brief: Assuring Appropriate Payment for Medicaid Prescription Drugs and Pharmacy Services* at WI-Prod-AWP-118999 (Mar. 14, 2001) (attached as Ex. 91) (“reducing the product cost reimbursement rate to providers for the product *without* making sufficient accompanying changes in the payment to the provider to administer and properly monitor the use of the drug will harm quality of care. That is because the ‘spread’ between the providers’ acquisition cost for a drug and the reimbursement rates being paid currently helps to compensate providers for inadequate payment for the costs of administration, education, and monitoring of the drug.”); Memorandum from Christopher Decker to the Wisconsin Pharmacy Reimbursement Commission (Oct. 31, 2005) (attached as Ex. 92); Memorandum from Chris Decker, PSW, to Members of the Joint Committee on Finance, *Wisconsin Medicaid Pharmacy Reimbursement: Why Changes Are Necessary* at PSW_00006123 (Apr. 30, 2005) (Ex. 65-F).

²³ See also Letter from Linda Reivitz, Secretary, DHSS, to Barbara Gagel, HCFA Regional Administrator (June 10, 1985) (attached as Ex. 95) (“Wisconsin’s dispensing fee is too low if

100. The LFB has examined the total reimbursement in analyzing budget proposals and making recommendations to the Legislature, and has acknowledged that “[t]he margin between the acquisition cost and the reimbursement rate, together with the dispensing fees, represents the pharmacies' total reimbursement for service costs.” 2001 LFB Paper at 4 (Ex. 35).

101. In 2003, the LFB informed the JCF that, “the total MA reimbursement to pharmacies for costs other than the product acquisition is estimated to total \$9.92 per brand name prescription (\$4.38 dispensing fee, plus a \$5.54 margin on AWP).” 2003 LFB Paper at 5 (Ex. 90).

102. In the same paper, the LFB informed the JCF that cutting the Reimbursement Rate on drugs from AWP-11.25% to AWP-15% would result in an average of a “\$2.22 margin on AWP,” which “may not cover all of a pharmacy’s costs to dispense a prescription.” *Id.*

103. In 2005, the LFB informed the JCF that cutting the Reimbursement Rate would result in a margin on AWP that may be insufficient to cover pharmacies’ dispensing costs. 2005 LFB Paper at 5-6 (May 26, 2005) (Ex. 66).

104. The federal government has been aware of and has approved the practice of cross-subsidizing inadequate dispensing fees through generous ingredient cost reimbursement since at least the 1980s. The chairman of an HHS task force appointed to study state Medicaid reimbursement, which ultimately participated in drafting the current

actual drug cost is used. ... Some other states have lower dispensing fees, but their more generous use of AWP based pricing may offset this.”); Memorandum from Christine Nye, Director, BHCF to George MacKenzie, Administrator, Division of Health at 2 (Nov. 18, 1988) (attached as Ex. 96) (“Since drug reimbursement consists of the sum of two parts, and HCFA is currently reviewing and reducing only the allowed drug cost portion, an imbalance is introduced if the dispensing fee portion is not evaluated at the same time. ... Additionally, implementation of an additional HCFA required rate cut regarding allowed cost, without a corresponding adjustment to dispensing fees, will not be acceptable to pharmacy providers.”).

regulatory language concerning federal upper limits for Medicaid, has stated:

The Medicaid task force I chaired at HHS was well aware that such cross-subsidization was occurring in practice in the states. We had no problem with this. Rather, this was entirely consistent with the Reagan administration's broad policy goals of limiting federal interference in day-to-day local politics and allowing state Medicaid agencies to make their own determinations that would accommodate local political constraints.

In coming to the recommendations that eventually led to the 1987 regulations, the Medicaid task force built upon preexisting reimbursement terminology and structures. We decided to maintain the existing structure of an ingredient cost, whether based on an 'Estimated Acquisition cost' or a specifically prescribed limit, and a separate dispensing fee that theoretically included profit. However, we also recognized that existing state practice was more flexible in that states did not calculate each part of the payment separately and accurately and instead utilized cross-subsidization. Accordingly, we included new language that was expressly intended to allow the existing practice of cross-subsidization to continue. This language consisted of including the term "in the aggregate" when describing the upper limits on payment for ingredient costs and dispensing fees. In other words, payment at the overall level (or "in the aggregate") was not to exceed the sum of an ingredient cost and a reasonable dispensing fee with regard to all the drugs used in the state program. But we left it to the states to decide whether they wanted to accomplish that through offsets and cross-subsidization (as many of them had been doing) or by seeking to accurately measure both aspects of the equation. So long as the overall level of payment was reasonable, our federal policy goals were satisfied. We explicitly considered and rejected the alternative approach commonly used in public utility regulation to rigorously define the accounting methodology for each separate component of the aggregate total. Helms Aff. ¶¶ 24-25 (Ex. 5).²⁴

E. The Evolution of the State's Reimbursement Rate Reflects An Ongoing Policy Debate.

1) In the 1970s, the State rejected a proposal to reimburse providers at their actual acquisition cost.

105. In 1974, the United States Department of Health, Education and Welfare ("HEW") published a Notice of Proposed Rulemaking in the Federal Register advising state Medicaid agencies that they should not reimburse pharmaceuticals at 100% of AWP,

²⁴ See also Transcript of Deposition of Robert Niemann ("Niemann Tr.") at 283-284 (Sept. 14, 2007) (Ex. 186) (testifying that plans to change from an AWP-based system to one based on actual acquisition costs included adding a dispensing fee into the methodology which was intended to account for a loss of margin to providers).

because published AWP's are "frequently in excess of actual acquisition costs to the retail pharmacist." Notice of Proposed Rule 39 Fed. Reg. 41480, Reimbursement of Drug Cost – Medical Assistance Program (Nov. 27, 1974) (to be codified at 45 C.F.R. pt. 250) (attached as Ex. 97).

106. Consequently, HEW proposed a rule (which was never implemented) that would have required states to reimburse at actual acquisition cost, instead of AWP. American Druggist News, "HEW Orders All States to Switch to Cost-Plus-Fee for Medicaid Rx's" (Jan. 1, 1975) (attached as Ex. 98).

107. Wisconsin's Lieutenant Governor Martin J. Schreiber responded to HEW with support for a proposed rule to reimburse at "actual acquisition cost of drugs to the provider," in addition to "a revised professional fee." Letter from Wisconsin Lt. Gov. Martin Schreiber to the Food and Drug Administration, Department of Health, Education and Welfare (Feb. 7, 1975) (Ex. 79).

108. Lieutenant Governor Schreiber informed HEW that pharmacists "of course, must be allowed reasonable profits in their Medicaid business," but stated that, in his opinion, Wisconsin's then-current practice of reimbursing pharmacists at 100% of AWP "allows providers to earn uncontrolled profits through bulk purchases, discounts from suppliers and inadequate monitoring of billing practices." *Id.*

109. On or about October 9, 1975, Governor Patrick Lucey appointed a Medicaid Pharmacy Task Force (the "Task Force") consisting of members of the pharmacy industry, state agencies, and the Legislature to examine "alternative methods of reimbursement" for drugs dispensed by Wisconsin pharmacies under Medicaid. 1976 Task Force Report at 1 (Ex. 29).

110. In a 1975 letter to Task Force members, Lieutenant Governor Schreiber stated that "once again pegging reimbursements to the highly-suspect Average Wholesale

Price figure published in trade publications . . . will result in increased Medicaid expenditures and will fail as long-term management techniques.” Letter from Wisconsin Lt. Gov. Martin Schreiber to Members of the Task Force on Medicaid Pharmacy Reimbursement at 1-2 (Dec. 19, 1975) (attached as Ex. 99).

111. The Task Force confirmed that AWP exceeds “actual drug costs.” 1976 Task Force Report at 3 (Ex. 29) (emphasis added).

112. The Task Force cited a federal agency estimate that, at the time, a “15 percent spread exists between [published] price and actual wholesale price.” *Id.*

113. Despite opposition from its pharmacy members, the Task Force majority recommended that pharmacies be reimbursed at actual acquisition cost, defined as “invoice cost minus bulk purchasing discounts plus billed warehousing costs[,]” rather than at AWP. *Id.* at 5.

114. Department of Health & Social Services (“DHSS”), predecessor to the Department of Health & Family Services, supported the Task Force’s recommendation, and conveyed this support to the Wisconsin Legislature, emphasizing potential cost savings. *See* Letter from DHSS to State Senator Henry Dorman and Assemblyman Dennis Conta, Co-Chairmen, Joint Committee on Finance at 2-3 (Jan. 5, 1976) (attached as Ex. 100).

115. The LFB informed the JCF that reimbursing “at the listed wholesale price . . . is not economical since it fails to take into account state variations from [sic] the national wholesale price list or discounts obtained through bulk purchasing.” 1975 Cattanach Memorandum at 4 (Apr. 25, 1975) (Ex. 30).

116. Wisconsin did not adopt the Task Force recommendation, but continued reimbursing providers for dispensing pharmaceuticals to Medicaid beneficiaries based on 100% of AWP. Vavra Tr. at 180-81, 202-03 (Ex. 1); State Plan Amendment No. 79-0032 at WI-Prod-AWP-022148 (Sept. 21, 1979) (Ex. 67).

2) In the 1970s, the State also rejected a proposal to purchase drugs directly for its Medicaid beneficiaries.

117. In addition to its recommendation to reimburse based on the actual acquisition costs of drugs, the 1975 Task Force recommended the implementation of a trial state purchasing program, under which the State would purchase drugs directly from manufacturers “using the mass purchasing power of the state to get lower prices.” 1976 Task Force Report at 4 (Ex. 29).

118. The Task Force estimated that a direct purchasing program would result in savings of 23%. *Id.*

119. The Task Force noted that other Wisconsin entities already purchase drugs directly from manufacturers or wholesalers. *Id.* This practice continues today. Vavra Tr. at 178-79 (Ex. 1).

120. Wisconsin did not implement the recommended trial direct purchasing plan for its Medicaid program but continued reimbursing based on AWP. Assembly Substitute Amendment 1 to 1975 Assembly Bill 1387 at 8 (Feb. 28, 1976) (attached as Ex. 101); Bulletin Assembly Bill 1387 (Dec. 11, 1976) (attached as Ex. 102); State Plan Amendment No. 79-0032 at WI-Prod-AWP-022148 (Sept. 21, 1979) (Ex. 67).

3) In 1984, the State rejected OIG’s recommendation to preclude the use of AWP.

121. In 1984, HCFA implemented an “EAC initiative” to “bring state prescription drug reimbursement practices into conformance with Federal law and regulations while allowing fair profits to providers and continuing services to recipients.” Letter from Barbara Gagel, HFCA Regional Administrator, to Linda Reivitz, Secretary, DHFS at 1 (May 14, 1985) (attached as Ex. 103).

122. HCFA’s EAC initiative coincided with the release of a 1984 OIG Report, which found that “pharmacies do not purchase drugs at the AWP published in the

“Bluebook,” Redbook,” or similar publications. Thus, AWP cannot be the best – or even an adequate – estimate of the prices providers generally are paying for drugs.” 1984 OIG Report at 22 (Ex. 8).

123. The 1984 OIG report recommended that HCFA “preclude the general use of AWP as the State [Medicaid] agencies’ ‘best estimate of prices providers generally are paying for drugs.’” *Id.* at 23.

124. DHFS received and reviewed this report. Vavra Tr. at 474 (Ex. 1).

125. DHSS Secretary Linda Reivitz responded to the EAC initiative and the OIG report, agreeing that a “reduction in drug reimbursement levels is possible by implementing a system not based on [AWP] as an upper reimbursement limit[,]” and noting that “other states have lower dispensing fees, but their more generous use of AWP based pricing may offset this, as could other regional differences.” DHSS also noted that “reductions [in Medicaid reimbursement] are certain to cause dissatisfaction and may impact provider participation in Wisconsin.” Letter from Linda Reivitz, Secretary, DHSS to Barbara Gagel, HFCA Regional Administrator (June 10, 1985) (Ex. 95).

126. Despite this initiative and the 1984 OIG report, Wisconsin continued reimbursing at 100% of AWP until July 1990. Boushon Tr. at 96-99 (Ex. 57); Vavra Tr. at 394-95 (Ex. 1).

4) In 1990, the State rejected a proposal to change reimbursement to a WAC-plus or actual acquisition cost system in favor of AWP-10%.

127. In 1989, HCFA issued a directive to the states, including Wisconsin, that they should not reimburse pharmacies for drugs at 100% of AWP because 100% of AWP “is not an acceptable estimate of prices generally and currently paid by providers.” HCFA, Revised State Medicaid Manual (Aug. 1989) (Ex. 64) (informing states that AWP over-represents costs by at least 10-20%); Memorandum from Mike Boushon, Pharmacy

Consultant to Peggy Bartels, Director, BCHF, and Dr. Dally (“Boushon Memorandum”) at 3 (Nov. 24, 1989) (attached as Ex. 104) (quoting the Revised Manual).

128. HCFA instructed the states, including Wisconsin, that they could use AWP in reimbursement only if they applied a “significant discount” to AWP. *Id.*

129. Based on this directive from HCFA, Wisconsin Medicaid officials considered lowering the Reimbursement Rate to “actual acquisition cost” or “wholesale cost [WAC] plus” (among other options). *Vavra Tr.* at 384-85 (Ex. 1).

130. These alternatives to AWP-based reimbursement were rejected because Medicaid officials were concerned that reimbursement at these lesser amounts would be “most unacceptable to [Wisconsin’s Medicaid] providers unless dispensing fees are altered significantly.” *Boushon Memorandum* at 3 (Ex. 104) (emphasis in original).

131. In lieu of actual acquisition cost or WAC plus reimbursement, Wisconsin Medicaid proposed changing the Reimbursement Rate to AWP-10%, a change it thought “might be acceptable to HCFA” and would be “more acceptable to providers since it would allow higher reimbursement for higher cost drugs.” *Id.* at 2.

132. The proposal to change the Reimbursement Rate to AWP-10% was described as an acceptable “middle ground” between HCFA’s demand for a rate cut, and the concerns expressed by Wisconsin’s pharmacy providers. *Id.* at 4.

133. At the same time as this proposed reduction in ingredient cost reimbursement, Wisconsin also proposed increasing the dispensing fee, recognizing that “pharmacy professional dispensing fees must be updated to reflect current overhead costs,” and that “[i]t is particularly important to implement these changes concurrently to minimize negative impact on providers.” *Memorandum from Christine Nye, Director, BCHF, to George F. MacKenzie, Administrator, Division of Health* at 1 (Jan. 12, 1990) (attached as Ex. 105).

134. In response to provider protest regarding the proposed changes, Christine Nye, Director, Bureau of Health Care Financing stated that:

The altered system is budget neutral with respect to total payments made for prescription (legend) drugs. The estimated acquisition cost (EAC) is being reduced for approximately 50% of individual drug payments. However, the maximum dispensing fee is being increased for nearly 100% of payments. *Facts: July 1, 1990 WMAP Modified Pharmacy Reimbursement Plan at 1* (attached to Letter from Christine Nye, BHCF, to James C. Olson, R.Ph. (Apr. 20, 1990)) (attached as Ex. 106).

135. In July 1990, the Legislature reduced the ingredient cost Reimbursement Rate from 100% of AWP to AWP-10% and increased the dispensing fee from \$3.83 to \$4.69. Vavra Tr. at 394-95 (Ex. 1).

5) In 1995, the State rejected a proposal to base reimbursement on providers' best price or the providers' actual cost of drugs.

136. In the mid-1990s, Governor Tommy Thompson issued a proposal to reimburse Medicaid providers at the lesser of: (a) the provider's best price; (b) the provider's actual cost; or (c) a different price if determined through contract. See DHSS, Office of Policy and Budget, *Analysis of Legislative Action 1995-97 Biennial Budget—Best Price Proposal at 1* (July 5, 1995) (attached as Ex. 108).

137. A LFB report analyzing Governor Thompson's proposal noted that:

Industry representatives claim that the adoption of the Governor's recommendation could affect the availability of pharmacy services in the state. To the extent that current payments under MA subsidize pharmacists' total costs of providing services, a rate reduction resulting from the best price requirement may reduce revenues to such an extent that some pharmacies may go out of business. Legislative Fiscal Bureau, Joint Committee on Finance, *Best Price Requirement (H&SS – Medical Assistance)*, Paper #403 at 2 (May 23, 1995) (attached as Ex. 107).

138. Governor Thompson's proposal was rejected "due to concerns over the administrative feasibility of the best price requirement, the potential negative financial impact on some providers, and the ability of providers to renegotiate existing contracts." DHSS, Office of Policy and Budget, *Analysis of Legislative Action 1995-97 Biennial*

Budget—Best Price Proposal at 2-3 (July 5, 1995) (Ex. 108).

139. Wisconsin ultimately implemented a \$.50 per prescription reduction in the dispensing fee, while maintaining ingredient cost reimbursement at AWP-10%. Vavra Tr. at 123-24 (Ex. 1).

140. According to DHFS officials, “[t]his arrangement was agreed upon by the industry in order to ‘save’ the reimbursement rate of AWP-10%.” E-mail from Kimberly Smithers to Carrie Gray (Aug. 20, 2001 7:26AM) (attached as Ex. 109).

141. Wisconsin’s designees characterized the \$.50 dispensing fee reduction as a “compromise” with Medicaid providers. See Vavra Tr. at 123-24 (Ex. 1); Transcript of Deposition of Kimberly A. Smithers (“Smithers Tr.”) at 146-48 (Aug. 15, 2007) (excerpts attached as Ex. 110).

6) In 1999, the State rejected a proposal to decrease reimbursement from AWP-10% to AWP-18%.

142. In September 1998, as part of the Governor’s 1999-2001 biennial budget proposal, and based in part on a 1997 OIG study indicating that retail pharmacies purchased brand name drugs at an average discount of AWP minus 18.3%, Wisconsin Medicaid officials proposed cutting the Reimbursement Rate from AWP-10% to AWP-18%. DHFS 1999-2001 Biennial Budget Issue Paper, *Cost of Drugs* at 3-4 (Sept. 15, 1998) (attached as Ex. 111).²⁵

143. Wisconsin pharmacists lobbied against the proposed rate cut. Letter from Andrew Peterson, RPh., to Senator Brian D. Rude (Oct. 7, 1998) (attached as Ex. 112) (“Please do all that you can to put an end to this proposal. Otherwise, it will be an end to me serving as a Medicaid provider.... My practice cannot endure another reimbursement

²⁵ DHFS initially recommended reducing the reimbursement rate to AWP-15% for the 1999-2001 biennium, but later changed its recommendation to AWP-18%. See DHFS 1999-2001 Biennial Budget Issue Paper, *Cost of Drugs* at 4 (June 2, 1998) (Ex. 31).

cut of any amount!”).

144. Two members of the Wisconsin Legislature, Senator Brian Rude and Representative David Brandemuehl, demanded that the DHFS explain why it was proposing to cut reimbursement to Wisconsin pharmacies. Letter from State Representative David A. Brandemuehl to Secretary Joe Leraan, DHFS (Oct. 15, 1998) (Ex. 75) (requesting a “detailed explanation” for the proposed reimbursement cuts at the behest of pharmacist constituents); Letter from Secretary Joe Leraan to State Senator Brian D. Rude (Oct. 26, 1998) (attached as Ex. 113) (responding to Senator Rude’s request for information regarding the budget proposal).

145. Wisconsin Medicaid officials responded to Senator Rude and Representative Brandemuehl, setting forth reasons supporting that a reimbursement cut was justified. Among other reasons, they listed the following:

- “The OIG report [estimating AAC at AWP-18.3%] results are further verified by two additional reports: Representative Barrett’s study of pharmacies in the Milwaukee area verified most brand name drugs are purchased at AWP-18%. A Federal Trade Commission (FTC) report shows the cost of drugs to pharmacies over the last several years dropped to Wholesale Acquisition Cost (WAC). The average WAC price is approximately equal to AWP-18% with a range from AWP-16 2/3 to AWP-20%.” Draft PSW Legislative Letter and Responses at WI-Prod-AWP-108023 (Ex. 81).²⁶
- “Because of the difference between what pharmacists pay for drugs (WAC) and how MA reimburses for drugs (AWP-10%), pharmacists often benefit from increases in drug costs. They profit from the difference between what they pay (WAC) and the higher ingredient costs reimbursed by MA (AWP-10%).” Draft PSW Legislative Letter and Responses at WI-Prod-AWP-108023 (Ex. 81).
- “Many states are considering using WAC instead of AWP, since WAC seems to more accurately reflect the cost of purchasing drugs.” *Id.*

²⁶ PSW wrote to members of the Wisconsin Legislature arguing, among other things, that the 1997 OIG study of pharmacy acquisition prices was flawed because it was based on “invoice prices,” and did not take account of the “additional costs associated with acquiring the drug product.” Memorandum from John A. Benske, PSW, to Members of the Joint Finance Committee at 2 (Apr. 13, 1999) (attached as Ex. 114).

146. On or about October 16, 1998, Governor Thompson wrote to the PSW, assuring its members that the Medicaid Reimbursement Rate would *not* be reduced:

I understand your concern regarding the 1999-2001 biennial budget request from the Department of Health and Family Services to reduce the Medicaid reimbursement rate to pharmacies.

Rest assured I remain committed to protecting the interests of pharmacies throughout the state of Wisconsin and will not approve this request to reduce the Medicaid pharmacist reimbursement in the 1999-2001 biennial budget.

Letter from Governor Thompson to Christopher Decker, PSW (Oct. 16, 1998) (Ex. 65-C).

147. After Governor Thompson sent this letter, DHFS policy makers directed DHFS staff to “*Cancel* this project effective immediately.” Memorandum from Peggy Bartels, Director, DHCF, to Mark Gajewski, Executive Program Director, EDS (Sept. 21, 1998) (attached as Ex. 115); Smithers Tr. at 134-37 (Ex. 110).

148. In order to assist the Legislature in deciding whether to adopt the proposed rate cut, the LFB told the JCF that “AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to the ‘sticker price’ of a car. It does not reflect the actual cost of acquiring the drug.” 1999 LFB Paper at 3 (Ex. 32).

149. The LFB provided the Legislature with a chart showing how much the State might save by cutting the Reimbursement Rate by different percentages, ranging from 1% to 8% (i.e., from AWP-11% to AWP-18%). *Id.* at 4-5.

150. Wisconsin pharmacists opposed the proposed reimbursement cut from AWP-10% to AWP-18%. Their arguments were summarized as follows:

The Pharmacy Society of Wisconsin (PSW) has indicated that reductions to Medicaid pharmacy reimbursement will threaten a pharmacy’s ability to service [Medicaid] recipients. According to the PSW, in the last ten years, there has been a 20% decline in the number of independently owned pharmacies in the state. . . . The Medical College of Virginia study concludes that low-reimbursement for drugs is a major factor in the decreasing number of community pharmacies. However, it should be noted that pharmacies may be experiencing lower reimbursement from commercial insurers and managed care plans, in addition to state [Medicaid] programs. *Id.* at 4.

151. The LFB advised the Legislature that if it was concerned that cutting the Reimbursement Rate to AWP-18% “would not adequately compensate pharmacies for their costs, it could either reduce reimbursement rates by a lesser amount or direct [Wisconsin Medicaid] to maintain current reimbursement rates.” *Id.*

152. The Legislature did not adopt the proposal to cut the Reimbursement Rate to AWP-18% but kept reimbursement at AWP-10%. Vavra Tr. at 416 (Ex. 1).

7) In 2001, the State rejected a proposal to decrease reimbursement from AWP-10% to AWP-15%.

153. In September 2000, as part of the 2001-2003 budget process, DHFS proposed cutting the Reimbursement Rate from AWP-10% to AWP-15%, arguing that the then-current rate of AWP-10% “overcompensates providers for the cost of drugs.” DHFS 2001-2003 Budget Issue Paper, *Medicaid Cost of Drugs* at 2 (Sept. 22, 2000) (attached as Ex. 116).

154. In 2001, then-Governor McCallum sent a letter to a pharmacy noting that “there is a great deal of evidence” indicating Wisconsin Medicaid is paying too much for prescription drugs, and cited a 1997 OIG report finding that “pharmacies generally obtain brand drugs” from their wholesalers at an average price of AWP minus 18.3 percent.” Letter from Governor McCallum to Al Bennin, Walgreens at 1 (Mar. 14, 2001) (attached as Ex. 117).

155. The LFB prepared another report for the Legislature’s JCF, stating that proposed rate cut to AWP-15% “would provide [retail pharmacies] an average margin of 3% of the AWP price for drugs purchased under [Medicaid], compared with approximately 8% of AWP under current reimbursement rates.” 2001 LFB Paper at 4 (Ex. 35) (also citing the 1997 OIG Report).

156. Wisconsin pharmacists objected to the proposed reduction in the

Reimbursement Rate. One pharmacy argued that cutting the Reimbursement Rate to AWP-15% could “pose a serious health and safety risk to the citizens of Wisconsin”:

The proposed reimbursement reduction changes the formula from Average Wholesale Price (AWP) less 10% to AWP less 15% or a decrease of 5%. AWP less 18.5% is our average net cost for brand drugs. Brand drugs represent 86% of our prescription drug revenue. This would result in an average profit of \$5.60 for every brand prescription dispensed to a Medical Assistance patient. This level of reimbursement is not sufficient to cover professional wages and other costs to ensure proper care and consulting of our patients. Letter from Stephen C. Morton to Governor Tommy Thompson (Nov. 6, 2000) (attached as Ex. 118).

157. During legislative hearings convened to consider the proposed rate reduction, a pharmacy owner from Green Bay, apparently “echoing [the] sentiments of other area pharmacists,” testified that the proposed cut was “absolutely without merit.” Wisconsin State Senator Dave Hansen, Press Release, *Senator Dave Hansen Recommends that Wisconsin Not Cut Pharmacy Reimbursement* (Apr. 3, 2001) (Ex. 78).

158. Following the hearings, Senator Dave Hansen issued a press release vowing to fight any reduction in the Reimbursement Rate, due to a concern that it would adversely affect pharmacies and patients:

From what we heard today, if the governor’s prescription drug plan is approved, rather than fixing the problem, it could create a crisis of sorts, particularly in urban and rural areas where there are large numbers of people receiving [Medicaid] prescription benefits. . . . I think there is a real risk of pharmacies closing, particularly in the smaller, more rural communities. I don’t want anyone to be denied access to life- or health-saving prescriptions because the state forced their pharmacist out of business. *Id.*

159. The Legislature did not approve the proposed rate cut to AWP-15%, but did modify the formula to AWP-11.25%. Vavra Tr. at 97 (Ex. 1); State Plan Amendment No. 01-0009 at WI-Prod-AWP-027602 (July 1, 2001) (Ex. 69).

160. The Milwaukee Journal Sentinel opined that:

Because of lobbying by pharmacies and their representatives, the [reimbursement rate] discount was knocked down from the proposed 15% to 11.2% [sic]. The new discount will cost taxpayers an additional \$20 million over the next two years. But even with a smaller discount than McCallum had proposed, some pharmacies may

still drop out of the Medicaid program because they can't make money staying in. That's a serious problem: In the long run, it will hurt both the Medicaid program and those it serves. Milwaukee Journal Sentinel Editorial, *Keeping Drugs Affordable* (Sept. 7, 2001) (attached as Ex. 119).

8) In 2002, the OIG recommended a further cut in Wisconsin's Reimbursement Rate.

161. In 2002, the OIG published a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Wisconsin Department of Health and Family Services." OIG Report, *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Wisconsin Department of Health and Family Services* (Mar. 2002) (attached as Ex. 120). The objective of the OIG study was "to develop for the Wisconsin Medicaid program an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs." *Id.* at WI-Prod-AWP-104222.

162. The OIG study concluded that pharmacies in Wisconsin were purchasing brand name drugs at 20.52 percent below AWP and generic drugs at 67.28 percent below AWP. *Id.* at WI-Prod-AWP-104224-25.

163. The State's designee testified that DHFS believed the OIG's conclusions were accurate. Vavra Tr. at 502-05 (Ex. 1).

164. The OIG study also concluded that pharmacies in Wisconsin were purchasing brand name drugs at or about the published WAC price. OIG Report, *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Wisconsin Department of Health and Family Services* at WI-Prod-AWP-104226 (Mar. 2002) (Ex. 120).

165. Based on these findings, the OIG recommended that Wisconsin "consider the results of this review as a factor in determining any future changes to pharmacy

reimbursement for Medicaid drugs.” *Id.* at WI-Prod-AWP-104226.

166. DHFS officials agreed to consider OIG’s findings in determining any future changes to its reimbursement methodology for drugs. *Id.* at WI-Prod-AWP-104226, WI-Prod-AWP-104234; Vavra Tr. at 507, 509 (Ex. 1).

9) In 2003, the State rejected a proposal to decrease reimbursement from AWP-11.25% to AWP-15%.

167. Later in 2003, Governor Jim Doyle proposed decreasing the Medicaid Reimbursement Rate to AWP-15%. Letter from Helene Nelson, Secretary, DHFS, to Representative Dean Kaufert and Senator Alberta Darling, Co-Chairs, Joint Committee On Finance (Mar. 25, 2003) (Ex. 34).

168. DHFS supported the Governor’s proposals, citing a 2001 OIG Report finding that pharmacies generally obtain brand name drugs at an average price of AWP-21.84%. DHFS, *Drug Reimbursement* at 1 (attached as Ex. 121).

169. DHFS specifically noted that this proposal “would leave a margin of 6.84% on average plus a dispensing fee of \$4.38.” *Id.*

170. In May 2003, the LFB informed the Legislature that decreasing the Reimbursement Rate to AWP-15%, coupled with other service cuts, would save \$20,517,800 in 2003-04 and \$25,795,000 in 2004-05. 2003 LFB Paper at 2 (Ex. 90).²⁷

171. Through the PSW, Wisconsin pharmacists opposed the rate cut, in part because “margins on the product reimbursement [are] necessary to cover the costs of dispensing medications to [Medicaid] recipients, since the current [Medicaid] dispensing fee is not sufficient to cover such costs.” *Id.* at 4.

172. Numerous pharmacists wrote to Governor Doyle urging him not to decrease

²⁷ The LFB also informed the JCF that Wisconsin Medicaid paid more for drugs than most third-party payors. *Id.* at 4 (“reducing reimbursement to pharmacies would address the disparity between what MA currently pays pharmacies for brand name drugs and what other third-party payers reimburse pharmacies.”).

the Reimbursement Rate from AWP-11.25% to AWP-15%.²⁸

173. Wisconsin decided not decrease the Reimbursement Rate from AWP-11.25% to AWP-15%. Instead, effective August 2003, Wisconsin changed its Reimbursement Rate to AWP-12%. Letter from Mark Moody, DHFS, to Wisconsin Pharmacists (Aug. 7, 2003) (attached as Ex. 138).

10) In 2004, the State reduced its Reimbursement Rate to AWP-13%.

174. Wisconsin received a 2003 OIG report entitled “State Strategies to Contain Medicaid Drug Costs,” stating, among other things, that “the OIG and other researchers have found AWP to substantially overstate pharmacies’ actual acquisition costs. . . .” OIG Report, *State Strategies to Contain Medicaid Drug Costs* at 9 (Oct. 2003) (Ex. 22).

175. In 2004, Wisconsin changed its Reimbursement Rate to AWP-13%. Vavra Tr. at 134-35 (Ex. 1).

11) In 2005, the State adopted a proposal to reduce the Reimbursement Rate from AWP-13% to AWP-16%.

176. In late 2004, Governor Doyle proposed decreasing the Reimbursement Rate to AWP-16%, reducing the dispensing fee to pharmacists from \$4.38 to \$3.88 per prescription, and basing reimbursement for physician-administered drugs on WAC rather

²⁸ See, e.g., E-mail from Lynnae Mahaney to Governor Doyle (June 27, 2003 4:04 pm) (attached as Ex. 122); E-mail from Peter Topolovich to Governor Doyle (June 27, 2003 4:27 pm) (attached as Ex. 123); E-mail from Dan Walters to Governor Doyle, (June 27, 2003 5:01 pm) (attached as Ex. 124); E-mail from Bruce Steinhagen to Governor Doyle (June 27, 2003 9:24 pm) (attached as Ex.125); E-mail from William Weiler to Governor Doyle (June 28, 2003 7:03 am) (attached as Ex.126); E-mail from Steven Wilke to Governor Doyle (June 28, 2003 8:55 am) (attached as Ex. 127) (attaching letter); E-mail from William Emmons to Governor Doyle (June 28, 2003 11:14 am) (attached as Ex. 128); E-mail from Mike Flint to Governor Doyle (June 28, 2003 9:27 pm) (attached as Ex. 129); E-mail from Barry Schulman to Governor Doyle (June 28, 2003 9:29 pm) (attached as Ex. 130); E-mail from Peg Breuer to Governor Doyle (June 29, 2003 10:11 pm) (attached as Ex. 131); E-mail from Joel C. Schulze to Governor Doyle (June 30, 2003 7:54 am) (attached as Ex. 132); E-mail from David Musa (June 30, 2003 8:37 am) (attached as Ex. 133); E-mail from Chris Witzany to Governor Doyle (June 30, 2003 9:14 am) (attached as Ex. 134); E-mail from Jamie Statz-Paynter to Governor Doyle (June 30, 2003 11:31 am) (attached as Ex. 135); E-mail from Jane Greishar to Governor Doyle (June 20, 2003 1:02 pm) (attached as Ex. 136); E-mail from Elizabeth DeVore to Governor Doyle (July 2, 11:12 am) (attached as Ex. 137).

than on a discount from AWP. DOA, 2005-07 Budget Issue Summary at WI-Prod-AWP-111935-37 (2004) (attached as Ex. 139).²⁹

177. DHFS supported this proposal, citing the 21% differential between AWP and actual cost information obtained from wholesalers as support. DHFS, 2005-2007 Biennial Budget Issue Paper, *Topic: Pharmacy Reimbursement at 2-3* (Jan. 25, 2005) (Ex. 33).

178. Pharmacists opposed the Governor's proposed rate cut.³⁰

179. The PSW sent an alternative budget proposal to the JCF, which would have eliminated AWP from Wisconsin's reimbursement formula in favor of a formula of WAC + 3%. Pharmacy Society of Wisconsin, Proposed Medicaid Budget Package at WI-Prod-AWP-106449-50 (attached as Ex. 151).

180. The LFB informed the JCF, among other things, that AWP was like a "sticker price on a car" that "very few purchasers actually pay." 2005 LFB Paper at 2-3 (May 26, 2005) (Ex. 66).

181. The LFB also noted that the Governor's proposal, if fully implemented, would yield savings of "\$16,217,900 in 2005-06 and by \$23,597,100 in 2006-07." *Id.*

182. The LFB also noted that "[a]s alternatives to the Governor's proposal, the Committee could consider maximum reimbursement rates for brand name and non-readily available generic drugs, including AWP-15%, AWP-14%, and the current AWP-13%." *Id.*

183. The Legislature decided not to support the Governor's proposal. Letter from

²⁹ See also 2005 LFB Paper at 2 (May 26, 2005) (Ex. 66).

³⁰ Email from Alan Lukazewski to Gov. Doyle (Feb 8, 2005 5:12 PM) (attached as Ex. 140); Email from Jon Wilson to Gov. Doyle (Feb. 13, 2005 9:49 PM) (attached as Ex. 141); Email from Kerry Jewison to Gov. Doyle (Apr. 9, 2005 2:15 PM) (attached as Ex. 142); Email from Alan Lukazewski to Gov. Doyle (Apr. 13, 2005 4:31 PM) (attached as Ex. 143); Email from Carol Davis to Gov. Doyle (July 7, 2005 1:56 PM) (attached as Ex. 144); Email from David Ailey to Gov. Doyle (July 12, 2005 2:23 PM) (attached as Ex. 145); Email from Charlene Freimark to Gov. Doyle (July 12, 2005 2:32 PM) (attached as Ex. 146); Email from Edward Rubin to Gov. Doyle (July 12, 2005 2:53 PM) (attached as Ex. 147); Email from Heather Manthey to Gov. Doyle (July 12, 2005 2:53 PM) (attached as Ex. 148); Email from Denise Dormzalski to Gov. Doyle (July 12, 2005 3:05 PM) (attached as Ex. 149); Email from Eleanor Mathwig to Gov. Doyle (July 12, 2005 3:14 PM) (attached as Ex. 150).

Senate Majority Leader Dale Schultz to Thomas Raabe (July 7, 2005) (Ex. 65-A); Letter from State Representative Sheryl K. Albers to Thomas Raabe (July 8, 2005) (Ex. 65-D).

184. In July 2005, Governor Doyle signed the 2005-07 Biennial Budget but exercised his veto power to reduce the Reimbursement Rate to AWP-16% and the dispensing fee by \$0.50. *Pharmacy Commission Scope* (Oct. 27, 2005) (attached as Ex. 152).

185. In August and September 2005, pharmacists wrote letters expressing disappointment with Governor's Doyle's veto.³¹

186. In September 2005, the Legislature tried, but failed, to override Governor Doyle's veto. See Legislative Fiscal Bureau, *History of the 2005-07 Biennial Budget* at 4-5 (Nov. 10, 2005) (attached as Ex. 160).

12) In late 2005, the Department of Administration suspended implementation of the reimbursement reduction.

187. In September 2005, the Department of Administration ("DOA") asked Wisconsin Medicaid officials to suspend implementation of the pharmacy reimbursement reductions until the Governor's Commission had an opportunity to make recommendations. Letter from Marc J. Marotta, Secretary, DOA, to Helene Nelson, Secretary, DHFS (Sept. 19, 2005) (attached as Ex. 161).

188. In October 2005, Governor Doyle announced the appointment of the "Governor's Commission to study pharmaceutical reimbursement in Wisconsin. Office of the Governor, Press Release, *Governor Doyle Announces Appointment of the Pharmacy Reimbursement Commission* (Oct. 27, 2005) (attached as Ex. 162).

³¹ See, e.g., E-mail from Gary Krider to Governor Doyle (Aug. 4, 2005 11:16 am) (attached as Ex. 153); E-mail from Mary Stehula to Governor Doyle (Sept. 9, 2005 4:44 pm) (attached as Ex. 154); E-mail from Diane Hausinger to Governor Doyle (Sept. 15, 2005 10:22 am) (attached as Ex. 155); E-mail from Paul Fritsh to Representative Hines (Sept. 19, 2005 5:24 pm) (attached as Ex. 156); Email from Nancy Elliott to Gov. Doyle (Sept. 20, 2005 9:55 AM) (attached as Ex. 157); E-mail from Troy Kienzle to Governor Doyle (Sept. 22, 2005 3:25 pm) (attached as Ex. 158); E-mail from Gary Donaldson to Governor Doyle (Sept. 23, 2005 5:09 pm) (attached as Ex. 159).

189. In March 2006, the Governor's Commission issued a report recommending a Reimbursement Rate cut to AWP-15%, and an increased dispensing fee to \$9.88 for generic drugs. 2006 Governor's Commission Report at 5 (Ex. 80).

190. The Governor's Commission found that AWP exceeds pharmacies' actual acquisition costs, and stated that "AWP is a reference 'price' for a single drug/dose combination that correlates with, *but does not represent*, the actual wholesale cost of the product." *Id.* at 4-5, 25 (emphasis added).

191. Wisconsin did not adopt the Governor's Commission's recommendations, and the Reimbursement Rate stayed at AWP-13% and the dispensing fee remained at \$4.38. Vavra Tr. at 158 (Ex. 1).³²

F. Defendants Are Not Required to Report AWP's.

192. Section 4401 of the Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396r-8 (the "Medicaid Rebate Act"), created the requirement that drug manufacturers enter into rebate agreements with the Secretary of HHS, who acted on behalf of the federal government and the States with Medicaid programs, including Wisconsin. *See* Sample Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer ("Rebate Agreement") (attached as Ex. 163).

193. The Rebate Agreement requires the drug manufacturer to pay rebates to the Medicaid program in order to have its drugs eligible for reimbursement under the Medicaid program, and specifies the price information the manufacturer is required to report in order to participate in the Medicaid program. *See id.* at §§ I-II. The rebates are calculated based upon this pricing information. *See Id.* at § II.

194. Among other information, the drug manufacturer is required to report

³² *See, supra*, n. 19.

average manufacturer prices (“AMPs”) and Best Prices (where applicable)³³ to CMS on a quarterly basis. *See* Rebate Agreement at § II(e) (Ex. 163).

195. The Rebate Agreement sets forth a definition of AMP as an average of the discounted unit price of a drug paid by wholesalers to manufacturers for drugs distributed to certain retail pharmacies. *Id.* at § I(a).

196. The Rebate Agreement also sets forth a definition of Best Price as the lowest price at which the manufacturer sells a single source or innovator multiple source drug. *Id.* at § I(d).

197. DHFS had access to AMP data from CMS. Collins Tr. at 192-93, 199, 205-07 (Ex. 37); Vavra Tr. at 521-22, 588 (Ex. 1).³⁴

198. No federal or state law or regulation or contract required drug manufacturers to report AWP or WAC to Wisconsin. There are also no federal or Wisconsin Medicaid statutes or regulations or contracts that define AWP, require Defendants to report AWP or WAC, or set forth a prescribed methodology for manufacturers to report AWP or WAC. *See* 42 U.S.C. § 1396r-8; Rebate Agreement (Ex. 163); Vavra Tr. at 159, 210 (Ex. 1).

199. Some Defendants do not know the prices at which wholesalers resell their drugs. *See e.g.*, Affidavit of Lesli Paoletti, Associate Director of Marketing, Roxane Laboratories, Inc. ¶ 8 (July 10, 2007) (attached as Ex. 165); Affidavit of David R. Gaugh, Vice President and General Manager, Ben Venue Laboratories, Inc. (“Gaugh Aff.”) ¶ 7 (July 10, 2007) (attached as Ex. 166); Affidavit of Christine G. Marsh, Executive Director of

³³ Rebates for single source and innovator multiple source drugs are based on Best Price and AMP. *See* 42 U.S.C. § 1396r-8(c)(1)-(2). Rebates for non-innovator, multiple source drugs are based on AMP. *See id.* at (c)(3).

³⁴ *See also* Plaintiff’s Response to Defendants’ First Set of Interrogatories and Document Requests at 4 (Dec. 19, 2005) (attached as Ex. 164). The Administrators in charge of running the Medicaid program have also testified that States have had access to AMPs. *See* Vladeck Tr. at 461:12-15; 463:19 - 464:06 (Ex. 6) (noting that it would be possible for states to compare AMP data to their reimbursement payments); Scully Tr. at 627:13-20 (Ex. 2) (“States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.”).

Contracts, Boehringer Ingelheim Pharmaceuticals, Inc. (“Marsh Aff.”) ¶ 7 (July 10, 2007) (attached as Ex. 167).

G. The State Did Not Receive the AWP’s It Used For Reimbursement From Defendants.

1) The State obtains its AWP’s from First DataBank, an independent pricing compendia.

200. The pricing information used by Wisconsin for Medicaid reimbursement purposes is supplied by First DataBank, not Defendants. Gray Tr. at 119, 125 (Ex. 51).

201. First DataBank is an independent pricing compendia with offices in San Bruno, California, Indianapolis, Indiana and St Louis, Missouri. Its servers are located and maintained in San Bruno, California. It has no offices in Wisconsin. Transcript of Deposition of Marilyn K. Davis (“Davis Tr.”) at 51-52 (Jan. 10, 2008) (attached as Ex. 168).

202. Wisconsin does not contract directly with First DataBank. Rather, its fiscal agent, Electronic Data Systems (“EDS”) contracts directly with First DataBank to provide AWP’s. Smithers Tr. at 33 (Ex. 110); Gajewski Tr. at 115-16, 127-29 (Ex. 39).³⁵

203. Drug pricing data is sent from FDB to EDS weekly, it is not sent directly to the State. Smithers Tr. at 132 (Ex. 110); Gajewski Tr. at 115 (Ex. 39).

204. First DataBank has provided pricing information to EDS since 1977. Gajewski Tr. at 121 (Ex. 39).

205. EDS pays for and negotiates the cost of pricing information and services it receives from FDB on behalf of the State. Gajewski Tr. at 150-51 (Ex. 39).

206. EDS has had a contract with the State since 1977. Gajewski Tr. at 94 (Ex. 39); Contract for MMIS and Fiscal Agent Services for the Wisconsin Medical Assistance Program and Amendments (Dec. 10, 1991) (attached as Ex. 170).

³⁵ See also Master Purchase Agreement Between Electronic Data Systems Corporation and First DataBank (contracts and renewal letters) (attached as Ex. 169).

207. EDS is charged with creating the Wisconsin Drug Master Tape after each monthly update of the Procedure and Pricing tape from the FDB tape. The tape is to be formatted according to specifications by the State and must contain State-defined data-elements from the FDB tape. EDS is required to maintain drug pricing “using the tape drug pricing mechanism from First DataBank.” Request for Proposals for the Performance of MMIS and Fiscal Agent Services for the Wisconsin Medical Assistance Program (“MMIS RFP”) at 40-63, 40-67 (Aug. 14, 1990) (attached as Ex. 171).³⁶

208. EDS applies a pricing algorithm to the pricing data received from FDB depending on the type of drug (e.g., brand vs. generic, innovator vs. non-innovator), as well as various filters, and then loads the processed data into a file, which the State can access. Smithers Tr. at 36-37 (Ex. 110).³⁷

209. The State generally does not have access to First DataBank’s data until after the filters and pricing algorithms are applied. Smithers Tr. at 47 (Ex. 110).

210. However, certain individuals employed by the State can access unfiltered First DataBank data through the “Data Warehouse,” which is maintained by EDS. Smithers Tr. at 47-51 (Ex. 110).

211. Information contained in this “Data Warehouse” is used solely for analysis

³⁶ See also EDS, A Proposal to the State of Wisconsin Department of Health and Social Services to Perform MMIS and Fiscal Agent Services for the Wisconsin Medical Assistance Program (Jan. 15, 1991) (excerpts attached as Ex. 172) (explaining that EDS contracts with FDB, and setting forth the process by which EDS updated the drug file by using the Blue Book tape to update the Wisconsin Master Tape from FDB). Nowhere in its Request for Proposal or in its contract with EDS does the State ask EDS to furnish the actual average of wholesale prices net of all discounts for Medicaid eligible drugs.

³⁷ Ms. Smithers specifically recalls four filters applied by EDS: (1) a filter ensuring that only NDCs covered by Medicaid are loaded; (2) a filter excluding drugs that have been terminated by CMS; (3) a negative formulary list, maintained by the State and sent to EDS; and (4) a filter excluding drugs with a package price exceeding a certain dollar amount. In addition to these filters, EDS applies a pricing algorithm to reduce the AWP by the applicable percentage and applies MAC reimbursement rates to generic drugs based on unit prices provided by the State via directives. Smithers Tr. at 37-42 (Ex. 110).

and not for purposes of reimbursement. Smithers Tr. at 51:13 - 52:3 (Ex. 110).

212. Although EDS contracts with FDB, the State made the decision to use FDB's prices. Gajewski Tr. at 128, 151 (Ex. 39); MMIS RFP at 40-67 (Ex. 171). EDS does not have the discretion to use alternative pricing sources without State approval. Gajewski Tr. at 128-29 (Ex. 39).

213. Whenever EDS receives a directive from the State to change the pricing or reimbursement formula, EDS does so automatically. EDS just applies the prices the State tells them to apply. Gajewski Tr. at 77-78 (Ex. 39). Essentially, "the State is the brains of the operation. EDS carries out what the brains want done." Gajewski Tr. at 70-71 (Ex. 39).

214. Even after Wisconsin Medicaid sent EDS reports from certain pharmaceutical manufacturers indicating that some of FDB's AWP's were inaccurate (*see, supra* ¶ 20, n. 10), EDS did not change how it calculated reimbursements for Wisconsin providers, because Wisconsin Medicaid did not ask EDS to make any changes to the drug pricing file. Gajewski Tr. at 176-81 (Ex. 39).

215. After Wisconsin Medicaid filed this lawsuit, no one at Wisconsin Medicaid suggested to EDS that they would like to change their reimbursement formula. Gajewski Tr. at 296 (Ex. 39).

216. The State continues to use EDS as its fiscal intermediary. EDS competed to act as the fiscal agent for Wisconsin Medicaid again in 2004; the contract was entered into in 2005 and will not be implemented until 2008. At the same time, the 1992 contract was extended through 2007. Gajewski Tr. at 102-03 (Ex. 39).

217. EDS continues to use First DataBank for drug pricing information, and neither EDS nor Wisconsin have ever complained to FDB that the prices it provides are inaccurate or fraudulent. Gajewski Tr. at 175 (Ex. 39); Davis Tr. at 79-81, 107 (Ex. 168).

2) **Prices that Defendants provided to First DataBank and the State have not been used for reimbursement purposes.**

a) *The State has not used federally-defined ASPs provided to it by Defendants for reimbursing pharmacy-dispensed drugs.*

218. Of the pricing information that Defendants have provided directly to the State, the State has not used it as a basis for reimbursement. Gray Tr. at 119-20, 143-48 (Ex. 51).

219. Since 2001, some Defendants have reported Average Sales Price (“ASP”) information directly to the State of Wisconsin and/or FDB. Gray Tr. at 218-19 (Ex. 51); Affidavit of Glen Weiglein ¶ 5 (Jan. 10, 2008) (attached as Ex. 173); AstraZeneca’s Supplemental Proposed Undisputed Facts (“AZPUF”) ¶ 97.³⁸

220. ASP represents a price based on actual sales transactions including discounts. OIG, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price* at 8 (June 2005) (attached as Ex. 174).

221. The OIG found that ASP is substantially lower than AWP. *Id.*

222. Wisconsin has not used or relied on this ASP information submitted by Defendants in setting, revising or evaluating Medicaid reimbursement for pharmacy-dispensed drugs. Gray Tr. at 218-19 (Ex. 51).³⁹

223. Since 2005, all drug manufacturers have been required to report ASP information to the federal government. 42 U.S.C. 1396r–8(b) (requiring all drug manufacturers to report ASP); 42 U.S.C. § 1395w-3a(c) (setting forth methodology for determining ASP).

³⁸ See also Plaintiff’s TAP Response at 2 (Ex. 61); Plaintiff’s Fourth Response at 2-3 (Ex. 62).

³⁹ See also Plaintiff’s TAP Response at 2 (Ex. 61) (“Beyond receiving the [ASP] information provided to the Plaintiff by TAP as part of this settlement, no other use has been made of [such] information in the operation of the State Medicaid Program.”); Plaintiff’s Fourth Response at 2 (Ex. 62) (incorporating by reference Plaintiff’s answer regarding TAP’s ASP information as responsive for all Defendants); AZPUF ¶ 99.

224. Starting in October 2005, the State has used this ASP information to reimburse for physician-administered drugs but not pharmacy-dispensed drugs. Vavra Tr. at 137-38 (Ex. 1).

b) *The State has not used the pricing information that Defendants provided to First DataBank in reimbursing for drugs under Medicaid.*

225. Some Defendants provided First DataBank with suggested AWP for their products. Other Defendants reported only WACs (or WAC equivalents), at least for certain periods. Some Defendants provided WACs (or WAC equivalents) as well as suggested list prices or AWP. Some Defendants provided prices in some combination of these ways depending upon the time period. Affidavit of Gregory K. Bell (“Bell Aff.”) ¶¶ 12-14 (July 13, 2007) (attached as Ex. 175).⁴⁰

226. First DataBank did not always report the suggested AWP it received from Defendants, if it got one at all. Bell Aff. ¶ 13 (Ex. 175).⁴¹

⁴⁰ For specific examples of various pricing information reported to FDB by individual Defendants, *see, e.g.*, Transcript of Deposition of Gregory K. Bell (“Bell Tr.”) at 62-63, 66 (Aug. 17, 2007) (attached as Ex. 175) (Bristol-Myers Squibb does not report AWP, but instead reports “Wholesale List Price”; whereas Novartis reports AWP and WAC); Affidavit of Pamela Marrs ¶ 11 (July 10, 2007) (attached as Ex. 177) (Dey reports both an AWP and a WAC to First DataBank for its drugs); Affidavit of Glenn Weiglein ¶ 11-12 (June 20, 2007) (attached as Ex. 178) (TAP used to report both AWP and WAC, but has reported only WAC for several years); Gaugh Aff. ¶ 10 (Ex. 166) (Ben Venue does not report AWP for its products, but has instead provided WAC and, until several years ago, a “Hospital List Price”); Marsh Aff. ¶ 11 (Ex. 167) (Boehringer currently reports WACs, and has not reported suggested AWP since 2002); Affidavit of David A. Moules (“Moules Aff.”) ¶¶ 4-7 (attached as Ex. 179) (GSK and its predecessors reported several different types of pricing information at different times within the last two decades, including WAC equivalents called “Net Wholesale Price” and “Wholesaler Purchase Price,” a “Suggested List Price” that was generally understood by the reporting services as a suggested AWP, and an AWP for one corporate predecessor during the early-mid 1990s; since 2001 GSK has reported only a WAC); Affidavit of Robert B. Funkhouser (“Funkhouser Aff.”) ¶ 9 (July 12, 2007) (attached as Ex. 180) (Merck reported a direct price or list price).

⁴¹ *See also* Bell Tr. at 79-87 (providing examples of FDB publishing different AWP from those reported by Defendants); Affidavit of Claire Brunken (“Brunken Aff.”) ¶ 16 (July 12, 2007) (attached as Ex. 181) (Aventis’s suggested AWP were not always the same as those published by the pricing compendia); Moules Aff. ¶ 7 (Ex. 179) (decisions on what AWP to publish for GSK’s products and how to derive that AWP from GSK’s reported pricing information was made

227. Many Defendants explicitly defined their suggested AWP, WACs and/or WAC equivalents in letters they sent to First DataBank – and those definitions made clear that (a) AWP (or suggested list prices) were *not* actual average prices or the same as prices charged in the marketplace and (b) WACs (or WAC equivalents) were *list* prices to wholesalers that did *not* include discounts, rebates, or chargebacks.⁴²

228. Wisconsin did not use these suggested AWP in reimbursing for drugs. Gray Tr. at 119-20, 143-48 (Ex. 51).

c) Instead, the State used the Blue Book AWP, which are set by First DataBank, for reimbursement purposes.

229. During the relevant time period, First DataBank published two pricing benchmarks: “Suggested Wholesale Price” and “Blue Book AWP”. Morgan Tr. at 33-34, 45 (Ex. 4).

230. Wisconsin uses the Blue Book AWP for reimbursement, which First DataBank obtains from the wholesaler, rather than the SWP, which is suggested by the manufacturer. See Business Objects Data Dictionary at 5 (Apr. 21, 2004) (attached as Ex. 182) (defining Wisconsin AWP Package Price as “an amount that is 90% of the blue book average wholesale package price, which is based on surveys of drug wholesalers. This is used in the Wisconsin drug reference file.”); Davis Tr. at 107-09 (Ex. 168); Vavra Tr. at 97 (Ex. 1); First DataBank EWI Version 2.1, EDS State of Wisconsin Functional Specifications (attached as Ex. 187) ([REDACTED]); First DataBank EWI Version 2.0, EDS State of Wisconsin

by FDB, not GSK); Funkhouser Aff. ¶ 9 (Ex. 180) (FDB did not always follow Merck’s suggested AWP in the period where Merck suggested an AWP mark up).

⁴² See, e.g., Moules Aff. ¶¶ 4-7 (Ex. 179) (GSK’s price reporting letters included specific definitions starting in 1999-2000 of WAC-equivalents NWP and WPP and of “Suggested List Price.” Starting in 2001, those letters defined the only price reported by GSK (WAC) as “the listed price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates, or chargebacks.”); Brunken Aff. ¶¶ 17-18 (Ex. 181) (noting that Aventis included similar definitions in its price lists).

Functional Specifications (attached as Ex. 188) (██████).

231. First DataBank defines “Suggested Wholesale Price” or “SWP” as: “[T]he manufacturer’s suggested price for a drug product from wholesalers to their customers (i.e., retailers, hospitals, physicians and other buying entities). SWP is a suggested price and does not represent actual transaction prices. First DataBank relies on manufacturers to report or otherwise make available the values for SWP data field.” First DataBank, Drug Price Policy at 1 (May 2, 2005) (attached as Ex. 183).

232. In a 2005 e-mail to several Wisconsin DHFS employees, First DataBank employee Rebecca Aldaz defined BlueBook AWP as follows:

Blue Book AWP (BBAWP) as published by First DataBank is intended to represent an average of wholesalers' catalog or list prices for a drug product to their customers (i.e., retailers, hospitals, physicians and other buying entities). First DataBank historically relied upon wholesalers to provide information relating to their catalog or list prices for purposes of publishing the BBAWP data field. First DataBank periodically surveyed full-line national wholesalers to determine the average mark-up applied to a manufacturer's line of products or a specific product. The average mark-up of the wholesaler(s) responding to the survey was applied against the WAC or Direct Price with the resulting value populating the BBAWP field. E-mail from Rebecca Aldaz to Dale Rehm, DHFS (Apr. 21, 2005 11:20 am) (attached as Ex. 184).

233. As of 2003, the NDDF Glossary, which Wisconsin received,⁴³ contained the following relevant definitions:

AWP – “Average Wholesale Price. Represents the most common wholesaler price charged to the retailer or hospital. To ensure both the accuracy and timeliness of reporting this information, FDB determines the AWP by a variety of methods. See also Blue Book AWP Package Price. (BBPKG).”

Blue Book AWP Package Price – “The Blue Book Average Wholesale Price package price of an NDC that a wholesaler charges the retailer or hospital; based on surveys of drug wholesalers and manufacturer-supplied information.”

⁴³ First DataBank provides Wisconsin Medicaid with its National Drug Data File, which contains definitions for every field available from FDB. Gray Tr. at 116-17, 208-09 (Ex. 51).

Suggested Wholesale Unit Price – “A field in the National Drug Code Price Table and the NDC Price Type Description Table. This field is being maintained for existing customers only. The value is the AWP suggested by the manufacturer.” First DataBank NDDF Plus Glossary at GL 3-4, GL 43 (attached as Ex. 185).⁴⁴

234. The Manager of Editorial Services of First DataBank, Patricia Kay Morgan, who was responsible for the database containing drug pricing information, testified that First DataBank determined the Blue Book AWP based upon surveys of wholesalers, and the manufacturer does not set the Blue Book AWP published by First DataBank. Morgan Tr. at 38-39; 42-43 (Ex. 4).

235. If the wholesalers in First DataBank’s survey stated that they use the manufacturer’s suggested wholesale price as the AWP, then First DataBank would use its “Suggested Wholesale Price” as its “Blue Book AWP”. Even though First DataBank used the manufacturer’s suggested wholesale price, First DataBank considered this AWP a surveyed price because it was based on feedback from wholesalers. Morgan Tr. 45:2-46:11 (Ex. 4).

V. LEGAL STANDARD

To succeed on its motion for summary judgment, Plaintiff bears the burden of demonstrating that there is no issue of material fact,⁴⁵ that the law resolving the issue that is the subject of the motion is clear,⁴⁶ and that it has proven every required element of its

⁴⁴ See also Business Objects Data Dictionary at 5 (Apr. 21, 2004) (Ex. 182)(stating that “the Blue Book Average Wholesale Package Price ... is based on surveys of drug wholesalers.”).

⁴⁵ *Metropolitan Ventures, LLC v. GEA Associates*, 2006 WI 71, ¶¶ 20-21, 717 N.W.2d 58, ¶¶ 20-21, 291 Wis.2d 393, ¶¶ 20-21, *opinion clarified on denial of reconsideration*, 2007 WI 23, 299 Wis.2d 174, 299 Wis.2d 174 (a “material fact” for summary judgment purposes is any fact that would influence the outcome of the controversy).

⁴⁶ See, e.g., *Lecus v. American Mutual Insurance Co. of Boston*, 81 Wis.2d 183, 189, 260 N.W.2d 241, 243 (Wis. 1977).

claims through proper supporting evidence, by identifying the portions of the record that demonstrate the absence of a genuine issue for trial.⁴⁷

The summary judgment standard for Defendants' cross-motion for summary judgment is the same. However, because Plaintiff bears the burden of proof for proving the elements of its claims, "the ultimate burden...of demonstrating that there is sufficient evidence...to go to trial at all" is on Plaintiff.⁴⁸ Defendants therefore succeed on their cross-motion if they can "demonstrate that the evidence is insufficient to sustain the plaintiff's burden on one or more elements of the plaintiff's proof."⁴⁹

VI. ARGUMENT⁵⁰

The State moves for summary judgment on two claims—§ 100.18(1) and § 100.18(10)(b). Section A, *infra*, contains a brief background of the case. Section B explains why this Court should abstain from deciding the merits of this case based on separation of powers principles. Sections C and D explain why the State's Motions with respect to its § 100.18 claim cannot be granted, both as a matter of law and because the State has not set forth material facts necessary to sustain such a claim.⁵¹ In Section E, Defendants explain

⁴⁷ Wis. Stat. § 802.08; *see also Voss v. City of Middleton*, 162 Wis.2d 737, 748, 470 N.W.2d 625, 629 (Wis. Ct. App. 1991); *Leske v. Leske*, 197 Wis.2d 92, 97, 539 N.W.2d 719, 721 (Wis. Ct. App. 1995); *see also Brown v. LaChance*, 165 Wis.2d 52, 60-61, 477 N.W.2d 296, 300 (Wis. Ct. App. 1991), *review denied* 479 N.W.2d 173.

⁴⁸ *Transportation Insurance Co., Inc. v. Hunzinger Construction Co.*, 179 Wis.2d at 290, 290-291, 507 N.W.2d 136, 139 (Wis. Ct. App. 1993).

⁴⁹ *Id.*

⁵⁰ Defendants incorporate by reference the arguments the AstraZeneca Defendants ("AstraZeneca"), the Johnson & Johnson Defendants ("Johnson & Johnson"), Novartis Pharmaceuticals Corporation ("Novartis") and Sandoz Inc. ("Sandoz") make in their respective Oppositions to Plaintiff's Motions.

⁵¹ Although Plaintiff has not explicitly moved on its claims on behalf of Medicare Part B beneficiaries or State programs other than Medicaid (e.g. BadgerCare, SeniorCare, or other managed care entities), Plaintiff does seek restitution for "Wisconsin, its citizens and State programs who have been harmed by Defendants' practices." *See* Second Amended Complaint at ¶ 82.C (hereinafter "Complaint at ___"); *see also, id.* at ¶¶ 61, 67-71 (discussing State Programs and Medicare Part B). Notably, the State has not set forth undisputed facts establishing (1) that State programs such as BadgerCare, SeniorCare or other managed care entities

that § 100.18(10)(b) does not create a cause of action separate from the State's § 100.18(1) claim and any liability thereunder depends on material facts not set forth by the State. Section F explains that the State's § 100.18(1) and § 100.18(10)(b) claims relating to WAC, like its allegations regarding AWP, fail as a matter of law and rely on material facts not set forth by Plaintiff.

A. Factual Introduction.

1) The State's pharmaceutical Reimbursement Rate must comply with the federal requirement of ensuring equal access to care.

The State's participation in Medicaid is voluntary, but the State must comply with federal program requirements if it chooses to participate.⁵² Among other requirements, the State must submit a "state plan" for approval to the Secretary of U.S. Health and Human Services ("HHS") that sets forth the methods for reimbursing health care providers for goods and services.⁵³

Wisconsin's state plan "must describe comprehensively the agency's methodology of payment for, *e.g.*, prescription drugs."⁵⁴ Within the limits imposed by federal regulations,⁵⁵ the State is given wide discretion in deciding how to reimburse Medicaid providers for pharmaceuticals. (DAPUF ¶ 80) A key limit to that discretion is that the reimbursement level must be "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."⁵⁶

reimbursed for drugs based on AWP; or (2) that Medicare, if and when it used AWP in setting its reimbursement rate, used Defendants' reported AWPs (if any) to do so.

⁵² See generally *Wilder v. Va. Hospital Ass'n*, 496 U.S. 498, 502 (1990).

⁵³ *Id.*; see 42 U.S.C. § 1396a(a); 42 C.F.R. §§ 430.10, 447.201.

⁵⁴ 42 C.F.R. § 447.518(a).

⁵⁵ 42 C.F.R. §§ 447.514 & 447.304.

⁵⁶ 42 U.S.C. § 1396a(a)(30)(A).

Federal regulations require that reimbursement for brand name drugs not exceed, *in the aggregate*, the lower of: (1) the estimated acquisition costs (“EAC”) *plus* reasonable dispensing fees; or (2) the providers’ usual and customary charges to the general public.⁵⁷ Multi-source drug reimbursement must not exceed, *in the aggregate*, a reasonable dispensing fee plus an amount established by the federal Centers for Medicare and Medicaid Services (“CMS”) equal to 150% of the published price for the least costly therapeutic equivalent.⁵⁸

The federal government does not require the use of AWP by a state Medicaid program. (DAPUF ¶ 35) In fact, it specifically prohibits states from using *undiscounted* AWP in their reimbursement formulas (DAPUF ¶ 37), and has discouraged states from using AWP at all. (DAPUF ¶ 36); *see also* (DAPUF ¶ 7) Some state Medicaid programs do not reimburse based on AWP. (DAPUF ¶ 39)

The State, however, has elected to use AWP, as reported by First DataBank, in its reimbursement formula for certain drugs since at least 1979. (DAPUF ¶¶ 40-44, 200, 202-204) Specifically, from at least the late-1970s until June 1990, Wisconsin reimbursed based on the lower of (1) EAC, which Wisconsin defined as the Direct Price charged by certain manufacturers, 100% AWP or MAC plus a reasonable dispensing fee; or (2) “usual and customary charge.” (DAPUF ¶ 40) Since then, the State has changed its definition of EAC by increasing the percentage discount from AWP⁵⁹ and dropping Direct Price, but has continued to reimburse at the lower of: (1) EAC plus a reasonable dispensing fee or (2) usual and customary charge. The State has never reimbursed for pharmaceuticals based upon the “wholesale acquisition cost” or “WAC.” (DAPUF ¶¶ 41, 45)

The State also employs non-AWP reimbursement methodologies for reimbursing

⁵⁷ 42 C.F.R. § 447.512(b). (emphasis added)

⁵⁸ 42 C.F.R. § 447.512(a).

⁵⁹ In July 1990, Wisconsin Medicaid changed its definition of EAC from 100% AWP to AWP-10%. In July 2001, it changed it to AWP-11.25%. In August 2003, it changed it to AWP-12%. And, in 2004, it changed it to AWP-13% where it remains. (DAPUF ¶¶ 41, 43)

certain drugs. For example, Wisconsin reimburses certain generic drugs on the basis of maximum allowable cost (“MAC”), which is calculated based on actual cost plus 10% to 25%. (DAPUF ¶ 44) Similarly, the State reimburses for physician-administered drugs (PADs) based on Average Sales Price (ASP) plus 6%. (DAPUF ¶ 42) Notably, the State changed its reimbursement formula for PADs in 2005, a year after it filed its Complaint in this case.

2) The State’s Reimbursement Rate is set through a complex legislative process with a goal of ensuring equal access to care by covering providers’ costs and allowing providers a profit margin on the drugs they dispense to Medicaid beneficiaries.

The State’s decision to use AWP in its reimbursement formula is a result of a “complex and interdependent legislative process that begins with the DHFS and ends at the end of the Governor’s veto pen.” (DAPUF ¶ 50) Every other year, DHFS, which runs the Medicaid program, submits a proposed budget to the Governor, which may include a proposed change to the reimbursement formula. (DAPUF ¶ 51) The Governor reviews and modifies any proposed changes to the reimbursement formula and submits them to the State legislature. (DAPUF ¶ 52) The LFB prepares a summary of the Governor’s proposed changes, and may propose changes of its own, for the JCF’s consideration. (DAPUF ¶ 54) The JCF votes on the proposed changes, then submits its proposal to the full Legislature. (DAPUF ¶ 55) After adoption by the Legislature, the bill is sent to the Governor for his signature. (DAPUF ¶ 55) Once signed by the Governor, the reimbursement formula is published in the State’s state plan amendment, which is signed by a representative of the Governor’s office, subject to public comment, and submitted to CMS for approval. (DAPUF ¶ 56)

In setting the Reimbursement Rate, the Legislature and Governor’s Office are well aware that providers may choose not to participate in the State’s Medicaid program if the Reimbursement Rate is inadequate. (DAPUF ¶ 67) Given the federal requirement that

Wisconsin set its Medicaid reimbursement at an amount “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area” (DAPUF ¶¶ 63), a requirement which Wisconsin takes seriously (DAPUF ¶ 66), the Legislature and Governor’s Office are heavily influenced by the lobbying efforts of pharmacists. (DAPUF ¶¶ 71-72) In fact, each time a change has been proposed to lower the reimbursement formula (by increasing the percentage discount from AWP), pharmacists have threatened to withdraw from the Medicaid program, declaring that they could not continue providing drugs to Medicaid beneficiaries if the State’s reimbursement amounts dropped too low. (DAPUF ¶¶ 68-70, 129-35, 143-44, 146,150, 156-57, 160, 171-72, 178-79, 185) In turn, the Legislature has declined to make the proposed change, either to the extent originally proposed, or at all. (DAPUF ¶¶ 71-72, 113-16, 125-26, 129-35, 137-41, 143-47, 150-52, 156-60, 171-73, 178-79, 183, 185-86)

Rather than decreasing reimbursement to approximate actual acquisition cost, the State has affirmatively chosen to reimburse at more than providers’ actual acquisition costs to allow providers’ a profit margin to ensure their continued participation in the Medicaid program. (DAPUF ¶¶ 63-81) In fact, it has been a stated goal of the State since at least 1975 to allow providers who participated in Medicaid to profit. (DAPUF ¶¶ 75-108)

The State also has chosen to reimburse at more than the providers’ cost to offset low dispensing fees. (DAPUF ¶¶ 82-104) The State has known that the fees it paid providers for dispensing drugs were significantly lower than the actual costs providers incurred in dispensing them. (DAPUF ¶¶ 82-94) The State’s own consultants confirmed that the State was substantially under-reimbursing providers for their costs in dispensing pharmaceuticals. (DAPUF ¶¶ 82-91) For example, Dr. David Kreling, a consultant retained by the State, advised it that its dispensing fees in 2000 and 2002 were inadequate by at

least \$2.00 per prescription. (DAPUF ¶¶ 87-90) Later, in 2006, the Governor's Commission confirmed that dispensing fees were inadequate, this time by at least \$5.00 per prescription. (DAPUF ¶¶ 91-92)⁶⁰

The State intended for the margin on its reimbursement for drugs to cross-subsidize these low dispensing fees. (DAPUF ¶¶ 95-103) For example, in 1989 the bureau responsible at the time for administering Medicaid, "acknowledge[d] that AWP is inflated, but argue[d] that total payments are not excessive because dispensing fees are artificially low and off-set the over allowance." (DAPUF ¶ 99) Similarly, the Legislative Fiscal Bureau explicitly relied on the presence of a margin to ensure adequate compensation to providers for dispensing drugs to Medicaid beneficiaries. (DAPUF ¶¶ 100-103)

The federal Medicaid rules permit the State to use drug reimbursement to subsidize low dispensing fees. (DAPUF ¶¶ 95-104) Reimbursement for brand name drugs is limited to the *aggregate* of the lower of: (1) the EAC *plus* reasonable dispensing fees; or (2) providers' usual and customary charges to the general public. (DAPUF ¶¶ 33-34, 104) Thus, as long as the combined reimbursement amount for the drug cost and dispensing fee is lower than providers' usual and customary charges, the State has not violated federal regulations. Robert Helms, chairman of a federal task force appointed to study state Medicaid reimbursements confirmed this to be true:

The Medicaid task force I chaired at HHS was well aware that such cross-subsidization was occurring in practice in the states. We had no problem with this. Rather, this was entirely consistent with the Reagan administration's broad policy goals of limiting federal interference in day-to-day local politics and allowing state Medicaid agencies to make their own determinations that would accommodate local political constraints.

In coming to the recommendations that eventually led to the 1987 regulations, the Medicaid task force built upon preexisting reimbursement terminology and structures. We decided to maintain the existing structure of an ingredient cost,

⁶⁰ The inadequacy of the dispensing fee dates from at least the 1970s, when the State commissioned a consultant to assess the adequacy of dispensing fees. (DAPUF ¶ 83)

whether based on an ‘Estimated Acquisition cost’ or a specifically prescribed limit, and a separate dispensing fee that theoretically included profit. However, we also recognized that existing state practice was more flexible in that states did not calculate each part of the payment separately and accurately and instead utilized cross-subsidization. Accordingly, we included new language that was expressly intended to allow the existing practice of cross-subsidization to continue. This language consisted of including the term “in the aggregate” when describing the upper limits on payment for ingredient costs and dispensing fees. In other words, payment at the overall level (or “in the aggregate”) was not to exceed the sum of an ingredient cost and a reasonable dispensing fee with regard to all the drugs used in the state program. But we left it to the states to decide whether they wanted to accomplish that through offsets and cross-subsidization (as many of them had been doing) or by seeking to accurately measure both aspects of the equation. So long as the overall level of payment was reasonable, our federal policy goals were satisfied. We explicitly considered and rejected the alternative approach commonly used in public utility regulation to rigorously define the accounting methodology for each separate component of the aggregate total. (DAPUF ¶ 104)

3) The State chose to use AWP to accomplish these goals because it represented more than providers’ acquisition costs.

The State chose to use AWP in its reimbursement formula to accomplish these goals *because* it represented more than a providers’ acquisition cost for drugs. The undisputed and overwhelming evidence shows that the State has known, since at least the mid-1970s, that AWP does *not* represent an actual average of wholesale prices. This evidence includes, but by no means is limited to:

- A 1976 Task Force report concluding that the published AWP’s “overstate actual drug costs.” (DAPUF ¶¶ 10, 111)
- Testimony that by 1998, Wisconsin Medicaid commonly referred to AWP as “ain’t what’s paid.” (DAPUF ¶ 18)
- A 1999 LFB report informing the JCF that: “AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to the ‘sticker price’ of a car. It does not reflect the actual cost of acquiring the drug.” (DAPUF ¶ 10)
- Testimony that on multiple occasions between 1984 and 2003, the State received detailed reports from OIG that concluded, after comprehensive studies, that pharmacies generally purchase brand name drugs at significant discounts from AWP and purchase generic drugs at even more significant discounts from AWP. (DAPUF ¶¶ 7, 11-12, 36, 122-24, 142, 161-66, 168, 174).

- A 2002 DHFS commissioned study concluding that AWP exceeded Wisconsin pharmacists' actual acquisition costs by 17.52 to 17.58% for brand name drugs and 74.44 to 76.16% for generics. (DAPUF ¶ 21)
- A 2006 Governor's Commission report confirming that AWP "does not represent[] the actual wholesale cost of the product." (DAPUF ¶ 190)

These are just examples; there is much more evidence to support this point. This evidence goes to the heart of the State's claims and Defendants' defenses. The State's knowledge that AWP did not represent an actual average of wholesale prices and its decision to use it to further policy goals, disproves, for example, Plaintiff's claims that Defendants made an "untrue, deceptive or misleading" statement and that the State was materially induced into an obligation by such a statement. It also defeats Plaintiff's assertions of causation and reliance.⁶¹

B. The Court Should Abstain From Adjudicating This Case on the Merits In Accordance with Separation of Powers Principles.

Separation of powers principles require the Court to abstain from deciding this case on the merits, because doing so would require the Court to rule in a manner inconsistent with the legislative and executive branches' actions and decisions when they formulated the State's Medicaid pharmaceutical reimbursement policy. "The doctrine of separation of powers, while not explicitly set forth in the Wisconsin constitution, is implicit in the division of governmental powers among the judicial, legislative and executive branches."⁶² Wisconsin courts have "long recognized a rule prohibiting the exercise of legislative, executive or administrative functions by the courts."⁶³ Thus, under separation of powers principles, "the judicial branch is foreclosed from making legislative decisions itself."⁶⁴

⁶¹ This knowledge also demonstrates that Plaintiff's claims are time-barred by the applicable statutes of limitations, as discussed in Defendants' Cross-Motion *infra*.

⁶² See, e.g., *State v. Chvala*, 2004 WI App 53, ¶ 44, 271 Wis.2d 115, ¶ 44, 678 N.W.2d 880, ¶ 44.

⁶³ *Casanova Retail Liquor Store, Inc. v. State*, 196 Wis.2d 947, 955, fn 6, 540 N.W.2d 18, 20, fn 6 (Wis. Ct. App. 1995).

⁶⁴ *Id.* at 954.

When an issue committed to the legislative or executive branches is brought before the courts, it is often described as a “political question” that is non-justiciable.⁶⁵ Separation of powers principles direct that the Court should “not be drawn into decided issues that are essentially political in nature . . . and not susceptible to judicial management or resolution.”⁶⁶ Deciding this case would result in the Court doing just that.

Wisconsin’s Medicaid pharmaceutical Reimbursement Rate was created by the legislative and executive branches after considerable deliberation and compromise. *See generally*, (DAPUF ¶¶ 50-62, 67-104, 105-191) Plaintiff has conceded the inherently political nature of the setting of this rate, admitting “that ‘AWP’ and the reimbursement formula and the dispensing fee are the product of the legislative process...that begins with [DHFS] and ends at the end of the Governor’s veto pen.” (DAPUF ¶¶ 50, 58)

Yet, the Attorney General is asking the Court to change this reimbursement formula – both retrospectively and prospectively – by seeking a ruling that AWP represents something vastly different from what the Legislature and the Governor’s office have understood it to mean for decades when developing Medicaid pharmaceutical reimbursement policy. The Attorney General asks the Court to decide that AWP should mean the actual average of wholesale prices and to require Defendants to report AWP’s that conform to this definition.⁶⁷ To do so would require the Court to override what the legislative and executive branches deliberately fashioned through years of debate and compromise, substitute its own judgment for that of the legislative and executive branches, and intrude into the legislative

⁶⁵ *Baker*, 369 U.S. at 210 (“The nonjusticiability of a political question is primarily a function of the separation of powers.”); *see also Vincent*, 2000 WI 93, ¶ 192; *In re John Doe Proceeding*, 2004 WI 65, ¶ 25.

⁶⁶ *Mills v. County Bd. Of Adjustments*, 2003 WI App 66, ¶ 17, 261 Wis.2d 598, ¶ 17, 660 N.W.2d 705, ¶ 17.

⁶⁷ *See, e.g. Complaint* at ¶¶ 82B, 86B, 91B and 100B.

and executive functions. This is clearly beyond the scope of the judicial function.⁶⁸ The judiciary also lacks the resources – resources that are available to the legislative and executive branches – necessary to decide this case as Plaintiff requests.

- 1) **The Court cannot grant the relief requested without making a policy determination that is inconsistent with Wisconsin’s current policy.**

Separation of powers principles dictate that a Court should not decide a political question if there is an “impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion.”⁶⁹ Granting Plaintiff’s requested relief would require the Court to take a position that is inconsistent with the State’s decades-long policy of ensuring access by maintaining appropriate levels of reimbursement under Medicaid. (DAPUF ¶¶ 63-191) By asking the Court to rule that AWP did not reflect more than providers’ costs of pharmaceuticals – when in actuality the State’s legislative and executive branches specifically relied upon the fact that AWP *did* reflect more than those costs when legislating the State’s reimbursement formula (DAPUF ¶¶ 74-79, 95-103, 128-135) – the Attorney General is asking the Court to undo the policy decisions of other branches of government.

Since at least 1975, the State has chosen, as a policy matter, to allow providers to realize an appropriate return on Medicaid transactions. (DAPUF ¶¶ 74-81) In retaining an AWP-based reimbursement system, the State has acted with the specific understanding that AWPs reflected something greater than a providers’ actual cost for a drug (DAPUF ¶¶ 1-30, 74-79, 96-103, 105-191), and has set its AWP-based reimbursements where it did precisely

⁶⁸ *Baker*, 369 U.S. at 210. (“In determining whether a question falls within (the political question) category, the appropriateness under our system of government of attributing finality to the action of the political departments and also the lack of satisfactory criteria for a judicial determination are dominant considerations.”) (quoting *Coleman v. Miller*, 307 U.S. 433 (1939)).

⁶⁹ *Id.* at 217.

because it *wanted* to ensure that participating providers would be reimbursed in excess of their acquisition costs. (DAPUF ¶¶ 63-81)

This policy is demonstrated by the State’s alternative reimbursement methodologies for some drugs, such as certain generic drugs and PADs, which are explicitly set above providers’ acquisition costs. For example, Wisconsin reimburses certain generic drugs on the basis of a MAC, which is calculated based on actual cost *plus* 10% to 25%. (DAPUF ¶ 44) Similarly, the State reimburses for physician-administered drugs (“PADs”) based on ASP *plus* 6%. (DAPUF ¶ 42) Tellingly, the State changed its reimbursement formula for PADs just two years ago, in 2005, after this case was filed. *Id.* If the State had wanted to change its AWP-based reimbursement methodology for brand name pharmacy-dispensed drugs since the filing of this lawsuit, it could have done so when it changed its reimbursement formula for PADs. It did not.

The legislative and executive branches could have chosen to replace AWP-based reimbursement with a formula based on actual acquisition cost – which is exactly what the Attorney General seeks to impose through this lawsuit – but have *expressly declined to do so* on several occasions. For example, in 1975, Governor Lucey appointed a Task Force, which recommended that the State reimburse for pharmaceuticals based on providers’ actual invoice prices instead of First DataBank’s AWPs because First DataBank’s AWPs reflected more than actual acquisition costs. (DAPUF ¶¶ 109-114) But, the Legislature refused to implement this recommendation. (DAPUF ¶ 116) In the late 1980s, the State again considered reimbursing for pharmaceuticals under the Medicaid Program based on actual acquisition cost, but again declined to do so. (DAPUF ¶¶ 129-131, 135)

Since then, the legislative and executive branches have repeatedly considered increasing the percentage discount from AWP to more accurately reflect provider acquisition costs but have not done so (or at least not to the level originally proposed) for policy reasons.

(DAPUF ¶¶ 142-191) In considering these proposals, the Legislature repeatedly was informed that the current AWP-based reimbursement formula resulted in reimbursements that exceeded provider acquisition costs and presented with detailed analyses of the millions of dollars in reduced expenditures that could be achieved by increasing the percentage discount from AWP. (DAPUF ¶¶ 10, 79, 101-02, 115, 148-49, 155, 170, 180-81) Armed with this information, and following a public airing of the issues and input from pharmacists, the legislative and executive branches repeatedly either declined to reduce the Reimbursement Rate outright, or at the level originally proposed. (DAPUF ¶¶ 62, 68-72, 116, 126, 138-141, 150-152, 158-159, 171-173, 183-187, 191) Indeed, to this very day – years after claiming to have been defrauded by the use of AWPs and after a comprehensive review of Medicaid pharmacy reimbursement by the Governor’s Commission – the State has elected to retain AWPs as the benchmark for Medicaid reimbursement. The Court should reject efforts to upset this delicate balance by interjecting itself into what clearly is a political debate.

2) The Court lacks judicially discoverable and manageable standards for resolving the issues presented in this case.

“It is not this court’s function to decide what the law ought to be, but rather to construe and apply the law as the legislature has enacted it to the facts before us.”⁷⁰ This is in part because Courts lack “judicially discoverable and manageable standards for resolving” issues like the one in this case – political questions that are legislative in nature.⁷¹ As explained below, this Court lacks the resources to consider or manage the potential ramifications of changing the State’s Medicaid reimbursement formula.

⁷⁰ *Kenison v. Wellington Ins. Co.*, 218 Wis.2d 700, 710, 582 N.W.2d 69, 73 (Wis. Ct. App. 1998) (“It is the role of the legislature [not the courts] to evaluate the public policy considerations regarding the wisdom of a statute, just as it is its role to cure unfairness of a statute, if any.”)

⁷¹ *Baker*, 369 U.S. at 217; *see also Vincent*, 2000 WI at ¶¶ 196-197, 200-201.

a) *The Court lacks the resources to determine the appropriate Reimbursement Rate under Wisconsin Medicaid.*

Respectfully, the Court lacks the resources to determine whether a Reimbursement Rate based on an actual average of wholesale prices paid by providers is appropriate under Wisconsin Medicaid given the numerous interests that must be considered in making such a decision. In setting the reimbursement formula as it did, with the clear understanding that published AWP's were higher than actual average prices paid by providers, the Legislature and the Governor have considered a number of competing interests, weighing the interests of Medicaid beneficiaries (to whom the State is obligated by federal regulations to provide adequate access), the interests of Medicaid providers (who need an economic incentive to serve Wisconsin Medicaid clients), and the interests of the taxpayers (to whom the State is accountable for costs).

These other branches are aided by a number of entities in reaching their decisions whether to adopt or reject a proposal to change reimbursement. The Legislature is aided by Wisconsin's LFB, which analyzes Reimbursement Rate change proposals (DAPUF ¶ 54), and the impact of those proposals on providers' decisions to participate in Wisconsin Medicaid. (DAPUF ¶¶ 100-03, 137, 150-51, 155, 171) The LFB considers, among other things, recommendations by DHFS (DAPUF ¶¶ 51-54, 114); federal government reports on the costs of acquiring pharmaceuticals (DAPUF ¶¶ 11-12, 155); conclusions of its consultants on drug costs and dispensing fees (DAPUF ¶ 87, n. 18); the impact a given rate proposal would have on Wisconsin's Medicaid budget (DAPUF ¶¶ 149, 170, 181); as well as comments by the Pharmacy Society of Wisconsin. (DAPUF ¶¶ 137, 150, 171) The LFB then provides the JCF an analysis of these factors. (DAPUF ¶ 54) Based on these analyses, the Legislature determines what reimbursement formula to adopt. (DAPUF ¶ 54-55)

The executive branch, with the assistance of its own staff, the Department of Administration and DHFS, weighs various interests in considering proposals to change the reimbursement formula under Medicaid. Every other year, as part of the State's biennial budgetary process, DHFS submits a proposed budget to the Governor's office, including any recommendations for changes to the Reimbursement Rate. (DAPUF ¶ 51) The Governor's office considers DHFS's budget proposals, modifies them if it so chooses, and submits them to the Legislature. (DAPUF ¶ 52) The evidence shows that the Governor's office was armed with information from various constituencies when it considered these proposals. (DAPUF ¶¶ 69, 71-72, 76, 109-113, 117-119, 127-128, 136, 146, 154, 167-172, 176-78, 184-85, 187-90)

Respectfully, the Court lacks similar resources to consider and make decisions of this kind. Such decision-making should be left to the Legislature and the Governor's office.

b) The Court lacks the ability to manage the crippling effects on Wisconsin Medicaid if it revises the meaning of AWP.

The Court should not decide this case because it lacks the ability to manage the impact that a ruling requiring that AWP be reported as an actual average of wholesale prices will have on State Medicaid. The effect of such a ruling might be to cripple Wisconsin's Medicaid program.

First, some Defendants may have difficulty accurately determining an actual average of wholesale prices for pharmaceuticals that are sold by wholesalers because they do not know the prices at which wholesalers resell their drugs. (DAPUF ¶ 199) Detailed, transaction based information about wholesale prices necessary to determine an *actual* average would therefore have to be obtained either from wholesalers themselves or through a third-party data gathering company.

Second, even if Defendants had access to the information necessary to calculate an actual average of wholesale prices for their products, they may be unable to report them

consistently and in a fashion ordered by this Court. There is no definition of or explanation for how to determine such an actual average of wholesale prices. (DAPUF ¶ 198) Thus, it is unclear (for example) whether such an average would be expected to capture all sales from wholesalers to their customers, or just sales to pharmacies, or just sales to pharmacies and certain other customers – *i.e.*, what sales would need to be captured or excluded. It also is unclear what time period should be used to calculate the average (e.g., quarter, calendar year, or other period), and how often the average should be recalculated, and how any retroactive rebates or price concessions should be treated. In contrast, pricing terms such as ASP and AMP are federally defined. (DAPUF ¶¶ 195-96, 220, 223)

Third, if AWP's were redesigned to be actual average prices, the State's current AWP-based drug Reimbursement Rate would immediately fall to levels insufficient to sustain the State's Medicaid program. The State currently reimburses providers for brand name drugs at AWP-13%, plus a dispensing fee. (DAPUF ¶¶ 43, 191) From this reimbursement, providers are expected to recover their costs of purchasing and dispensing drugs and to realize a reasonable return. (DAPUF ¶¶ 74-79, 81) As the State has recognized, its dispensing fee is, and historically has been, well below the actual cost of dispensing drugs. (DAPUF ¶¶ 82-95) As such, the AWP-13% portion of the drug reimbursement formula not only reimburses providers for their costs, but is intended to cross-subsidize historically low dispensing fees in order to ensure that providers recognize the reasonable return necessary and intended to foster participation in and access to Wisconsin's Medicaid program. (DAPUF ¶¶ 95-104)

If the Court were to suddenly require that AWP reflect an actual average of wholesale prices, reimbursements would be cut to at least 13% below what the average pharmacy pays to buy drugs, resulting in a system in which providers would actually incur a *loss* virtually every time they dispensed drugs to Medicaid beneficiaries. Many providers would cease

participating in the Medicaid program. (DAPUF ¶¶ 67, 70, 72) This, in turn, would jeopardize Wisconsin's right to federal money since the federal government requires that the State provide to its Medicaid population the same access to drugs as the general population (DAPUF ¶¶ 63-66), as well as prevent many Medicaid beneficiaries from obtaining necessary pharmaceutical products. To stave off that catastrophe, the Court might be asked to recalculate the dispensing fee, thus drawing the Court even further – and ever more inappropriately – into the complexities of rate-setting that are the province of the political branches. Entering this fray also may require the Court to sit for years as a monitor of price reporting – a function for which the Court, most respectfully, may be unprepared and ill-suited.

C. The State is Not Entitled to Summary Judgment as a Matter of Law on Its § 100.18(1) Claim.

Even if the Court decides the case is justiciable, Plaintiff has failed to establish that it is entitled to summary judgment on its § 100.18 claims.

1) The State's § 100.18 claims fail because § 100.182, and not § 100.18, applies to conduct relating to drugs.

The State's § 100.18 claims fail because § 100.182, and not § 100.18, exclusively governs conduct related to drugs. *Gallego v. Wal Mart Stores East, Inc.* is persuasive, if not controlling on this point.⁷² In *Gallego*, the Court of Appeals refused to permit the plaintiff to proceed with a claim under § 100.18 based on alleged misrepresentations relating to food on the ground that a closely-analogous statute governing misrepresentations relating to food, § 100.183, would otherwise be “rendered superfluous” were the plaintiff permitted to proceed under both statutory provisions.⁷³ First, the Court found that the regulation of

⁷² *Gallego*, 2005 WI App. at ¶ 11.

⁷³ *Gallego*, 2005 WI App. at ¶ 16. Section 100.183 provides in relevant part: “[n]o person . . . shall . . . make . . . an advertisement of any sort regarding articles of food, which advertisement contains any assertion, representation or statement which is untrue, deceptive or misleading.”

representations with respect to food under § 100.183 was better read as part of a “larger, comprehensive scheme” to regulate the food industry.⁷⁴ The Court noted that § 100.183 was consistent with the enforcement provisions provided in Wis. Stat. ch 97 (entitled “Food Regulation”).⁷⁵ Second, the Court determined that the Legislature could not have intended to apply a similar remedy for misrepresentations with respect to the sale of food under two separate statutes.⁷⁶ The Court found persuasive the fact that at the time § 100.183 was enacted, both § 100.183 and § 100.18 imposed criminal penalties. The Court reasoned that “if the legislature intended § 100.18(1) to apply to the sale of food, it did not need to create § 100.183 in order to authorize a criminal penalty for food fraud.”⁷⁷ Accordingly, the Court of Appeals concluded that both § 100.18(1) and § 100.183 are “specific” statutes:

As we have explained, Wis. Stat. § 100.18 deals with misrepresentations in the sale of “real estate,” non-food “merchandise, securities, employment or service,” while Wis. Stat. § 100.183 applies to misrepresentations “regarding articles of food.” The statutes are thus separate, different and non-overlapping.⁷⁸

Similarly, here, § 100.182, not § 100.18(1), applies to representations regarding drugs. First, § 100.182 is part of Wisconsin’s “larger, comprehensive scheme” to regulate the drug industry, as well as Wisconsin’s pattern of enforcing its drug statutes and regulations using criminal penalties.⁷⁹ For example, Wis. Stat. ch. 450, entitled “Pharmacy Examining Board,” imposes criminal sanctions on those who violate state regulations on dispensing, preparing, labeling, and renewing drug prescriptions.⁸⁰ Indeed, as is the case with food, prescription

⁷⁴ *Gallego*, 2005 WI App at ¶ 20.

⁷⁵ *Id.*

⁷⁶ *Id.* at ¶ 15.

⁷⁷ *Id.*

⁷⁸ *Id.* at ¶ 18.

⁷⁹ *See, e.g.* Wis. Stat. § 450.11 (providing guidelines for, among other things, dispensing drugs, preparing prescriptions, and renewing prescriptions, and providing criminal sanctions for violations of those provisions); *see also* Wis. Stat. §§ 450.12, 450.13, 450.15; *see also generally* Wis. Stat. ch 961 (entitled Uniform Controlled Substances Act).

⁸⁰ *See* Wis. Stat. § 450.11(1)-(7), (9). *See also* Wis. Stats. §§ 450.18 (imposing fines and imprisonment for violations of most Chapter 450 statutes and regulations), 450.06(4) (imposing

drugs are extensively regulated in Wisconsin, indicating that the Legislature has thoroughly considered what aspects of, and to what extent, the prescription drug industry should be regulated.⁸¹ The Legislature's specific, purposeful enactment of § 100.182 is yet another example of its clear intent to closely regulate the prescription drug market within the State wholly apart from § 100.18(1).

Second, as with food representations under § 100.183, similar remedies are available under both § 100.18 and § 100.182.⁸² Were § 100.18 intended to cover drugs, there would have been no need to enact a separate statute for drugs that provides similar civil remedies, and § 100.182 would thus be "rendered superfluous." The case is even stronger here than it was with § 100.183 in *Gallego* because § 100.182 not only imposes the same civil remedies available under § 100.18, but also imposes criminal penalties. The criminal penalties provided under § 100.182 are consistent with Wisconsin's pattern of enforcing its drug regulations using criminal penalties,⁸³ strongly suggesting that the Legislature intended § 100.182 to be the sole provision governing representations related to drugs.

forfeitures for violations of licensure requirements), 450.09(8) (imposing forfeitures for violations of pharmacy practice regulations), 450.10(2) (imposing forfeitures for "unprofessional conduct"), 450.15(2) (unlawful "placing" of prescription drugs is a felony), 450.155 and 450.16 (felony for violating laws regarding display, advertisement, and sale of contraceptives). *See also, generally*, Wis. Stats. Ch. 961 (Uniform Controlled Substances Act).

⁸¹ *See, e.g.*, Wis. Stats. §§ 450.09 (pharmacy practice), 450.12(2), (3) (labeling prescriptions), 450.13 (dispensing prescriptions), 450.15(1) ("placement" of prescription drugs). Further, the state's Pharmacy Examining Board has promulgated extensive regulations on drug manufacturing (Wis. Admin. Code § 12.01 et seq.), distribution (Wis. Admin. Code § 13.01 et seq.), and on the filing, dispensing, and labeling of drug prescriptions (Wis. Admin. Code Phar. § 8.01 et seq.).

⁸² Section 100.182 includes the same remedies as § 100.18 although it does not include a private cause of action or authorize the DOJ to institute an action. Wis. Stat. § 100.26(4) and § 100.182(5). Unlike § 100.18, violators of § 100.182 are subject to criminal penalties. *See* Wis. Stat. § 100.26(7).

⁸³ *See* n. 79, 80 and 81, *supra*. Indeed, as in § 100.182 and § 450.11, Wisconsin's statutes regulating health care providers overwhelmingly employ criminal "enforcement mechanisms." *See, e.g.*, Wis. Stats. §§ 447.09 (dentistry), 448.09 (physicians, physicians assistants, and general medical practice), 448.59 (physical therapists), 448.69 (podiatrists), 448.94 (dietitians), 448.959 (athletic trainers), 448.970 (occupational therapists), 449.11 (optometrists). *See also* Wis. Stats. §§ 153.90 (imposing criminal penalties for violating statutes regarding the collection and

2) Section 100.18 does not apply to drugs.

Just as the *Gallego* Court found with respect to food, the legislative history shows § 100.18 does not apply to false representations concerning drugs. Section 100.18(1) was originally enacted in 1913 to regulate fraudulent advertising. Over the years, the Legislature expanded the list of items expressly covered by the statute⁸⁴ but has never expanded the list to cover drugs. As it now reads, § 100.18 is expressly limited to misrepresentations concerning real estate, merchandise, securities, service, employment,⁸⁵ property (including personal property),⁸⁶ motor fuel,⁸⁷ motor vehicles,⁸⁸ and/or the nature or location of a business.⁸⁹ On its face, § 100.18(1) does not apply explicitly to conduct regarding “drugs” or “pharmaceuticals.” Furthermore, no item enumerated in § 100.18 can be reasonably read to mean drugs or pharmaceuticals.

Clearly, drugs are not subsumed under the terms real estate, securities, service, employment, property, motor fuel, motor vehicles, or the nature or location of a business. Nor are drugs included in the term “merchandise,” for at least two reasons. First, at the time § 100.18 was enacted, “merchandise” was not defined to include drugs.⁹⁰ Instead, it was

dissemination of patient health care information) and 252.25 (imposing criminal penalties for violating statutes regarding communicable diseases and public health).

⁸⁴ For example, in 1915, “livestock” was added to the list of items covered, Laws of Wisconsin, ch. 84 (1915) (attached as Ex. 190), but was dropped in 1925. Laws of Wisconsin, ch. 264 (1925) (attached as Ex. 191). In 1929, the legislature added “real estate.” Laws of Wisconsin, ch. 185 (1929) (attached as Ex. 192). In 1945, “employment” was added. Laws of Wisconsin, ch. 399 (1945) (attached as Ex. 193). In 1994, the legislature enacted subsection (10m), which enumerated practices constituting deceptive or misleading advertising by sellers of motor vehicles. The statute now also includes regulations on advertising the price of motor fuel. Wis. Stat. § 100.18.

⁸⁵ Wis. Stat. §§ 100.18(1) and (9)(a). *See also*, §§ 100.18(3m) and (10)(b) for additional references to “merchandise.”

⁸⁶ Wis. Stat. §§ 100.18(2) (3), and (5).

⁸⁷ Wis. Stat. § 100.18(6) and (8).

⁸⁸ Wis. Stat. § 100.18 (10m).

⁸⁹ Wis. Stat. § 100.18(10)(a), and (10r).

⁹⁰ Nor is “merchandise” currently defined as including drugs.

defined as “commodities which merchants usually buy and sell.”⁹¹ Specifically excluded from the definition of “merchandise” was real estate and articles “required for immediate consumption,” such as drugs.⁹² Later, the Wisconsin Legislature added “real estate” and “employment” to its list of regulated items,⁹³ but it never added “food” or “drugs.”

In addition, as discussed above, the Legislature enacted a separate statute, § 100.182, to govern conduct relating to drugs, further indicating that it never intended § 100.18 to apply to drugs.⁹⁴ While the legislative history is silent on this issue, *Gallego* is again persuasive.⁹⁵ Faced with a similar question – whether food is merchandise – the court in *Gallego* found that the Legislature did not intend “merchandise” in § 100.18 to include food since it enacted a separate statute, § 100.183, to govern misrepresentations related to food.⁹⁶ Likewise, it is clear the Legislature did not intend for § 100.18 to cover conduct relating to drugs since it enacted a separate statute, § 100.182, to specifically govern conduct relating to that commodity.

3) § 100.18(1) does not apply to the conduct alleged in this case.

Even if § 100.18(1) applied to drugs, the State has not established that § 100.18(1) applies to the conduct alleged here. Section 100.18(1) only provides a remedy for a person who was induced or was in a position to be induced into an obligation by a false or misleading representation.⁹⁷ Plaintiff has articulated no coherent theory regarding what

⁹¹ See Black’s Law Dictionary 773 (2d ed. 1910).

⁹² *Id.*

⁹³ In 1929, the Legislature added “real estate.” Laws of Wisconsin, ch. 185 (1929) (Ex. 192). In 1945, “employment” was added. Laws of Wisconsin, ch. 399 (1945) (Ex. 193).

⁹⁴ Wis. Stat. § 100.182(2).

⁹⁵ See *Gallego*, 2005 WI App at ¶¶ 11, 13-14, 18.

⁹⁶ *Id.*

⁹⁷ *Lands’ End, Inc. v. Remy*, 447 F.Supp.2d 941, 949-950 (W.D. Wis. 2006); see also *K&S Tool & Die Corp.*, 2006 WI App at ¶ 19; *Kailin v. Armstrong*, 2002 WI App 70, ¶ 44, 252 Wis.2d 676, ¶ 44, 643 N.W.2d 132, ¶ 44; *Zeller v. Northrup King Co.*, 125 Wis. 2d 31, 39 (Wis. Ct. App. 1985).

obligation, if any, it was induced into by Defendants' conduct. For that reason alone, the State has not satisfied its burden for summary judgment on its § 100.18(1) claim.

Even if one considers *possible* scenarios of what the State *may* have been induced into by the AWP – purchasing drugs, reimbursing providers, purchasing First DataBank's data, or basing its Medicaid Reimbursement Rate on AWP – none of those scenarios work with § 100.18(1). For this reason, § 100.18(1) does not apply to the conduct alleged here.

For example, § 100.18(1) does not apply because the State was not induced by the allegedly false AWP into *purchasing drugs*. The State Medicaid program did not purchase Defendants' drugs (DAPUF ¶ 31), and the State has proffered no evidence showing they played any role in providers' decisions to purchase or prescribe Defendants' drugs. The State cannot escape this shortcoming by alleging that *providers* were the ones induced by First DataBank's AWP into purchasing Defendants' drugs. The State has never alleged or set forth facts showing that providers were deceived by First DataBank's AWP.⁹⁸ Indeed, such claims would be nonsensical, given that providers – as direct purchasers of drugs – clearly knew what they themselves were paying for drugs. Moreover, the State is not bringing this case on behalf of providers; it is bringing this case on its own behalf in an effort to recover supposedly excessive reimbursements paid to providers.⁹⁹ Thus, the State must prove that First DataBank's AWP induced *it* to act differently.¹⁰⁰ It has not done so.

Nor could the State have been induced by the allegedly false AWP into *reimbursing* providers for drugs. Assuming *arguendo* that the State's payments to providers for drugs could constitute a "purchase" required by § 100.18(1), the State cannot establish that Defendants' allegedly false AWP induced *it* to "purchase" these drugs. At most, the State can only establish that it received AWP from First DataBank for drugs for which the State

⁹⁸ See generally, Complaint.

⁹⁹ *Id.* at ¶¶ 1, 66, 82, 86, 91, 95 and 100.

¹⁰⁰ See *Lands' End*, 447 F.Supp.2d at 950.

had already agreed providers would be reimbursed. Section 100.18(1) does not apply, however, to misrepresentations made post-sale.¹⁰¹ Once a party agrees to purchase a product, any subsequent misrepresentation by the seller affecting the purchase is not actionable under § 100.18(1).¹⁰² The undisputed evidence shows that the State agreed to reimburse providers for drugs they dispensed to Medicaid patients long before the State received the specific AWP for those drugs. (DAPUF ¶¶ 32, 203)

The State also cannot plausibly argue that it was induced by Defendants' allegedly false AWP into purchasing *First DataBank's* AWP. The State is not seeking damages for the amounts it paid for First DataBank data. It is seeking damages for alleged over-reimbursements to providers.¹⁰³

Finally, the State cannot argue it was induced by Defendants' allegedly false AWP into reimbursing providers *based on AWP*. Section 100.18(1) is intended to protect consumers from false advertising in connection with a sale.¹⁰⁴ It is not intended to protect a party from intentionally basing a Reimbursement Rate on a figure that it subsequently believes to be inaccurate.¹⁰⁵

These scenarios illustrate that Plaintiff is attempting to fit a square peg into a round hole by bringing this case under § 100.18(1). Plaintiff has never articulated a logically

¹⁰¹ *Kailin*, 2002 WI App. at ¶¶ 43-44; *see also Zeller*, 125 Wis.2d at 39.

¹⁰² *Kailin*, 2002 WI App. at ¶¶ 43-44.

¹⁰³ *See, e.g.* Complaint at ¶¶ 82, 86, 91 and 95.

¹⁰⁴ *See Lands' End, Inc.*, 447 F.Supp.2d at 950; *see also K&S Tool & Die Corp.*, 2006 WI App 148 at ¶ 19; *Zeller*, 125 Wis. 2d at 38-39.

¹⁰⁵ *See Lands' End*, 447 F.Supp.2d at 950 (dismissing plaintiff's § 100.18 claims because (1) it was plaintiff's customers, not plaintiff, who purchased merchandise through the alleged scheme; (2) plaintiff's customers who purchased merchandise through the alleged scheme "were not deceived into purchasing goods they did not wish to purchase and were not subjected to any misrepresentations about the goods they ultimately purchased. They obtained exactly what they sought: Lands' End merchandise from the Lands' End website;" and (3) though plaintiff may have been subject to defendants' misrepresentations, such misrepresentations "cannot be characterized as statements made "to the public relating to the purchase of merchandise.""))

coherent theory as to how it would do this and, more importantly, could not come forward with undisputed evidence in support of such a theory.

D. The State is Not Entitled to Summary Judgment Because Its § 100.18(1) Claim Depends on Material Facts Not Set Forth By Plaintiff.

Even assuming *arguendo* that § 100.18 applies to the conduct alleged here, the State has failed to set forth material facts upon which this claim relies.¹⁰⁶

1) The State has not set forth undisputed material facts showing that the AWP's were "untrue, deceptive, or misleading."

Plaintiff has not set forth undisputed facts showing that the AWP's it obtained from First DataBank were "untrue, deceptive, or misleading," as it must to sustain a claim under § 100.18(1). Rather, the State claims that the AWP's were "untrue, deceptive, or misleading" simply because they did not represent "actual averages of wholesale prices." The State has produced no evidence to support that it understood AWP's to mean what its lawyers say and completely ignores that AWP is and was widely understood by both the reimbursement community (providers, Medicaid, Medicare officials, etc.) and the State itself to be a benchmark figure, that did *not* represent actual averages of wholesale prices.

a) AWP is not an "untrue" statement.

The State's understanding of AWP is relevant to whether the AWP's at issue were untrue, deceptive, or misleading statements.¹⁰⁷ A representation "is untrue if it is false."¹⁰⁸

¹⁰⁶ Importantly, given Judge Krueger's May 18, 2006 Order, and the finding that the State's "§ 100.18 claims are governed by the three year statute of repose," the State may only make claims under § 100.18 for conduct that occurred three years prior to the filing of the complaint. *See* Remainder of the Decision and Order on Defendants' Motions to Dismiss at 9 (entered May 18, 2006) (hereinafter "May 18, 2006 Order at ___"). For Defendants named in the initial complaint filed in June 2004, "it is determined that any Wis. Stat. § 100.18 claims accruing prior to June 16, 2001 are barred." *Id.* However, not all Defendants were named in the initial complaint. Some were added by the First Amended Complaint, filed November 1, 2004, or by the Second Amended Complaint, filed June 28, 2006. For these Defendants, the State may only make claims under § 100.18 for conduct that occurred after November 1, 2001, or June 28, 2003.

¹⁰⁷ At the very least, where "competing inferences exist as to the meanings of representations...the issue of whether these representations are untrue, deceptive or

The State proffers that the term AWP should be deciphered from an opinion of a judge interpreting a statutory term in a wholly different pharmaceutical reimbursement scheme, rather than looking to its own understanding of the term. It incorrectly argues that its own understanding of the term should have no bearing on the determination of whether Defendants made a representation that was untrue. Whether a representation is false, however, cannot be divorced from the reader's understanding of the term.

Several examples are instructive. Under the State's ill-conceived reading of the statute, were the Milwaukee Brewers to win the National League pennant this year and advertise the sale of tickets to the "World Series," they would violate § 100.18(1) because, notwithstanding common knowledge to the contrary, the "World Series" involves only teams from the United States (and occasionally Canada) and not the "world." Similarly, under the State's unfounded interpretation of the statute, a lumber store would be liable under the statute for advertising a sale on 2 x 4's despite common knowledge that so-called 2 x 4's actually measure 1¾ x 3 ½ inches. There are many other examples. The point here is only that, under Wisconsin law, a statute cannot be interpreted to yield absurd results.¹⁰⁹ The State's proffered interpretation that common understanding should be suspended in applying the statute violates this fundamental precept.

The undisputed evidence shows that the reimbursement community, including the State, clearly understood AWP to be a benchmark that did *not* represent an actual average of

misleading under sec. 100.18(1), is not one appropriately decided on a motion for summary judgment." *Rach v. Kleiber*, 123 Wis.2d 473, 485, 367 N.W.2d 824, 830 (Wis Ct. App. 1985) (finding that material issue of fact as to whether there existed competing reasonable inferences as to meaning of representation of "new" construction precluded summary judgment).

¹⁰⁸ See *Uebelacker v. Paula Allen Holdings, Inc.*, 464 F.Supp.2d 791, 804 (W.D. Wis. 2006).

¹⁰⁹ See *State ex rel. Reimann v. Circuit Court for Dane County*, 214 Wis.2d 605, 622, 571 N.W.2d 385, 391 (Wis. 1997) ("[I]t is a fundamental rule of statutory construction that any result that is absurd or unreasonable must be avoided."); see also *State v. Martinez*, 2007 WI App 225, ¶ 17, 741 N.W.2d 280, ¶ 17.

wholesale prices.¹¹⁰ (DAPUF ¶¶ 1-23) Importantly, the State has come forward with *no evidence whatsoever* that it understood AWP to mean what its Complaint alleges. Rather, it is clear that the State had an entirely different understanding. The State has known for over 30 years that AWP represented an amount in excess of the providers' actual costs of acquiring a drug.¹¹¹ (DAPUF ¶¶ 9-23) Numerous documents in the State's files confirm that it knew AWP did not represent provider's actual acquisition costs. For example:

- The 1976 Task Force report concluding that AWP's "overstate actual drug costs." (DAPUF ¶ 10)
- A 1995 Wisconsin Department of Agriculture, Trade and Consumer Protection report stating that "[t]he "Actual Acquisition Cost" is the true cost that retailers pay. This amount may, and does, differ significantly from the AWP." (DAPUF ¶ 16)
- A 1999 LFB report confirming that "AWP is . . . analogous to the 'sticker price' of a car. It does not reflect the actual cost of acquiring the drug." (DAPUF ¶ 10)

Wisconsin pharmacies also understood AWP did not reflect an actual average of their acquisition costs. (DAPUF ¶¶ 2-3, 13-15, 96) For example:

- [REDACTED] (DAPUF ¶ 3)

¹¹⁰ Even the State's lawyers admit that some within Wisconsin Medicaid "[REDACTED]" (DAPUF ¶ 23). *See also Rach*, 123 Wis.2d at 481 (considering industry usage when deciding if the term "new" was false under § 100.18).

¹¹¹ Notably, it cannot be argued that the State cannot be estopped from prosecuting Defendants on the basis of "errors or misconduct on the part of governmental employees," or that a government entity cannot be held liable for representations made by its employees that are inconsistent with regulations or statutes or outside the scope of the employee's authority. These arguments are flawed for several reasons. First, Defendants do not contend that the State's employees committed any error or misconduct. The State's knowledge of the true meaning of AWP is *not* limited to a few employees, but was shared by the two branches of Wisconsin government involved in setting reimbursement, and was an integral part of each decision to maintain or change the reimbursement rate or methodology. (DAPUF ¶¶ 9-23, 61-81, 95-191) Additionally, Wisconsin courts have applied the doctrine of estoppel to prevent the State from prevailing on similar claims. *See, e.g., Wisconsin Dept. of Revenue v. Moebius Printing Co.*, 89 Wis.2d 610, 641, 279 N.W.2d 213, 226 (Wis. 1979); *State v. City of Green Bay*, 96 Wis. 2d 195, 201-202, 210-211, 291 N.W.2d 508, 511, 515-516 (Wis. 1980).

- [REDACTED] (DAPUF ¶¶ 14-15)

The federal government understood this as well. (DAPUF ¶¶ 5-8) For example:

- In 1989, it prohibited states from reimbursing on an undiscounted AWP because AWP represented more than actual cost. (DAPUF ¶¶ 37, 127-28)
- It issued numerous reports beginning in the mid-1980s through the present concluding that published AWP's were significantly above acquisition costs. (DAPUF ¶ 7)
- The former Administrator for CMS testified that he knew as far back as 1990 that AWP was substantially in excess of the price at which wholesalers could actually acquire drugs. (DAPUF ¶ 6)

First DataBank, the source from which the State obtained AWP's, does not consider its AWP a transaction price. First DataBank has stated that its AWP's represent an "average of wholesalers' catalog or list prices for a drug product to their customers." (DAPUF ¶ 232) Patricia Kay Morgan, the First DataBank employee responsible for First Databank's editorial policies from 1999 to 2005, testified that AWP is a "benchmark" or "reference" price and that it has been no secret in the industry that pharmacies were able to purchase drugs based on prices which were lower than AWP's. (DAPUF ¶ 4)

Plaintiff's sole support for its assertion that AWP was an "untrue" statement is a post-complaint decision by a United State District Court Judge in Massachusetts interpreting the term "average wholesale price" in the context of a Medicare statute.¹¹² That decision is inapplicable to this case. This Court is not interpreting a statute or even a regulation. The terms "AWP" and "average wholesale price" do not appear in any federal Medicaid statute or in any Wisconsin statute or regulation. (DAPUF ¶¶ 1, 35, 198) Under Medicaid, the states have wide discretion in deciding how to reimburse Medicaid providers.

¹¹² See *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277, 287-88 (D. Mass. 2006) (Saris, J.); see also 42 U.S.C. § 1395u(o).

(DAPUF ¶¶ 34, 80) They are not required to use AWP and have been discouraged by the federal government from doing so. (DAPUF ¶ 35-36) In this context, the State's own understanding of the term AWP¹¹³ is thus critical to an understanding of whether AWP is an "untrue" statement.

b) AWP is not a "deceptive" or "misleading" statement.

Similarly, Plaintiff has not set forth facts showing that it was deceived or misled by the AWP's. A statement is deceptive or misleading "if it causes a reader or listener to believe something other than what is in fact true or leads to a wrong belief."¹¹⁴ The undisputed evidence shows that Plaintiff knew AWP did not represent an actual average of wholesale prices and legislated Wisconsin's drug reimbursement methodologies on the basis of this understanding in order to carry out its goals. (DAPUF ¶¶ 9-23, 63-191)

Again, the State's understanding of AWP is directly relevant to determining whether AWP's reported by First DataBank were "deceptive" or "misleading" statements. Plaintiff attempts to avoid this by citing to a Federal Trade Commission Act case, which finds that under the FTCA it is not necessary to show that a statement was relied upon for there to be a violation.¹¹⁵ But this is not true for an action under § 100.18. The Wisconsin Supreme Court has held that plaintiff must prove that it was "materially induced" to act based on the

¹¹³ In an opinion issued by Judge Saris in another AWP-related litigation, the Judge noted that the meaning of AWP as defined by Florida was a "critical question[]" in the litigation. *In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F.Supp.2d 65, 73-74 (D. Mass. 2006) (addressing federal question jurisdiction on a motion to remand). There, as here, AWP was not defined in any Florida statute or regulation, *id.* at 70, nor had there been any support presented showing that Florida had "merely incorporated the federal definition of AWP...into its own statute." *Id.* at 74. As such, the Judge found that the federal definition of AWP did not inform "the meaning of the term under the Florida Medicaid statute." *Id.* Here, because Plaintiff has similarly not made any showing that Wisconsin affirmatively incorporated the federal definition of AWP into its reimbursement rate, Plaintiff's citation to a federal definition of AWP as used in a Medicare statute is irrelevant.

¹¹⁴ See *Uebelacker*, 464 F.Supp.2d at 804.

¹¹⁵ See, e.g., Plaintiff's Motion for Partial Summary Judgment on Liability Against AstraZeneca LP at pp. 22-25. Importantly, here, the State is not seeking to implement the prophylactic purpose of the statute." It is seeking damages on its own behalf for amounts it claims it over-reimbursed providers for drugs as a result of Defendants' actions.

deceptive or misleading statement for there to be a violation of § 100.18.¹¹⁶ This element therefore is defeated by evidence that the State did *not* act based on an understanding that First DataBank’s AWP’s represented actual averages of wholesale prices.¹¹⁷

The FTC case cited by Plaintiff does not support the contention that the State’s knowledge is irrelevant to determining whether AWP was a deceptive or misleading statement in any event. Instead, the case stands for the proposition that a statement is only deceptive or misleading if there is a “probability that the reader will be misled.”¹¹⁸ The State has provided *no evidence* that it was misled.

The State’s argument also defies logic. If it truly had been deceived or misled into believing that First DataBank’s AWP’s meant actual averages of wholesale prices net of all discounts and rebates, then it would not have reimbursed providers at discounts from First DataBank’s AWP (e.g., AWP-13%), which – if the State’s proffered interpretation of AWP is accepted – would also require one to believe that the State intended providers participating in the Medicaid program to incur a loss on virtually every prescription they filled, particularly when viewed in light of the State’s deficient dispensing fees. (DAPUF ¶¶ 82-95) The record is clear that the State was rightly concerned with providing sufficient access to care for its Medicaid beneficiaries, and would not have endangered its Medicaid program by reimbursing providers at well below their actual costs. (DAPUF ¶¶ 63-104, 137-38, 150-51, 156-60)

¹¹⁶ *K&S Tool & Die Corp.*, 2007 WI 70, ¶¶ 35-37 (internal citations omitted) (finding that “proving causation in the context of §100.18(1) requires a showing of material inducement” and explaining that “the test is whether (plaintiff) would have acted in [the misrepresentation’s] absence.”) (quoting Wis. Jury Instr. 2418).

¹¹⁷ *See id.* at ¶ 36 (“[T]he reasonableness of a plaintiff’s reliance may be relevant in considering whether the representation materially induced the plaintiff’s pecuniary loss”); *Werner v. Pittway Corp.*, 90 F.Supp.2d 1018, 1034 (W.D. Wis. 2000) (dismissing a §100.18 claim on the grounds that plaintiffs “did not rely on any statements from defendants regarding” a defective carbon monoxide detector); *Ball v. Sony Electronics, Inc.*, No. 05-C-307-S, 2005 WL 2406145 at *3 (W.D. Wis. Sept. 28, 2005) (plaintiff must demonstrate reliance to satisfy § 100.18).

¹¹⁸ *Federal Trade Commission v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d. Cir. 1963).

2) The State has not set forth undisputed material facts showing that it was materially induced by Defendants' representations to act.

In Plaintiff's rush to convince the Court of the simplicity of its case, it also failed to set forth any evidence showing that it was induced by Defendants' AWP's to act in some manner. To establish causation, an essential element of its § 100.18 claim, Plaintiff must prove that the statement "materially induced" it to act differently than it otherwise would have acted.¹¹⁹ Yet, Plaintiff has failed to set forth undisputed facts that it relied on First DataBank's AWP's to represent something they do not and that this reliance induced it to act.

a) The State has failed to show that it relied on AWP's as representing an actual average of wholesale prices.

To satisfy the causation element of its claim, the State must, at a minimum, show that it relied on First DataBank's AWP's as representing an actual average of wholesale prices.¹²⁰ Yet, the State has proffered no evidence of such reliance. To the contrary, the undisputed evidence shows that the State did *not* rely on AWP being an actual average of wholesale prices. Wisconsin courts have held that the causation element of § 100.18 may be defeated by evidence that Plaintiff did not rely on the alleged misrepresentations.¹²¹

¹¹⁹ *K&S Tool & Die Corp.*, 2007 WI 70, ¶¶ 35-37 (finding that "proving causation in the context of §100.18(1) requires a showing of material inducement" and explaining that "the test is whether (plaintiff) would have acted in [the misrepresentation's] absence.") (quoting Wis. Jury Instr. 2418).

¹²⁰ *See id.*; *see also Werner*, 90 F.Supp.2d at 1034 (dismissing a §100.18 claim because "[n]ot only have plaintiffs failed to show that they relied upon a misleading statement within the relevant [statute of limitations] period, they have no evidence that they relied on statements from defendants at any time.")

¹²¹ *K&S Tool & Die Corp.*, 2007 WI 70, ¶ 36 ("the reasonableness of a plaintiff's reliance may be relevant in considering whether the representation materially induced the plaintiff's pecuniary loss"); *Werner*, 90 F.Supp.2d at 1034.

- i) *The undisputed facts demonstrate that the State did not rely on AWP as meaning an actual average of wholesale prices.*

There is overwhelming, undisputed evidence that the State did not rely on AWP as representing providers' actual acquisition costs. First, numerous documents from the State's files show it did not rely on AWP as meaning an actual average of wholesale price. For example:

- A 1989 memorandum in which DHFS proposes to decrease the Reimbursement Rate from 100% AWP to AWP-10% because undiscounted AWP "is not an acceptable estimate of prices generally and currently paid by providers." (DAPUF ¶ 127)
- A 1998 email between Ted Collins, Wisconsin Medicaid's Pharmacy Consultant, to Alan White, Director of the Bureau of Program Integrity for DHFS, referred to AWP as "ain't what's paid." (DAPUF ¶ 18)
- A 2001 LFB report noting that retail pharmacies would still profit from dispensing drugs to Medicaid beneficiaries even if the State were to decrease the Reimbursement Rate to AWP-15%. (DAPUF ¶ 155)

Second, the State's use of actual retail level transaction prices to calculate MACs reveals that it did not rely on AWP to reflect actual averages of wholesale prices. (DAPUF ¶ 24-30) For the entirety of the relevant time period, the State had access to acquisition cost information for both generic and brand name drugs through invoices and wholesaler data. (DAPUF ¶¶ 24-25) The State's designee explained that the State used this information for setting MAC rates precisely *because* First DataBank's AWP did not reflect actual acquisition prices. (DAPUF ¶¶ 26-27)

Finally, the State's receipt of average sales price ("ASP") information from a number of Defendants demonstrates that the State did not rely on First DataBank's AWP to represent actual transaction prices.¹²² (DAPUF ¶¶ 218-224) Since 2005, drug

¹²² Notably, the State also had access to average manufacturer price, or AMP, data from CMS. AMP has been defined as the average of the discounted unit price of a drug paid by wholesalers to manufacturers for drugs distributed to certain retail pharmacies. (DAPUF ¶¶ 195, 197).

manufacturers have been required by federal statute to report ASPs to the federal government for physician-administered drugs. (DAPUF ¶ 223) Some Defendants reported ASPs to the State as early as 2001. (DAPUF ¶¶ 25, 219) The methodology for calculating ASPs is set out in a federal regulation. *Id.* ASPs are intended to approximate the actual average sales price to providers of a given drug and generally reflect prices significantly below corresponding AWP. (DAPUF ¶ 221) After receiving ASPs, the State eventually changed its Reimbursement Rate for physician-administered drugs to an ASP-based methodology in October 2005, but never did so for pharmacy dispensed drugs.¹²³ (DAPUF ¶¶ 42-43, 219)

ii) *The undisputed facts demonstrate that it would have been unreasonable for the State to rely on AWP as meaning an actual average of wholesale prices.*

Even if Plaintiff had provided evidence that it relied on First DataBank's AWP as meaning an actual average of wholesale prices, Defendants would be entitled to present evidence to the Court or a jury that Plaintiff's reliance was unreasonable. The Wisconsin Court of Appeals has held that although "reasonable reliance" is not an *element* of a § 100.18 claim, the reasonableness of a purchaser's reliance *may "be considered by a jury in determining whether 'the purchaser in fact relied' on the seller's representation."*¹²⁴ Not only does the undisputed evidence show that the State did not rely on AWP to represent a

¹²³ And, even when adopting ASP-based reimbursement for physician-administered drugs, it *added* a percentage markup to ASP. (DAPUF ¶ 42).

¹²⁴ *Malzewski v. Rapkin*, 2006 WI App 183, ¶ 24, Dissent ¶ 28, 296 Wis.2d 98, ¶ 24, Dissent ¶ 28, 723 N.W.2d 156, ¶ 24, Dissent, ¶ 28 (citing *K&S Tool & Die Corp.*, 2006 WI App. 148, ¶¶ 39-45) (emphasis added). The Wisconsin Supreme Court recently accepted review of a Court of Appeals decision, *Novell v. Migliacco*, on the issue of whether "reasonable reliance" is required under a § 100.18 claim. *See* 2006 WI App 244, ¶ 12, 297 Wis.2d 584, ¶ 12, 724 N.W.2d 703, ¶ 12 (quoting *Malzewski*, 2006 WI App 183, ¶ 24). Because the pending review leaves open the possibility that this Court (or a jury) could examine whether Plaintiff's purported reliance on AWP representing actual averages of wholesale prices was reasonable in determining liability on a § 100.18 claim, the Court, at a minimum, should not enter summary judgment on this issue until the law in this area has been clarified.

provider's actual acquisition cost, but it also shows that it would have been patently unreasonable for the State to have relied on AWP as representing an actual average of acquisition costs in light of the mountains of evidence available to the State that this was not the case. For example, it would have been unreasonable for the State to rely on First DataBank's AWP as representing actual acquisition costs:

- after receiving and reviewing numerous reports from the federal government instructing the State that AWP represented more than provider acquisition cost (including one which concluded that pharmacies in Wisconsin were purchasing brand name drugs at 20.52 percent below AWP and generic drugs at 67.28 percent below AWP) (DAPUF ¶¶ 7, 11, 161-63);
- when its own consultant advised the State that Wisconsin pharmacies purchased brand name drugs at prices approximately 17.5% below AWP (DAPUF ¶ 21);
- after two Governor-commissioned pharmacy task forces, one in 1976 and another in 2006, concluded that AWP represented well more than the actual averages of wholesale prices (DAPUF ¶¶ 109-112, 188-190); and
- after receiving actual retail level transaction prices and ASP information, all reflecting prices significantly below AWP. (DAPUF ¶¶ 25, 27, 221)

b) The State has failed to show that Defendants' AWP induced it to act differently.

The State also has failed to proffer undisputed facts showing that it was induced by First Databank's AWP to act any differently that it would have if it had known that AWP were "inflated" as it now claims.¹²⁵ The State has failed to establish that Defendants' AWP induced it to: (1) purchase drugs that it would not have otherwise purchased; (2) reimburse for drugs that it otherwise would not have reimbursed for; (3) purchase anything that it would not have otherwise purchased;¹²⁶ or (4) reimburse for drugs in a manner different than it did, as discussed in Section VI.C.3, *supra*.

¹²⁵ *K&S Tool & Die Corp.*, 2007 WI 70, ¶¶ 35-37.

¹²⁶ For a more complete analysis of this argument, also see AstraZeneca's Response at Section III, which Defendants incorporate by reference.

Importantly, Plaintiff has failed to establish what seems to be its central allegation – that it would not have reimbursed based on AWP but for Defendants’ representations. The State continues to reimburse based on AWP *to this very day* (DAPUF ¶ 43), despite having brought this lawsuit over three years ago claiming it was being misled by AWP. The undisputed evidence shows that over the years the State has considered using alternative reimbursement methodologies (*i.e.*, ones not based on AWP) (DAPUF ¶¶ 105-116, 121-41, 179), or buying drugs directly from manufacturers (DAPUF ¶¶ 117-120), precisely because it knew AWP did not approximate acquisition costs. (DAPUF ¶¶ 9-23, 63-81, 95-104) Each time, the State rejected the alternatives and decided to continue using AWP to reimburse for brand name drugs. (DAPUF ¶ 105-141)

3) The State has not set forth undisputed material facts showing that Defendants affirmatively represented that AWP were an actual average of wholesale prices.

Plaintiff’s Motions also should be denied because they do not set forth undisputed material facts demonstrating that Defendants *affirmatively represented* that the AWP obtained from the pricing compendia were actual averages of wholesale prices. The only fact the State asserts (and a disputed one at that) is that Defendants provided the AWP that the compendia published.¹²⁷ Noticeably absent is any evidence of a specific statement by Defendants that the published AWP represented actual averages of wholesale prices.

Section 100.18(1) requires an affirmative “statement or representation” that is “untrue, deceptive or misleading.” It requires a Defendant to *make* a representation. It is not enough for Plaintiff merely to assert that Defendants failed to disclose the “true meaning” of AWP, or that Defendants provided AWP information to a third party and that, based upon Defendants’ silence, the State assumed or thought that the AWP equaled actual

¹²⁷ See, *e.g.* Complaint at ¶ 36.

averages of wholesale prices (ostensibly based on an opinion that, interestingly, was issued after it filed its lawsuit). As the Wisconsin Supreme Court has made clear, a mere failure to disclose does not give rise to a § 100.18(1) claim because § 100.18(1) “does not purport to impose a duty to disclose, but, rather, prohibits only affirmative statements, representations, or statements of fact that are false, deceptive or misleading.”¹²⁸

Because Judge Krueger has already ruled that a three year statute of repose applies to Plaintiff’s § 100.18 claims,¹²⁹ Plaintiff must proffer evidence that each Defendant against which it has moved made an affirmative representation that was untrue, deceptive or misleading within the three years prior to the filing of this lawsuit.¹³⁰ The State has not done this. In fact, Plaintiff has failed to offer any evidence whatsoever, from any time, let alone undisputed evidence, of an affirmative statement made by any Defendant representing that AWP’s were actual averages of wholesale prices. Rather, evidence exists that some Defendants affirmatively represented to the State and First DataBank that AWP does *not represent* an actual average of wholesale price – though they had no obligation to do so. (DAPUF ¶¶ 20, 198)

Importantly, the mere use of the term AWP does not qualify as the affirmative representation necessary to state a claim under § 100.18(1). AWP is a term of art understood by the reimbursement community to be a benchmark figure representing something different than a providers’ actual acquisition cost. (DAPUF ¶ 1-8) Accordingly,

¹²⁸ *Tietsworth v. Harley-Davidson Inc.*, 2004 WI 32, ¶ 40, 270 Wis. 2d 146, ¶ 40, 677 N.W.2d 233, ¶ 40 (“Silence – an omission to speak – is insufficient to support a claim under Wis. Stat. § 100.18(1).”); *id.* (“[§ 100.18(1)] does not purport to impose a duty to disclose, but, rather, prohibits only affirmative statements, representations, or statements of fact that are false, deceptive, or misleading.”)

¹²⁹ See May 18, 2006 Order at 9.

¹³⁰ For Defendants named in the initial complaint filed in June 2004, “it is determined that any Wis. Stat. § 100.18 claims accruing prior to June 16, 2001 are barred.” May 18, 2006 Order at 9. For Defendants added by the First Amended Complaint, filed November 1, 2004, claims accruing prior to November 1, 2001 are barred. For Defendants added by the Second Amended Complaint, filed June 28, 2006, claims accruing prior to June 28, 2003 are barred.

use of the term AWP¹³¹ by itself cannot be considered an affirmative representation of anything except this common understanding of AWP.¹³²

E. The State is Not Entitled to Summary Judgment on Its § 100.18(10)(b) Claim.

Plaintiff is not entitled to summary judgment on its § 100.18(10)(b) claim because § 100.18(10)(b) does not give rise to a cause of action separate from § 100.18(1) and does not apply to the conduct alleged here. Plaintiff also has failed to set forth material, undisputed facts satisfying its burden under § 100.18(10)(b) by failing to show that Defendants represented AWP to be a wholesale price and that the representation, if any, was deceptive.

1) § 100.18(10)(b) does not create a separate cause of action.

Section 100.18(10)(b) is not a cause of action separate from § 100.18(1); it merely defines one type of conduct that the Legislature deems to be “deceptive” under § 100.18(1).¹³³ Other subsections of § 100.18 also provide statutorily defined “deceptive” conduct.¹³⁴ Plaintiff’s § 100.18 claims thus are limited to its § 100.18(1) claim and its motions for

¹³¹ Some Defendants did not provide First DataBank with AWP’s at all. (DAPUF ¶ 225)

¹³² Even if use of the term AWP could be construed as an affirmative representation, the State has not set forth undisputed facts showing that Defendants’ AWP’s were sent to or used by the State. Given § 100.18(1)’s requirement that the untrue, deceptive or misleading representation be made or published to the Plaintiff, it is material whether or not Defendants’ alleged representations were actually made or published to the State. The undisputed evidence shows that the State did not receive Defendants’ AWP’s. (DAPUF ¶¶ 225-35) Rather, it received First DataBank’s AWP’s (known as “Bluebook AWP’s”) to process the State’s claims. (DAPUF ¶ 230-31) The Bluebook AWP’s were independently set by First DataBank and based on wholesaler surveys. (DAPUF ¶¶ 230, 232-35) See J&J’s Response at Section I.A.iii and Novartis’ Response at Section IV.D.1 for a more complete discussion of this argument, which Defendants incorporate by reference.

¹³³ Cf. *Wild v. Hillery*, Nos. 01-C0461-C, 01-C-463-C, 2003 WL 23200305, at * 3 (W.D. Wis. May 29, 2003) (“A review of § 100.18 suggests that (1) is the prohibitory subsection of the statute; [subsection] (9) merely defines the “deceptive advertising” that subsection (1) prohibits. Subsection (11)(b) gives individuals the right to sue if they suffer pecuniary loss because of a violation of the state.”)

¹³⁴ See, e.g. § 100.18(3m)(it is deceptive to represent merchandise to be a closing-out sale if the merchandise is not of a bankrupt or insolvent business) and § 100.18(10r) (it is deceptive or misleading for a person who is conducting business from a location outside of a community or region to use the name of the community or region in its corporate or trade name).

summary judgment on its § 100.18(10)(b) claim should be denied for the reasons already discussed *supra* in Sections VI.C.1 and VI.C.2.

2) § 100.18(10)(b) does not otherwise apply to this case.

Even if § 100.18(10)(b) were a stand alone cause of action, it does not apply to the conduct alleged here. Although there are no cases interpreting § 100.18(10)(b), both the plain language and the drafting history of this subsection indicate that it was not intended to apply to the present factual situation. The statute was enacted to protect retail consumers from the improper use of comparative pricing advertising, in which retailers advertise that merchandise is being sold at a “manufacturer’s price” or a “wholesaler’s price,” when the advertised price is actually much higher than the “real” wholesaler’s or manufacturer’s prices. The original draft of this subsection explained that: “[t]his bill is designed to specifically prohibit current advertising abuses by some retailers, particularly those who operate a ‘mail order’ or ‘catalogue’ business and who either represent themselves or their prices as ‘wholesaler’s’ or ‘manufacturer’s’, or by similar terminology.”¹³⁵

The cases cited by Plaintiff in its Motions support the notion that § 100.18(10)(b) does not apply to the conduct alleged in this case. Specifically, Plaintiff cites to two Federal Trade Commission cases that Plaintiff asserts are consistent with § 100.18(10)(b). Tellingly, both of these cases deal with retailers that had engaged in deceptive *comparative price* advertising.¹³⁶ Plaintiff has not come forward with evidence that any Defendant here

¹³⁵ Drafting Record, L. 1961, c.376, p.4 (attached as Ex. 189).

¹³⁶ In *L. & C. Mayers Co. v. FTC*, the court found that a jewelry retailer which made sales to the public, but held itself out as a wholesaler, was engaged in a deceptive trade practice. *See* 97 F.2d 365, 367 (2d Cir. 1938) (explaining that the “theory of the Commission’s complaint is that the company sells to ultimate consumers; that in aid of such sales it uses catalogues designating itself as a wholesaler and that the purchasing public regards it as such...that consumers infer from this representation that they are buying at the prices at which retailers purchase, thereby saving an amount equal to the retailer’s profit”). Similarly, in *Federated Nationwide Wholesalers Service v. FTC*, the court upheld the FTC’s cease and desist order relating to a catalog retailer that was masquerading as a wholesaler by deceptively claiming that it was

comparatively represented advertised drug prices as “wholesale prices.” As such, § 100.18(10)(b) does not apply to the conduct alleged.

3) The State has not set forth undisputed facts showing that a representation was made that AWP was a “wholesaler’s price” as required under § 100.18(10)(b).

The State also has not set forth facts showing that there was a representation that AWP was a “wholesaler’s price.” Section 100.18(10)(b) provides that:

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.¹³⁷

The State has failed to provide undisputed facts demonstrating that any Defendant held out any AWP to be a “manufacturer’s or wholesaler’s price,” as required by this subsection. The undisputed evidence instead shows that AWP is *not* a “manufacturer’s or wholesaler’s price.” Instead, the “wholesale acquisition cost” or “WAC” is the wholesale list price not taking into account discounts and rebates, and the State knew this to be the case. (DAPUF ¶¶ 46-48, 78-79, 145, 164-66)

Ample undisputed evidence shows that the State knew and understood, during the relevant time period, that AWP was not a wholesaler’s price. (DAPUF ¶ 1-23) For example:

- In 1984, the State received and reviewed a report from the Office of Inspector General (“OIG”) of HHS informing states, including Wisconsin, that AWP “cannot be the best—or even an adequate—estimate of the prices providers generally are paying for drugs.” (DAPUF ¶¶ 7, 122-124)
- In 2001, Wisconsin received and reviewed a report from the GAO confirming that AWP “is not necessarily the price paid by a purchaser...or ‘wholesale’ price.” *Id.*
- In 2001, Wisconsin also received and reviewed a report from the OIG confirming that AWP “bear[s] little or no resemblance to actual wholesale prices.” *Id.* at n.1.

offering products at wholesale prices. *See* 398 F.2d 253, 255 (2d Cir. 1968) (“The complaint set out several statements and representations appearing in the petitioners’ catalogs, circulars, and letters of solicitation to the effect that the petitioners were wholesalers and that their merchandise was being offered at wholesale prices.”)

¹³⁷ Wis. Stat. § 100.18(10)(b).

- In 2006, the Governor’s Commission confirmed that AWP “does not represent[] the actual wholesale cost of the product.” (DAPUF ¶ 190)

F. The State is Not Entitled to Summary Judgment on Its § 100.18 Claims With Respect to “WAC.”

Plaintiff is not entitled to summary judgment on its claims with respect to “WACs” or WAC equivalents because, as with its claims regarding AWP, the State has not set forth undisputed facts essential to proving its claims, including: (1) that Defendants affirmatively represented WACs to be something they are not;¹³⁸ (2) that the representations caused Plaintiff’s losses;¹³⁹ and (3) that the representations were untrue, deceptive or misleading.¹⁴⁰

First, the State has not set forth undisputed facts demonstrating that Defendants affirmatively represented WACs to be wholesale prices of drugs net of rebates, discounts and chargebacks. Plaintiff has simply asserted that WACs were reported by some Defendants and published by First DataBank. As has previously been discussed in Section V.E.3, silence is insufficient to meet this requirement. Plaintiff must prove that an affirmative representation was made. It has not done so.¹⁴¹

Second, the State has not set forth undisputed facts showing that the published WACs caused its losses. As established above, causation is an essential element of a § 100.18 claim. As such, Plaintiff must prove that it relied on Defendants’ representations (if any) that WAC represented a price net of rebates, discounts and chargebacks, and would have acted differently if not for Defendants’ representations. Not only has Plaintiff failed to offer evidence proving such reliance, but the undisputed evidence shows that the State *never* used or relied upon WACs for reimbursement purposes. (DAPUF ¶ 45)

¹³⁸ *K&S Tool & Die Corp.*, 2007 WI 70, ¶ 19.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ Some Defendants explicitly defined the WACs or WAC equivalents they provided to the pricing services as list prices that did not include discounts, rebates or chargebacks (DAPUF ¶ 227), a definition that was later adopted in the Medicare Modernization Act. (DAPUF ¶ 46).

Finally, the State has not set forth undisputed facts demonstrating that the WACs were “untrue, deceptive, or misleading.” Rather, the State claims that WACs were “untrue, deceptive, or misleading” simply because they were not reported net of rebates, discounts, and chargebacks.¹⁴² The undisputed evidence shows, however, that it was widely understood that published WACs were list prices that represented wholesale prices of drugs not including account rebates and discounts. (DAPUF ¶¶ 46-49) The State’s designee confirmed that this was the State’s understanding of the term. (DAPUF ¶ 48)

¹⁴² See, e.g. Complaint at ¶¶ 49 and 53.

VII. CROSS-MOTION ARGUMENT¹⁴³

A. The Court Should Dismiss This Case In Accordance With Separation of Powers Principles.

Defendants move for summary judgment on all of Plaintiff's claims – Counts I through V of the Complaint – because they involve political questions not properly justiciable by this Court. Defendants incorporate the legal arguments and undisputed facts discussed in Section VI.B *supra*. For these reasons, the Court should grant Defendants' cross-motion for summary judgment and enter judgment in Defendants' favor on Counts I through V as to all Defendants.

B. The State's § 100.18(1) Claim Fails as a Matter of Law Because § 100.182, and Not § 100.18(1), Applies to Conduct Relating to Drugs, Because § 100.18(1) Does Not Apply to Drugs and Because § 100.18(1) Does Not Apply to the Conduct Alleged.

Defendants also move for summary judgment on the State's § 100.18(1) claim – Count I of the Complaint – because § 100.18(1) does not apply to the conduct alleged or to misrepresentations concerning drugs. Moreover, the State's § 100.18(1) claim fails because § 100.182, and not § 100.18, applies to conduct relating to drugs. Defendants incorporate the legal arguments and undisputed facts discussed in Section VI.C *supra*, § 100.18(1). For these reasons, the Court should grant Defendants' cross-motion for summary judgment against the State's § 100.18(1) claim and enter judgment in Defendants' favor on Count I as to all Defendants.

C. The State's § 100.18(10)(b) Claim Fails as a Matter of Law Because § 100.18(10)(b) Does Not Create a Separate Cause of Action and Because It Does Not Apply to the Conduct Alleged.

Defendants move for summary judgment on the State's § 100.18(10)(b) claim – Count II of the Complaint – because § 100.18(10)(b) does not create a cause of action separate from

¹⁴³ This Cross-Motion is filed on behalf of all Defendants. Defendants reserve their right to move for summary judgment on other grounds at a future date, in the event their present cross-motion is denied.

§ 100.18(1). Even if it did, it does not apply to the conduct alleged here and does not apply to misrepresentations concerning drugs, which are regulated under a separate provision, § 100.182. Defendants incorporate the legal arguments and undisputed facts discussed in Section VI.E *supra*. For these reasons, the Court should grant Defendants' cross-motion for summary judgment against the State's § 100.18(10)(b) claim and enter judgment in Defendants' favor on Count II as to all Defendants.

D. The State's § 133.05, § 49.49 and Unjust Enrichment Claims are Time-Barred.

Defendants move for summary judgment on the State's § 133.05, § 49.49 and unjust enrichment claims – Counts III, IV and V of the Complaint – because they are barred by the applicable statutes of limitations. Plaintiff filed its initial complaint in this matter on June 3, 2004. The applicable statutes of limitations for Plaintiff's § 133.05, § 49.49 and unjust enrichment claims are six years. As such, any and all claims that accrued before June 3, 1998 – six years prior to the filing of the complaint – are time-barred.

1) Six year statutes of limitations and the discovery rule applies to each of these claims.

This Court already has held that a six year statute of limitations applies to the State's § 133.05, § 49.49 and unjust enrichment claims.¹⁴⁴ Specifically, Wis. Stat. § 133.18(2) provides that a civil action for damages under § 133.05 “is barred unless commenced within 6 years after the cause of action accrued.”¹⁴⁵ Similarly, § 893.43 provides that the State's § 49.49 claim, which is grounded in fraud, must “be commenced within 6 years after the cause

¹⁴⁴ See May 18, 2006 Order at 8 (ruling that Plaintiff's § 100.18 claims are governed by a three year statute of repose and that “the balance of [Plaintiff's] claims are governed by the six year statute of limitations for contractual matters in Wis. Stat. § 893.43 or the default statute of limitations in Wis. Stat. § 839.93.”). See Wis. Stat. § 839.93 (actions grounded in fraud must be commenced within 6 years after the cause of action accrues); see also *Boldt*, 101 Wis. 2d at 578 (applying contract limitations period found in Wis. Stat. § 893.43 to unjust enrichment claim); see also Wis. Stat. § 133.18(2) (a civil action for damages under Ch. 133 is barred unless commenced within 6 years after the cause of action accrues).

¹⁴⁵ Wis. Stat. § 133.18(2).

of action accrues.”¹⁴⁶ Likewise, § 893.43 provides that an action to recover for unjust enrichment must also be filed within six years from the date the claim accrues.¹⁴⁷

Wisconsin’s discovery rule – which applies to each of these three claims – provides that a cause of action accrues when the plaintiff discovered or, in the exercise of reasonable diligence should have discovered, the facts underlying its claim.¹⁴⁸ Under Wisconsin law, Plaintiff’s claims accrued when it had “possession of such essential facts as will, if diligently investigated, disclose the [alleged] fraud.”¹⁴⁹

2) The State’s claims accrued when it knew or should have known that AWP did not represent an actual average of wholesale prices.

The State has alleged that Defendants violated § 49.49, § 133.05 and were unjustly enriched because the State understood AWP to be an actual average of wholesale prices and Defendants “reported” something different.¹⁵⁰ Consequently, each of these causes of action

¹⁴⁶ Wis. Stat § 893.43.

¹⁴⁷ See *Boldt*, 101 Wis. 2d at 578 (applying contract limitations period found in Wis. Stat. § 893.43 to unjust enrichment claim).

¹⁴⁸ *Pritzlaff v. Archdiocese of Milwaukee*, 194 Wis.2d 302, 315-316, 533 N.W.2d 780, 785 (Wis. 1995) (“It is well settled that a cause of action accrues when there exists a claim capable of enforcement, a suitable party against whom it may be enforced, and a party with a present right to enforce it...[T]he discovery rule is so named because it tolls the statute of limitations until the plaintiff discovers or with reasonable diligence should have discovered that he or she has suffered actual damage due to wrongs committed by a particular, identified person... ‘[D]iscovery’ in most cases is implicit in the circumstances immediately surrounding the original misconduct.”); *Carlson v. Pepin County*, 167 Wis. 2d 345, 481 N.W.2d 498 (Wis. Ct. App. 1992); see also Wis. Stat. § 893.93(1)(b); *Kohl v. F.J.A. Christiansen Roofing Co.*, 95 Wis. 2d 27, 33, 289 N.W.2d 329, 332 (Wis. Ct. App. 1980) (“The statute of limitations in a fraud action begins to run from the time the fraud is first discovered.”) (citing Wis. Stat. § 893.19(7)); Wis. Stat. § 133.18(4) (“A cause of action arising under [§ 133.05] does not accrue until the discovery, by the aggrieved person, of the facts constituting the cause of action.”).

¹⁴⁹ See *Milwaukee Western Bank v. A.A. Lienemann*, 15 Wis.2d 61, 65, 112 N.W.2d 190, 192 (Wis. 1961); see also, *Koehler v. Haechler*, 27 Wis.2d 275, 278, 133 N.W.2d 730, 732 (Wis. 1965) (finding that the “burden of diligent inquiry is upon the defrauded party as soon as he has such information as indicates where the facts constituting the fraud can be discovered.”); *Stroh Die Casting Co. v. Monsanto Co.*, 177 Wis.2d 91, 117-118, 502 N.W.2d 132, 142 (Wis. Ct. App. 1993) (finding that a diligent investigation is required for fraud claim), *review denied*, 505 N.W.2d 137 (Wis. 1993).

¹⁵⁰ See, generally Complaint at ¶¶ 87-100.

accrued when the State first learned (or in the exercise of reasonable diligence should have learned) that the AWP's it was using for Medicaid reimbursement purposes did not represent actual averages of wholesale prices.

a) Wis. Stat. § 49.49(4m) Claim

Section 49.49(4m)(a)(2) provides:

No person, in connection with medical assistance, may...[k]nowingly 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.¹⁵¹

On its face, the statute requires there be a statement or representation that is "false."

Under the State's theory, the requisite violative false statement or representation is the published AWP's that did not represent actual averages of wholesale prices.¹⁵² As such, once the State learned, or should have learned, that published AWP's were *not* in fact representative of actual averages of wholesale price, its § 49.49 claim would have accrued and the limitations period would have begun to run.¹⁵³

b) Unjust Enrichment Claim

Unjust enrichment is a "quasi-contractual" claim "grounded on the moral principle that one who has received a benefit has a duty to make restitution where retaining such a benefit would be unjust."¹⁵⁴

¹⁵¹ Wis. Stat. § 49.49(4m)(a)(2).

¹⁵² The State has alleged that by "publishing false and inflated wholesale prices," which were "represented...[to] reflect actual average wholesale prices," Defendants have "knowingly made or caused to be made false statements or representations of material fact for use in the determination and calculation of payment by the Wisconsin Medicaid Program in violation of Wis. Stat. § 49.49(4m)(a)(2)." See Complaint at ¶¶ 35, 36, 65 and 94.

¹⁵³ For causes of action sounding in fraud, such as the State's § 49.49 claim, "it is not necessary that a defrauded party have knowledge of the ultimate fact of fraud. What is required is that it be in possession of such essential facts as will, if diligently investigated, disclose the fraud." See *Milwaukee Western Bank*, 15 Wis.2d at 65; see also, *Koehler*, 27 Wis.2d at 278; *Stroh Die Casting Co.*, 177 Wis.2d at 117-118.

¹⁵⁴ *Watts v. Watts*, 137 Wis. 2d 506, 530, 405 N.W.2d 303, 313 (Wis. 1987).

The State's unjust enrichment claim rests on the premise that Defendants were unjustly enriched as a result of Plaintiff's alleged over-reimbursement to providers.¹⁵⁵ The cause of the State's alleged over-reimbursement under the State's theory is an AWP that does not represent an actual average of wholesale prices. As such, the State's unjust enrichment claim accrued when it discovered, or in the exercise of reasonable diligence should have discovered, this fact – namely, that AWP's were not representative of actual averages of wholesale prices.

c) Wis. Stat. § 133.05 Claim

Section 133.05(1), entitled "Secret rebates; unfair trade practices," 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.¹⁵⁶

On its face, the statute requires a payment or allowance that is "secret." Plaintiff alleges that Defendants have "discounted secretly from defendants' published prices" by providing "secret discounts, rebates and other economic benefits with the intent and effect of artificially inflating the private payer market for their products,"¹⁵⁷ that caused the State to reimburse providers more than it would have otherwise reimbursed.¹⁵⁸ Under this theory, once the State learned, or in the exercise of reasonable diligence should have learned, that AWP's were not actual averages of wholesale prices, the allegedly "secret" discounts and rebates would have been exposed, and the State's § 133.05 claim accrued.

¹⁵⁵ Complaint ¶¶ 96-100.

¹⁵⁶ Wis. Stat. § 133.05(1).

¹⁵⁷ Complaint ¶ 88.

¹⁵⁸ Complaint ¶¶ 87-91.

3) Defendants are entitled to summary judgment because the State knew or should have known that AWP did not represent an actual average of wholesale prices more than six years prior to the filing of its Complaint.

Defendants are entitled to summary judgment because the undisputed evidence shows that the State knew, or in the exercise of reasonable diligence should have known, that AWP did not represent actual averages of wholesale prices prior to June 3, 1998, six years before Plaintiff filed its Complaint. This evidence shows that the State has known for *over 30 years* that AWP did not represent an actual average of wholesale prices (DAPUF ¶¶ 7-30, 105-191), thereby establishing that the State had knowledge prior to June 3, 1998 for purposes of accrual of the State's claims. The undisputed evidence supporting this includes, but is by no means limited to the following:

- A 1975 letter from then-Lieutenant Governor to the Governor's Task Force, responsible for studying pharmaceutical reimbursement under Medicaid, stating: "once again pegging reimbursements to the highly-suspect Average Wholesale Price figure published in trade publications . . . will result in increased Medicaid expenditures and will fail as long-term management techniques." (DAPUF ¶ 110)
- A 1975 LFB report informing the Legislature that reimbursing based on AWP "is not economical since it fails to take into account state variations from [sic] the national wholesale price list or discounts obtained through bulk purchasing." (DAPUF ¶ 115)
- A 1975 letter from then-Lieutenant Governor Martin Schreiber to the FDA noting that Wisconsin's then-current practice of reimbursing pharmacists at 100% of AWP "allows providers to earn uncontrolled profits through bulk purchases [and] discounts from suppliers...." (DAPUF ¶ 108)
- A 1976 report from the Governor's Task Force concluding that AWP "overstate actual drug costs," citing a federal report estimating that a "15 percent spread exists between [published] price and wholesale price." (DAPUF ¶¶ 10, 111-12)
- A 1984 federal OIG report alerting Wisconsin that "[p]harmacists do not purchase drugs at the AWP published in the "Bluebook," "Redbook or similar publications. Thus, AWP cannot be the best--or even an adequate--estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices." (DAPUF ¶¶ 7, 122-124)

- A 1989 HCFA Revised State Medicaid Manual informing states that AWP overrepresented costs by at least 10-20% and prohibiting states from reimbursing on an undiscounted AWP. (DAPUF ¶¶ 127-28)
- A 1989 federal OIG report notifying Wisconsin that the OIG “continue[s] to believe that AWP is not a reliable price to be used as a basis for reimbursements for either the Medicaid or Medicare programs.” (DAPUF ¶¶ 7, n.5, 11)
- A 1995 Wisconsin Department of Agriculture, Trade and Consumer Protection study finding that “the AWP is the manufacturer’s suggested selling price for wholesalers to use. The “Actual Acquisition Cost” is the true cost that retailers pay. This amount may, and does, differ significantly from the AWP. (DAPUF ¶ 16) The State’s designee confirmed under oath that this was the State’s understanding of the term AWP. (DAPUF ¶ 17)
- A 1997 federal OIG report alerting Wisconsin to the fact that AWP did not represent actual cost. (DAPUF ¶¶ 7, 11) Wisconsin relied on this report numerous times in suggesting reductions to the Reimbursement Rate. (DAPUF ¶¶ 12, 142, 154-55)
- Testimony from the State’s pharmacy consultant that since at least February 1998, Wisconsin Medicaid has commonly referred to AWP as “ain’t what’s paid.” (DAPUF ¶ 18)

Were this not enough, the State flatly and unequivocally admitted to having knowledge about the “potential fraud” associated with AWP going back as far as 1997. Specifically, in a 2004 letter responding to a private attorney’s solicitation for AWP litigation business, which outlined the alleged facts underlying a potential fraud claim against drug manufacturers, DHFS wrote:

The issue you present is one of which we have been aware for several years. In 1997, and again in 2001, Wisconsin was one of the eight states that the Department of Health and Human Services’ Office of the Inspector General included in its survey of Medicaid Coverage of Prescription Drugs. That survey indicated that pharmacists could obtain brand name prescription drugs at 21.84 percent below the average wholesale price, while Medicaid reimbursement for those drugs averaged around 10-12 percent below the average wholesale price. We have been discussing this issue with the Wisconsin Department of Justice for some time. (DAPUF ¶ 22)

Even if the Court were not persuaded that the State had actual knowledge of its claims prior to June 3, 1998, there can be no question that it had information, which in the exercise of reasonable diligence, would have allowed it to discover that AWP did not

represent an actual average of wholesale prices well prior to that time. The evidence as outlined above is, at the very least, sufficient to have allowed the State to discover this fact.

In addition, since at least 1979, the State has had access to actual cost information from providers (DAPUF ¶¶ 24-25, 30), which if investigated, would have shown that the published AWP's did not reflect actual averages of wholesale prices. Moreover, starting in the mid-1980s, the State received and reviewed a series of reports from the federal government concluding that AWP's did not represent actual costs. (DAPUF ¶¶ 7, 11) These reports provided the State with sufficient notice that the AWP's it was using to reimburse on did not reflect providers' actual acquisition costs. Furthermore, since at least 1979, the State has had access to cost information for drugs it purchased for its own state entities, which, if investigated, would have clearly shown that the published AWP's did not reflect providers' actual acquisition costs. (DAPUF ¶ 24-25) Each of these facts alone is sufficient to have placed the State on inquiry notice of its claims. Together, they overwhelming support the fact that the State knew, or should have known, of its claims prior to June 3, 1998.

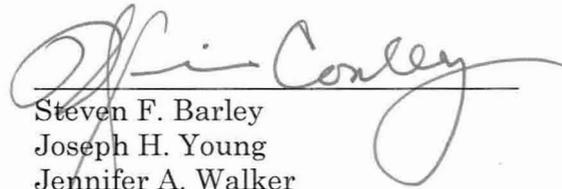
The undisputed evidence clearly establishes that the State has known for decades that AWP does not reflect an actual average of wholesale prices. Accordingly, Defendants' cross-motion for summary judgment on the State's § 49.49, § 133.05 and unjust enrichment claims should be granted and the Court should enter judgment in Defendants' favor on Counts III, IV and V as to all Defendants.

VIII. RELIEF SOUGHT

For the foregoing reasons, Defendants request the Court deny Plaintiff's Motions for Partial Summary Judgment Against AstraZeneca, Johnson & Johnson, Novartis and Sandoz and grant Defendants' Cross-Motion for Summary Judgment against all of the State's claims.

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Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2008, a true and correct copy of the foregoing was served upon all counsel of record via electronic service pursuant to Case Management Order No. 1 by causing a copy to be sent to LexisNexis File & Serve for posting and notification.

