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STATE OF WISCONSIN | CIRCUIT COURT Branch 7 | DANE COUNTY

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| STATE OF WISCONSIN, | ) | |
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| Plaintiff, | ) | Case No.: 04 CV 1709 |
| | ) | |
| v. | ) | |
| | ) | |
| AMGEN INC, ET AL., | ) | |
| | ) | |
| Defendants. | ) | |

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JAN 20 2005
STATE OF WISCONSIN
CIRCUIT COURT FOR DANE COUNTY

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR JOINT MOTION TO DISMISS THE AMENDED COMPLAINT**

The defendants by their respective attorneys, submit this Memorandum of Law in Support of Their Joint Motion to Dismiss the Amended Complaint:

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## INTRODUCTION

For over twenty years, the State of Wisconsin (the "State") has reimbursed pharmacies and physicians who dispense certain drugs to Medicaid recipients based on varying percentage discounts from the reported "average wholesale price" ("AWP") of the drug.[1] Numerous governmental reports issued and received by the State reflect its awareness that published AWPs represent a "non-discounted list price," and that "[p]harmacies purchase drugs at prices that are discounted significantly below AWP or list price."[2] *See also Louisiana v. Dep't of Health & Human Services*, 905 F.2d 877, 879-81 (5th Cir. 1990) (discussing a variety of pre-1990 federal reports confirming that AWPs significantly exceeded actual acquisition costs). Consistent with its understanding that AWP is "analogous to the 'sticker price' of a car,"[3] the State uses a Medicaid payment formula that reimburses pharmacies and physicians not *at AWP*, but at a *discount off of* AWP. Over the years, the State has periodically increased the discount off of AWP to lower its Medicaid expenditures.

Despite this history, the State now contends that its use of the AWP benchmark results from a widespread series of frauds committed by each of thirty-seven separate pharmaceutical manufacturers. Notably, the State does not allege any form of conspiracy, collusion, or unlawful agreement among the Defendant manufacturers; its frequent references to

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[1] As noted below, Wisconsin also has elected to reimburse for hundreds of drugs according to other payment formulae unrelated to AWPs. *See* 23-24, *infra.*

[2] Department of Health and Human Services, Office of Inspector General, *Medicare Action Transmittal No. 84-12,* reprinted in *Medicare and Medicaid Guide* (CCH) § 34,157 at 2 (1984) (Defs. App. Ex. 1.) Public record materials concerning AWP are included in Defendants' Appendix for the Court's judicial notice. *Freedom From Religion Found. v. Thompson*, 164 Wis. 2d 736, 740 n.4, 476 N.W.2d 318 (Ct. App. 1991).

[3] Wisconsin Department of Health and Family Services ("DHFS"), Joint Committee on Finance, Paper # 479, ¶ 4 at 3 (June 1, 1999) (Defs. App. Ex. 2.) (http://www.legis.state.wi.us/lfb/1999-01budgetdocuments/99-01BudgetPapers/479.pdf).

the Defendants' "scheme" are for rhetorical effect only. (*E.g.,* Am. Cmplt. ¶¶ 1, 32-33, 36-37, 45, 47-48, 53, 55-56). The State claims that each of the companies independently and separately posted "false and inflated" AWPs which were higher than the "true prices" for their drugs. (*Id.* ¶¶ 37, 48, 55.) According to the Amended Complaint, these inflated AWPs have resulted in overcharges to the State and its citizens (*id.* ¶¶ 56, 60), as well as to Wisconsin health insurers and HMOs who also are said to calculate reimbursement at a percentage discount from published AWPs. (*Id.* ¶¶ 67-74.) Wisconsin Medicaid does not make payments to the Defendant manufacturers; it makes payments to pharmacies and physicians. (Id. ¶ 58). Although the State acknowledges this fact, it nevertheless suggests that each Defendant profited indirectly from the alleged overpayments made to Wisconsin pharmacies and physicians. (*Id.* ¶¶ 52, 56, 71.)

The State's claims are legally insufficient on their face and contradicted by the public record. Each Count of the Amended Complaint should be dismissed.

***First***, and most fundamentally, the fraud allegations underlying each of the State's claims fall far short of the particularity required by Wis. Stat. § 802.03(2). The Amended Complaint makes no attempt to identify how each Defendant participated in an alleged fraud. Instead, virtually all of the allegations in the Amended Complaint are directed collectively at *all Defendants* and *all of their products*. Such "group pleading" does not provide the specificity required by § 802.03(2). Further, the Amended Complaint contains no particularized allegations (the "who, what, when, and where") as to what constitutes the alleged fraud. It identifies no false statements, no individuals who made such statements, and no date, time, or place where such statements were made. This failure to satisfy § 802.03(2) is not a mere technical pleading defect – it reflects the State's basic lack of a sustainable theory on which to rest its claims.

***Second,*** each claim of the Amended Complaint rests on the false premise that AWP was understood to reflect actual prices paid for drugs by pharmacies, doctors, and wholesalers. But the State never alleges that Defendants ever represented to it or others that AWPs reflected actual prices paid for drugs by pharmacies, doctors, or wholesalers. In fact, the indisputable public record – including numerous government reports issued by both the State and the federal government – shows precisely the opposite; AWPs have long been understood to be only benchmark prices, which exceed, sometimes by substantial margins, the actual acquisition prices paid by pharmacists, doctors, and wholesalers. Without plainly alleging that it understood, based on Defendants' representations, that AWPs reflect actual prices paid – which it cannot do – the State cannot establish any link between the alleged misconduct and any injury. This failure to allege any plausible causal link, besides highlighting the State's failure to satisfy § 802.03(2), is fatal to each of the claims presented.

***Third,*** the Wisconsin Attorney General has no power, absent a specific statutory grant, to pursue claims on behalf of its citizens. Yet no statutory authority exists, and none has been cited, to authorize the Attorney General to pursue claims to recover damages on behalf of third parties under any of the statutory claims asserted (Counts I – IV), or to pursue claims for unjust enrichment on behalf of either the State or its citizens (Count V).

***Fourth,*** the Amended Complaint fails adequately to plead key elements of the alleged claims.

- **False Advertising (Counts I and II).** In its false advertising claims under Wis. Stat. § 100.18, the State fails adequately to allege causation and reliance. Private consumers are not alleged to have received AWP data, let alone relied on it. Nor does the State allege that it relied on an understanding that AWP reflected actual acquisition costs (which the public record precludes it from asserting). The Amended Complaint also does not adequately allege that the AWPs were, in fact, "false." Finally, Defendants' alleged failure to disclose

the actual drug acquisition costs does not support a § 100.18 claim, which imposes no duty to disclose such prices.

- **Secret Discounts (Count III).** The State does not adequately allege the existence of "secret" discounts – given that discounting was widely known to exist by Wisconsin and the commercial marketplace. Nor does this claim identify, as required, how such discounting caused any injury to competition.

- **Medical Assistance Fraud (Count IV).** This State does not adequately allege that the alleged AWP inflation was material to the State's conduct. No such materiality can be properly alleged, given that the State has continued to use AWP as its reimbursement benchmark for certain brand-name drug reimbursements while publicly acknowledging that it is a benchmark price, not an actual sales price.

- **Unjust Enrichment (Count V).** This claim fails not only because the Attorney General has no statutory authority to prosecute it, but also because the State fails to allege each of its elements in the Amended Complaint.

***Fifth,*** the State's claims run afoul of Wisconsin's filed rate doctrine. The reimbursement rates set by Wisconsin's Medicaid program and by Medicare Part B for covered pharmaceuticals are lawful, government-set rates. The State's claim for damages requests that this Court decide that these reimbursement levels were incorrect and inflated – an exercise in judicial "second guessing" of government rates that the filed rate doctrine precludes.

***Sixth,*** the claims asserted in the Amended Complaint, which purport to reach back to 1992, are barred entirely or in substantial part by the applicable statutes of limitations. The applicable limitations periods range from 3 years (for the false advertising claims), to 6 years (for all the remaining claims). All claims arising before these periods, therefore, are barred.

## BACKGROUND

**Medicaid.** Medicaid is a cooperative federal-state program, jointly funded by the states and the federal government, to provide medical services to low income individuals. (Am.

Cmplt. ¶ 57.) Depending on a state's per capita income, the federal government pays for anywhere between 50% to 75% of the costs incurred by the state under its Medicaid program (for 2004, the federal government pays 58.41% of Wisconsin Medicaid costs, with Wisconsin bearing the remainder, *see* www.cms.hhs.gov.). States have discretion under federal law as to whether to include prescription drugs in their Medicaid programs, and also have some latitude in determining the reimbursement formula used for such prescriptions. *See* 42 C.F.R. §§ 447.331(b)(1) & (2). Different states have different ways of calculating Medicaid reimbursement rates, with some states basing reimbursement for medicines on indices other than AWP, such as "wholesale acquisition cost," "acquisition cost," or other benchmarks.[4] Wisconsin has for years elected to use AWP minus a percentage as its reimbursement benchmark, with the discount increasing over time from AWP minus 10% to AWP minus 13%.[5]

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[4] *See, e.g.,* Ala. Admin Code R. 560-X-160.06 (2002) (WAC + 9.2%); Mass. Regs. Code tit.114.3 § 31.01 (2003) (WAC + 10%); 1 Tex. Admin Code § 355.8541 (2003) ("wholesale estimated acquisition cost" or "direct estimated acquisition cost"); Md. Regs. Code tit. 10 § 09.03.01 (lowest of AWP-10%, WAC + 10%, distributor's price + 10%, or direct price + 10%); Ohio Admin. Code § 5101:3-9-05 (WAC + 9% for claims submitted after April 30, 2002). In addition, for many years some states such as New York have not used AWP or any other benchmark price to reimburse for physician-administered drugs covered by Medicaid, but instead have reimbursed for such drugs based on the "actual cost of the drugs to the practitioner." N.Y. Soc. Serv. Law § 367(a)(9)(a).

[5] Am. Cmplt. ¶ 57-58; see Wisconsin DHFS, Joint Committee on Finance, Paper # 479, 1 (June 1, 1999) (Defs. App. Ex. 2) ("most brand name drugs and generic drugs not listed on MAC list are reimbursed at the AWP minus 10%"); DHFS Memo to In-State Wisconsin Medicaid Certified Pharmacists, Changes in HIRSP's Drug Coinsurance Provisions and Reimbursement Rate Effective January 1, 2002, at 2 (Dec. 3, 2001) (Defs. App. Ex. 3) (Announcing that, as of January 1, 2002, "the reimbursement rate for prescription drugs not on the Maximum Allowable Cost (MAC) list will be at Average Wholesale Price (AWP) less 11.25 percent.") (http://www.dhfs.state.wi.us/hirsp/provider/pdfs/coinsurance-in-state.pdf); Wisconsin Medicaid & BadgerCare Update, No. 2003-142, PHC 1135 at 1 (August 2003) (Defs. App. Ex. 4) (Announcing that, effective August 15, 2003, the "Medicaid Average Wholesale Pricing (AWP) reimbursement rate for brand name legend drugs change to AWP minus 12%," and "will change to AWP minus 13%" as of July 1, 2004) (http://dhfs.wisconsin.gov/medicaid/updates/2003/2003-142.htm).

Wisconsin also has established a Maximum Allowable Cost ("MAC") program, which places a ceiling on the amount of payment for over a thousand "multiple-source" drugs, often described as generic drugs. *See* DHFS Current Policy, Brand Medically Necessary and Medicaid Maximum Allowable Cost List (April 2004) (Defs. App. Ex. 5) (http://www.pac. wisconsin.gov/pdf/ PAApril20pharmBMNMACcurrent%20policy_final.pdf); *see infra* at 24-25. Under the MAC program, prices are set at the lowest price at which the drug is widely and consistently available to pharmacies, doctors, and wholesalers, as determined by studies and surveys. *Id.* For those drugs subject to MAC pricing, AWP plays no role in calculating reimbursement levels.

Besides receiving funding from the federal government for drug payments under the Medicaid program, Wisconsin and other states also receive rebate payments from drug manufacturers. For a manufacturer's drugs to be eligible for reimbursement under Wisconsin's Medicaid program, the manufacturer must contract to pay rebates to Wisconsin for drugs provided to Medicaid patients based on each drugs "average manufacturer's price" ("AMP"), not AWP. *See* 42 U.S.C. § 1396r-8(a)(1), (B)(2), & 3. The rebate ranges from a minimum of 11% of the particular drug's AMP to considerably more, depending on the drug class and the drug's reported "best price." *See* 42 U.S.C. § 1396r-8(c)(1) & (3). The AMP is always lower than AWP, at times substantially, and is defined by federal law to take into account a variety of discounts extended to pharmacies and doctors. *See* 42 U.S.C. § 1396r-8(k)(1). By law, the federal government is required to keep each drug's AMP data confidential, including from the states. 42 U.S.C. §§ 1396r8(b)(3)(A), (D). The rebate payments from the manufacturers for each drug thus reduce the State's ultimate costs for Medicaid drug reimbursements to something less than its initial payment based on a discount from AWP.

**Medicare.** Medicare, a federal health insurance program for the elderly and disabled, has in the past authorized payments for certain limited categories of medicines administered by doctors (like chemotherapy treatments) under Medicare Part B. *See* 42 U.S.C. § 1395k(a)(1). The physician chooses which drug to administer, bills Medicare for the drug, and is reimbursed by Medicare at the applicable reimbursement rate. Medicare generally provides its beneficiaries coverage for 80 percent of the allowable amount for a covered drug, with the remainder the responsibility of the beneficiaries or their insurer. *See* 42 U.S.C. § 1395l(o). In the past, Medicare based its maximum reimbursement to doctors for Part B drugs on a percentage of AWP, with the rate set at 95% of AWP from 1997 to 2003. *See* Pub. L. No. 105-33 § 4566(a) (1997) (codified at 42 U.S.C. § 1395u(o)).

In 2003, however, Congress changed this reimbursement formula as part of the landmark Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "2003 Medicare Act"). In the 2003 Medicare Act, Congress revised both the AWP-based reimbursement system for Part B drugs and the associated reimbursement for physician services for administering those drugs. The new legislation maintained reimbursement at 95% of AWP for the balance of 2003, but provided that reimbursement would generally equal only 85% of AWP in 2004. *Id.* § 303(b). Beginning in 2005, AWP is no longer used as a benchmark for Medicare reimbursement, and instead drugs are reimbursed under either an "average sales price" methodology or through a competitive acquisition program, both of which are detailed in the legislation. *Id.* § 303(b)-(d); see Conference Joint Explanatory Statement P.L. 108-173, at 192 (http://waysandmeans.house.gov/media/pdf/hr1/hr1jtexplstate.pdf.) The 2003 Medicare Act also requires the Secretary of Health and Human Services to recognize the value of physician services in administering outpatient drugs in setting physician reimbursement rates, *see* 2003 Medicare

Act § 303(a), *see also* Joint Explanatory Statement at 144-45, and prohibits the Secretary from changing reimbursement levels for Part B drugs unless he "concurrently" adjusts reimbursement for related physician services. *See* 2003 Medicare Act § 303(f).

**Key Pricing Terms.** At the heart of the State's claims are two pharmaceutical pricing terms: "Average Wholesale Price," or "AWP," and "Wholesale Acquisition Cost," or "WAC." These terms derive their meaning not by statute or regulation – and the Amended Complaint does not contend otherwise – but from how they have been used and understood for years by pharmaceutical manufacturers and reimbursers such as the government and private insurers.

The State's Amended Complaint provides no particulars whatsoever -- either by reference to a statute, regulation or industry understanding and usage -- to support the unstated premise of its claims: that AWP and/or WAC are supposed to represent the actual acquisition cost or "true price" of a drug. (*See, e.g.*, Am. Cmplt. ¶¶ 35, 54.) As discussed further below, this premise is totally contradicted by an enormous public record of reports by both the State and the federal government as they have reported on drug reimbursement issues.

In fact, the State's vague and conclusory allegations about the central pricing terms at issue here are at odds with a public report recently prepared for the Centers for Medicare and Medicaid Services ("CMS"), the federal agency charged with administering Medicare and Medicaid. This report defines WAC and AWP as types of "list prices," neither of which capture discounts, rebates or other price concessions that result in a drug's actual acquisition cost or actual price. *See* Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, at 15-16 (June 21, 2004) (Defs. App. Ex. 6). In that CMS-sponsored report, these central pricing terms have been defined, in relevant part, as follows:

> Wholesale Acquisition Cost (WAC): The Wholesale Acquisition Cost (WAC) is a *list price* used for *invoices between drug manufacturers and wholesalers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. (emphasis in original).
>
> Average Wholesale Price (AWP): The Average Wholesale Price (AWP) is a *list price* used for *invoices between drug wholesalers and pharmacies or other appropriate drug purchasers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. ... [As the result of the application of a fixed percentage mark-up], the AWP is typically 20% to 25% above the WAC for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for generic drugs. (emphasis in original).

*Id.* at 15-16.

## ARGUMENT

### I. THE FRAUD ALLEGATIONS UNDERLYING EACH COUNT ARE NOT SET FORTH WITH THE PARTICULARITY REQUIRED BY WIS. STAT. § 802.03(2).

Each count of the Amended Complaint incorporates and is based on the State's core allegation that the Defendants fraudulently reported "false and inflated" AWPs and WACs, and concealed the "true price" of their drugs. (Am. Cmplt. ¶¶ 37, 47, 54.) When pleading a cause of action for fraudulent conduct, Wisconsin law requires that "the circumstances constituting fraud or mistake shall be stated with particularity." Wis. Stat. § 802.03(2). Thus § 802.03(2), like its federal counterpart Fed.R.Civ.P. 9(b), "requires specification of the time, place and content of an alleged false representation," meaning the "who, what, when, where, and how" of the false representation. *Friends of Kenwood v. Green*, 2000 WI App 217, ¶ 14, 239 Wis. 2d

78, 619 N.W.2d 271 (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)).[6] Among the purposes of this particularity requirement is to afford "notice to a defendant for the purposes of a response," to "protect defendants whose reputation could be harmed" by fraud claims filed without adequate pre-complaint investigation, and "to discourage the filing of suits in the hope of turning up relevant information during discovery." *Kenwood*, 2000 WI App 217, ¶ 14 *(citation omitted). See also Barry Aviation, Inc. v. Land O'Lakes Municipal Airport Comm.*, 219 F.R.D. 457, 460 (W.D. Wis. 2003) ("The purpose . . . of the heightened pleading requirement in fraud cases is to force the plaintiff to do more than the usual investigation before filing his complaint."). *Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999). The State's allegations fall far short of the obligations imposed by § 802.03(2), requiring dismissal of each Count.[7]

### A. The State Relies On Group Pleading Instead Of Identifying What Conduct Of *Each* Defendant Is Fraudulent.

The Amended Complaint repeatedly lumps all Defendants together in rote allegations of fraud, without specifying what conduct by each Defendant was fraudulent. Such group pleading does not satisfy the particularity required by § 802.03(2). Instead, "in a case

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[6] Wisconsin courts have recognized that the requirements of § 802.03(2) match those of Federal Rule 9(b), and rely on federal court decisions concerning Rule 9(b) in applying § 802.03(2). *E.g., Friends of Kenwood v. Green*, 2000 WI App 217, ¶ 14; *Rendler v. Markos*, 154 Wis. 2d 420, 428, 453 N.W.2d 202, 205 (Ct. App. 1990) ("Section 802.03(2) ... is identical to Fed.R.Civ.P. 9(b).").

[7] All Counts of the Amended Complaint incorporate by reference and rely on the same general allegations of "fraudulent" inflation of AWP and WAC. (Am. Cmplt. ¶¶ 76, 80, 84, 89, 93.) Under such circumstances, the particularized pleading requirements of § 802.03(2) apply to each Count. *See Lachmund v. ADM Investor Servs., Inc.*, 191 F.3d 777, 783 (7th Cir. 1999) ("when the plaintiff relies upon the same circumstances to establish both the alleged fraud and the agency relationship of a defendant, the reasons for more particularized pleading that animate Rule 9(b) apply with equal force to the issue of agency and to the underlying fraud claim"); *see*

involving multiple plaintiffs, multiple defendants and multiple representations," the complaint "must inform *each defendant* of the nature of his alleged participation in the fraud and specify who was involved in what activity." *Kenwood*, 2000 WI App 217, ¶ 18 (emphasis added) (citing *Vicom, Inc. v. Harbridge Merchant Services, Inc.*, 20 F.3d 771, 777-78 (7th Cir. 1994)); *see also Kenwood*, 2000 WI App 217, ¶ 20 ("It is insufficient [under § 802.03(2)] to lump the defendants together ... ."); *Friedman v. Rayovac Corp.*, 295 F. Supp. 2d 957, 992 (W.D. Wis. 2003) (fraud allegations "must be specific enough so that the defendants are notified of their purported role in the scheme"); *Barry Aviation v. Land O'Lakes Municipal Airport Comm.*, 219 F.R.D. 457, 460 (W.D. Wis. 2003) (holding fraud pleading requirements violated where "plaintiff lumps all defendants together"); *Grove Holding Corp. v. First Wisconsin Nat'l. Bank*, 803 F. Supp. 1486, 1511 (E.D. Wis. 1992) ("[c]ourts have been quick to reject pleadings in which multiple defendants are 'lumped together'").

Rather than identify specific conduct by each Defendant, the State repeatedly asserts conclusory group-based allegations such as:

- "Defendants have illegally misrepresented the true AWP for virtually all of their drugs," (Am. Cmplt. ¶ 37);
- "Defendants have similarly illegally and deceptively misrepresented and inflated the wholesale acquisition cost ("WAC") of their drugs," (Am. Cmplt. ¶ 44); and
- "*some* defendants have hidden their real drug prices by providing free drugs and phony grants to [medical] providers." (Am. Cmplt. ¶ 51 (emphasis added.))

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*also Friedman v. Rayovac Corp.*, 295 F. Supp. 2d 957, 978 (W.D. Wis. 2003) ("Rule 9(b) applies to all 'averments' of fraud.").

This failure to allege fraud with particularity as to each Defendant is highlighted by the handful of instances where the State cites "examples" of conduct as to a few particular Defendants, at particular times, and regarding particular drugs. (*See* Am. Cmplt. ¶¶ 39, 42.)

By lumping Defendants together in its allegations, the State violates § 802.03(2). Indeed, in *K-S Pharmacies, Inc. v. Abbott Laboratories*, this Court found that this type of group pleading did not meet Wisconsin's liberal pleading standard for non-fraud actions, let alone § 802.03(2). *Id.,* No. 94-CV-2384, Memorandum Opinion and Order, at 4-6 (Wis. Cir. Ct. Dane County May 17, 1996). As this Court reasoned in *K-S Pharmacies*: "Merely naming an entity as a defendant and then providing a general description of a complex scheme in which violations of law occur, does not mean that a defendant is able to know what role plaintiffs claim it played within that scheme." *Id.,* at 4. That is precisely what the State has attempted to do here. *See also Ackerman v. Northwestern Mutual Life Ins. Co.*, 172 F.3d 467, 470 (7th Cir 1999) ("[C]ompliance with [federal] Rule 9(b) is burdensome. But you cannot get around the requirements of the rule just by joining a lot of separate cases into one.").

**B. The State Does Not Identify Which Specific Drugs Are At Issue.**

The State acknowledges that there currently are over 65,000 separate National Drug Codes ("NDCs") for prescription drugs (Am. Cmplt. ¶ 28), but has failed to identify which of these drugs are at issue in this case. A central component of the State's obligation to plead fraud with particularity is to identify the drugs for each Defendant that it contends are at issue and explain why.

Other courts involved in AWP-related litigation have ruled that plaintiffs must at a minimum identify the specific drugs at issue. Thus, in rejecting the original complaint in the multi-district AWP litigation – a complaint with substantially more detail than the instant

Amended Complaint – Judge Saris ordered plaintiffs to make specific allegations on a drug-by-drug basis before she would permit them to proceed. *See In re Pharmaceutical Industry AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). Similarly, in the AWP actions brought by the Connecticut Attorney General, the court required the state to revise its complaint to provide more specificity, including the identity of the specific drugs at issue. *See* Order of February 11, 2004 in *State of Connecticut v. Pharmacia Corp.*, No. CV-03-0083297-S(XO7), *State of Connecticut v. Dey, Inc.*, No. CV-03-0083296-S(XO7), *State of Connecticut v. Glaxo SmithKline*, No. CV-03-0083298-S(XO7), *State of Connecticut v. Aventis Pharmaceuticals*, No. CV-03-0083299-S(XO7) (Ct. Super. Ct.) (Defs. App. Ex. 7). In response, the State of Connecticut filed revised complaints that assert claims concerning only a narrow set of drugs for each defendant.[8]

The body of the Amended Complaint identifies only four specific drugs manufactured by four of the thirty-seven named Defendants (Am. Cmplt. ¶¶ 39, 42.) The Exhibits attached to the Amended Complaint contain a longer list of drugs, but they do not purport to identify the drugs specifically at issue in the litigation. Moreover, the drugs named in the body of the Amended Complaint and set forth in the Exhibits are drugs covered by the Medicare program, many of which are drugs purchased by physicians and administered directly by them in physician clinics such as oncology clinics. (*See* Am. Cmplt. Ex. A, at 1 (HCFA Program Memorandum.)) These drugs represent only a small segment of the drugs covered by Medicaid, which also covers "self-administered" drugs (such as pills and syrups) that are typically sold in retail pharmacies. The State seeks to litigate about all Medicaid-covered retail

[8] This order and one of the Revised Complaints in the Connecticut action are included in the Defendant's Appendix. (Def. App. Ex. 7).

pharmacy dispensed drugs, yet it lists as examples of the drugs at issue only the unique and much smaller segment of drugs (mostly doctor-administered) covered by Medicare.

In addition, the State does not – and cannot – even allege that it actually paid for the Medicare-covered drugs listed in the Appendices based on AWP or WAC. To the contrary, for the approximately 400 national drug codes identified in Exhibit A, Wisconsin has since 2000 relied *not on published AWPs,* but on alternative pricing data supplied by the U.S. Department of Justice ("U.S. DOJ"). *See* OIG, *Medicaid's Use of Revised Average Wholesale Prices*, 1-4 * App. A at 10 (Sept. 2001) (listing Wisconsin as among states that used revised DOJ prices) (Defs. App. Ex. 8). And, of the 29 drugs listed as "examples" in Exhibit B to the Amended Complaint, at least 8 are included among the 400 listed in Exhibit A. Thus, of slightly more than 400 drugs identified in the Exhibits, only about 20 are actually reimbursed by the State based upon a discount from AWP.[9]

Despite the limited number of drug examples the State provides and the fact that the State does not even reimburse based on AWPs for the vast majority of those drugs, the State asserts that the case involves "virtually all of [Defendants'] drugs." (*See* Am. Cmplt. ¶ 37.) Such a conclusory statement provides none of the particularity required by § 802.03(2), and is patently contradicted by the public record.

In sum, the State cannot satisfy § 802.03(2) without specifying which drugs it seeks to place at issue and pleading the essential facts necessary to state a claim as to *each* such drug. The State fails to meet this burden.

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[9] Likewise, there are over 1000 generic drugs for which Wisconsin determines reimbursement based on its Maximum Allowable Cost program, not AWP. *See infra* at 24. For these drugs, too, Wisconsin does not use AWP in its reimbursement formula.

### C. The State Does Not Adequately Plead What The Fraud Is.

The State also violates § 802.03(2) by failing to articulate with particularity the nature of the allegedly fraudulent conduct at issue. The State broadly describes at least three fraudulent "schemes" in which "defendants" are alleged to have engaged – one involving alleged misrepresentations to the State concerning Medicaid reimbursements (Am. Cmplt. ¶¶ 35-36, 55-61); one involving alleged misrepresentations to large insurance carriers impacting reimbursements due under privately negotiated agreements with pharmacy benefit managers ("PBMs") (Am. Cmplt. ¶¶ 67-74); and one involving individual consumers who made a copayment for their Medicare-reimbursed prescriptions (Am. Cmplt. ¶¶ 62-66.) The State also alleges fraudulent price inflation for two separate drug pricing benchmarks, "average wholesale prices" or "AWPs," and wholesale acquisition costs or "WACs." (Am. Cmplt. ¶¶ 34, 44.) But the State nowhere alleges particular facts to demonstrate how any one Defendant's conduct was fraudulent in each of these alleged schemes, how that Defendant engaged in such conduct, when or where the conduct occurred, or whether AWPs or WACs or both were involved.

In fact, as noted in the Background section above, the State's core fraud allegation – that Defendants' AWPs, or WACs, or "similar terms" are "false and inflated" (Am. Cmplt. ¶¶ 33-34) – is left undefined and confused. The State does not point to any substantive statutory or regulatory definition for either of these key terms, nor does it provide any particulars about why or how any of the thousands of these benchmark prices have been inflated. And many of the State's allegations contradict any claim that AWP should represent what providers pay for drugs. The State alleges, for example, that the State's Medicaid reimbursement formula for pharmacies is AWP minus 12% ("with some exceptions") (Am. Cmplt. ¶ 58), but does not explain what makes a particular AWP "fraudulent." Is any AWP fraudulent if it exceeds prices to pharmacies

by more than 12%? On what grounds? The State does not say. Similarly, the specific examples identified of allegedly fraudulent AWPs have spreads between reported AWPs and acquisition costs ranging from 297% to over 1000% (Am. Cmplt. ¶¶ 39, 42), but the State does not explain whether these spreads are typical of when the AWP becomes fraudulent or whether substantially lower spreads are also at issue.[10] The State at one point suggests that a reported AWP becomes false and inflated *whenever* it exceeds an average of actual acquisition prices for a particular drug. (Am. Cmplt. ¶ 35). But no explanation is provided how the State could possibly be defrauded by *any* spread between AWP and acquisition costs, no matter how small, when the State acknowledges that its Medicaid reimbursement is not set at AWP, but rather at a discount off AWP. The Amended Complaint thus does not meet the minimum standard of providing "sufficient detail" so "that the defendant, *and the court*, can obtain a fair idea of what the plaintiff is complaining, and can see that there is some basis for recovery." *K-S Pharmacies, Inc. v. Abbott Laboratories*, No. 94-CV-2384, Memorandum Decision and Order, at 4 (Wis. Cir. Ct. Dane County Sept. 5, 1995) (Krueger, J.) (emphasis in original).

The Amended Complaint is even more vague and conclusory when it steps away from claims relating to its own Medicaid payments and purports to assert fraud claims on behalf of private parties such as insurance companies and individual consumers. In only nine paragraphs, the State purports to encompass within this lawsuit claims that concern *private* drug

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[10] Exhibit B to the Amended Complaint lists drug prices that purportedly were "available" in 2000 for less than AWP. But the State submitted a similar list with its original Complaint, which attributed the "available price" to Wisconsin's Department of Corrections. To the extent Exhibit B derives from the same source, it does not support the State's claims, because it has long been recognized that drug purchases by government units are not comparable to drug purchases by others. *See* 65 Opinions of the Attorney General 59 (Apr. 23, 1976) (recognizing that sales of drugs to government units were exempt from price discrimination law applicable to purchasers generally).

reimbursement agreements entered into between PBMs and Wisconsin health insurers and HMOs, which are wholly outside the Medicaid and Medicare programs. (Am. Cmplt. ¶¶ 67-75.) The State alleges that "PBMs have systematically entered into contracts with private payers, including those located in Wisconsin, which utilize defendants' inflated wholesale prices as a base point in connection with their fees, and defendants so know." (Am. Cmplt. ¶ 74.) Yet the State fails to identify a single private payer or PBM, a single contract or contract term, or how any specific Defendant engaged in any fraudulent conduct with respect to such entities. The State's sweeping, all-inclusive allegations, devoid of particulars as to the alleged victims or perpetrators (including even their identities), are insufficient under § 802.03(2).

Nor are these failings merely technical pleading deficiencies. As discussed further below, *infra* at 18-25, Wisconsin has long known that AWP exceeds, at times significantly, both WAC and acquisition costs of doctors, pharmacies, and wholesalers. In fact, Wisconsin has both published and received reports to this effect since as early as the 1980s, and years ago rejected proposed legislation whose very purpose was to reduce the spread between its Medicaid reimbursements and the acquisition costs of pharmacies and doctors by increasing the percentage discount off AWP used by the State's reimbursement formula. Under such circumstances, there is every reason to question whether the State, if put to the test, could assert (let alone prove) a plausible fraud theory.[11]

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[11] The Amended Complaint is so devoid of any specifics that it fails even to satisfy Wisconsin's pleading standards for non-fraud actions. Even when liberally construed, the Amended Complaint does not "fairly inform" each Defendant of what it "is called upon to meet by alleging specific acts." *Scholfield v. Abbott Laboratories*, No. 96-CV-0460, Memorandum Decision and Order, at 4 (Wis. Cir. Ct. Dane County Oct. 7, 1997) (Krueger, J.); *Wulff v. Rebbun*, 25 Wis. 2d 499, 502, 131 N.W.2d 303 (1964); *see also Hlavinka v. Blunt, Ellis & Loewi, Inc.*, 174 Wis. 2d 381, 404, 497 N.W.2d 756 (Ct. App. 1993) (complaint must "sufficient detail" so "that the defendant, and the court, can obtain a fair idea of what the plaintiff is complaining....").

## II. THE STATE CANNOT ESTABLISH A CAUSAL LINK BETWEEN THE ALLEGED MISCONDUCT AND ANY INJURY SUFFERED BY IT OR OTHERS.

The State never affirmatively alleges that it or others in the industry that used AWP in their reimbursement formulae actually believed and relied on the notion that AWP reflected actual acquisition prices. *See infra* at 28-29. Absent such an allegation, there is no cognizable link between the alleged misconduct (AWPs "inflated" above acquisition costs) and any claimed injury. This deficiency alone justifies dismissal of all damage claims in the Amended Complaint.

Nor can this pleading failure be overcome by an opportunity to amend. Decades of government reports and studies – either authored by the State or received by it from the federal government – repeatedly confirm that AWPs were benchmark prices that exceeded, often substantially, acquisition costs. In fact, for more than a decade, state Medicaid programs have been prohibited by the federal government and the courts from using undiscounted AWPs as a basis for estimating the acquisition costs of drugs. *See Louisiana v. Dep't of Health & Human Services*, 905 F.2d 877, 879-881 (5th Cir. 1990). In the *Louisiana* case, HCFA had rejected Louisiana's proposal to use AWP without a discount to estimate drug acquisition costs for its Medicaid program. The Fifth Circuit upheld HCFA's decision, citing numerous federal reports provided to the states showing that AWPs "are significantly higher than the prices pharmacies generally pay for their drugs." *Id.* (internal quotes omitted). This Court may appropriately take judicial notice of such public record material in the context of a motion to dismiss.[12]

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*Freedom From Religion Foundation v. Thompson*, 164 Wis. 2d 740, n.4, 476 N.W.2d 318 (Ct. App. 1991) (courts may take judicial notice of public records on a motion to dismiss); *see also Erickson v. Wis. Dep't. of Corr.*, No. 04-C-265-C, 2004 WL 1629537, at *1 (W.D. Wis. Jul. 19, 2004) (holding that a court, when ruling on motion to dismiss under federal Rule 12(b)(6), may take judicial notice of "facts that are of public record, are generally known or are easily

### A. For Well Over Twenty Years, Published Federal Reports And Studies Have Recognized That AWP Substantially Exceeds Acquisition Costs.

As far back as 1984, the Inspector General of HHS issued a report, sent to every State Medicaid agency, alerting Wisconsin to the fact that, "[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." *Medicare Action Transmittal No. 84-12,* reprinted in *Medicare and Medicaid Guide* (CCH) § 34,157 at 2 (1984) (Defs. App. Ex. 1); *see id.* at 12 (same). The report further noted that prices charged to retail pharmacies could be as much as 42% below AWP. *Id.* at 2-3. The fact that AWP is a benchmark price has been recognized in numerous other public reports, including the following:

- In 1977, HCFA told the States that "[i]n order to set estimated acquisition costs which come close to [actual acquisition costs], some states, for example, begin with AWP prices but apply a percentage markdown to determine acquisition costs," and noted that any States that reimbursed at AWP without discounting have not "made a real effort to approach [actual acquisition costs]." HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, Medicaid—Formula For Determining EAC For Drugs, reprinted in *Medicare and Medicaid Guide* (CCH) ¶ 28,714. (Defs. App. Ex. 9)

- In 1984, the HHS OIG reported that "AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, ... rebates, or free goods that do not appear on the pharmacists' invoices," and recommends that State agencies be precluded from using AWP without a discount in determining reimbursement amounts. The report found pharmacy drug purchases were made at prices averaging approximately 15.93% below AWP, with some at 42% below AWP. HCFA Medicaid Transmittal, No. 84-12 (Sept. 1, 1984), (enclosing HHS-OIG, "Changes to the Medicaid Prescription Drug Program Could Save Millions.") (Defs. App. Ex. 1).

- In 1989, the HHS-OIG reported: "we continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the

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determined"); *Menominee Indian Tribe of Wisconsin v. Thompson*, 161 F.3d 449, 455 (7th Cir. 1998) (court may take judicial notice of public records without converting motion to dismiss into motion for summary judgment).

Medicaid or Medicare Programs. When AWP is used, we believe it should be discounted." HHS-OIG, "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program," reprinted in *Medicare and Medicaid Guide* (CCH) ¶ 38, 215 at 5 (Oct. 1989) (Defs. App. Ex. 10).

- In 1992, shortly after Medicare began covering a subset of prescription drugs already covered by Medicaid (including certain drugs often administered directly by physicians), the HHS-OIG published a study of 13 physician-administered chemotherapy drugs which showed that the physicians' actual costs were as much as 83% lower than AWPs for those drugs and concluded that "AWP is not a reliable indicator of the cost of a drug to a physician." HHS-OIG, "Physicians' Costs for Chemotherapy Drugs (Nov. 6, 1992), at 2, 5, Appendix III (Def. App. Ex. 11) (http://oig.hhs.gov/oas/reports/region2/29101049.pdf).

- In 1996 and 1997, the HHS-OIG publicly issued thirteen audit reports finding that AWPs significantly exceed pharmacies' acquisition costs. (Defs. App. Exs. 12-24).

- In 1997, a congressional committee stated that "the Office of Inspector General reports that [AWP-based] Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." *Balanced Budget Act of 1997: Report of the House Comm. on the Budget*, H. Rep. No. 105-149 at 1354 (1997) (Defs. App. Ex. 25) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=105_cong_reports&docid=f:hr149.105.pdf).

- In 1997, the OIG reported that "published AWPs . . . bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." OIG, *Excessive Medicare Payments for Prescription Drugs* at ii (Dec. 1997) (Defs. App. Ex. 26) (http://oig.hhs.gov/oei/reports/oei-03-97-00290.pdf).

Indeed, in connection with legislative efforts to change Medicare's AWP-based reimbursement system in1997, the Secretary of HHS testified that "the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs." 1997 Senate Hearings at 265 (Defs. App. Ex. 27); *see also Louisiana v. Dep't of Health & Human Services*, 905 F.2d 877, 880 (5th Cir. 1990) (federal government prohibited use of undiscounted AWPs as a proxy for

acquisition costs, and court upheld prohibition while describing findings in 1975, 1977, 1984, and 1985 that AWP substantially exceeded drug acquisition costs).

These federal reports are a small number of examples from the enormous public record that demonstrate that AWPs have long been understood to be benchmark prices that do not reflect fully-discounted transaction prices for drugs paid by pharmacies, wholesalers, or doctors. A broader listing of this public record has been compiled and is attached for the Court's judicial notice as Attachment A to this brief.

### B. Wisconsin DHFS Reports Have Similarly Recognized That AWP Is A "Sticker Price" That Well Exceeds Acquisition Prices.

Consistent with these federal reports, the Wisconsin Department of Health and Family Services ("DHFS") has itself repeatedly recognized in public documents that AWPs do not reflect actual acquisition costs for pharmacies and doctors. For example, in 1999 DHFS reported that the "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." Wisconsin DHFS, Joint Committee on Finance, Paper # 479, ¶ 4 at 3 (June 1, 1999) (Defs. App. Ex. 2) (http://www.legis.state.wi.us/lfb/1999-01budgetdocuments/99-01BudgetPapers/479.pdf). The DHFS continued that, "[a]s a result, 44 of 45 states that use the AWP as the basis for [medical assistance] drug reimbursement discount the AWP by a specified amount." *Id.* The DHFS went on to discuss federal studies that confirmed that AWP substantially exceeded actual drug acquisition costs. *Id.* ¶ 4, at 3-4.

Similarly, a 2001 DHFS report acknowledged that "[t]wo studies, one by the U.S. Department of Health and Human Services, Office of the Inspector General and another study of the Kentucky Department of Medicaid Services found that pharmacies' average acquisition cost

for most brand name drugs is approximately AWP-18%." DHFS, Joint Committee on Finance, Reimbursement Rates for Prescription Drugs, Paper 474, ¶ 11, at 3 (June 4, 2001) (Defs. App. Ex. 28) (http://www.legis.state.wi.us/lfb/2001-03budget/2001-03budgetpapers/474.pdf). In that Report, DHFS discussed the Governor's proposal to increase the discount rate for Medicaid reimbursement for brand name drugs from AWP minus 10% to AWP minus 15%, and noted such a discount increase would still provide pharmacies with payments that exceeded their drug acquisition costs. *Id.* ¶ 12, at 4. DHFS further acknowledged that "[t]he margin between the acquisition cost and the reimbursement rate, together with the dispensing fee, represents the pharmacies' total reimbursement for service costs." *Id.* ¶ 13, at 4. *See also* DHFS, Drug Reimbursement (Feb. 27, 2003) (Defs. App. Ex. 29) (recognizing another federal study concluding that AWPs for brand name drugs typically exceeded acquisition costs by over 20%).

Even more telling than the language of these reports is the legislative activity that accompanied them. Wisconsin Medicaid has for years calculated reimbursements for prescription brand-name medicines by taking a double-digit discount off the published AWPs. The precise amount of the discount has varied over time, with the discount set for "most brand name drugs" at AWP-10% in 2001 and before, at AWP-11.25% in 2002, at AWP-12% as of August 2003, and at AWP-13% as of July 2004. *See* n.5, *supra*. These reimbursement rates have changed as the legislature and DFHS have aimed to strike an appropriate balance between containing program costs and assuring access to pharmaceuticals for Medicaid recipients, with larger proposed discounts of up to AWP-18% having been rejected by the legislature in 1999 and 2001. Wisconsin DHFS, Joint Committee on Finance, Paper # 479, ¶ 7 at 4-5 (June 1, 1999) (Defs. App. Ex. 2); DHFS, Joint Committee on Finance, Reimbursement Rates for Prescription Drugs, Paper 474, at 1 (June 4, 2001) (Defs. App. Ex. 28). Throughout the relevant time period,

however, Wisconsin has maintained a "spread" between the dispenser's acquisition cost and the State's reimbursement rate. *See, e.g.,* DHFS, Drug Reimbursement, at 1 (Feb. 27, 2003) (Defs. App. Ex. 29) (noting that Medicaid reimbursement for brand name products set at AWP minus 11.25% while acquisition costs averaged about AWP minus 21.84 %) (http://dhfs.wisconsin.gov/aboutdhfs/OSF/SummaryPapers/DrugReimburs.pdf). Far from establishing reliance on a "fraud," the regulatory history establishes beyond dispute that the State is and has been aware that AWP exceeds provider acquisition costs, that a discount from AWP is one way to reach the desired reimbursement level, and that the appropriate "spread" between pharmacy acquisition costs and reimbursement is a matter of legislative policy intended to assure proper compensation for providers and access to care for Medicaid recipients.

### C. Recognizing That AWP Exceeds Acquisition Prices, Wisconsin Uses Other Payment Formulas Unrelated To AWP For Hundreds Of Drugs.

As already noted, for well over a thousand drugs, Wisconsin has opted to jettison the use of AWP entirely and to rely on other payment methodologies. As to these drugs, the broad strokes of the Amended Complaint have no conceivable application.

**DOJ Recommended Prices.** Appendix A to the Amended Complaint is a September 2000 Program Memorandum from the federal agency that administers Medicaid and Medicare (then known as the Health Care Financing Administration or "HCFA," now known as the Center for Medicare and Medicaid Services or "CMS"). The CMS Memorandum identified 400 drugs for which the Department of Justice ("DOJ") had surveyed drug wholesalers and developed alternative pricing benchmarks based on the wholesalers' prices to retail outlets. (Am. Cmplt. App. A; HCFA Medicare Transmittal AB-00-86 (September 8, 2000)). Along with many other states, Wisconsin adopted this alternative pricing data as the basis for Medicaid

reimbursement of the 400 drugs. *See* OIG, *Medicaid's Use of Revised Average Wholesale Prices*, 1-4 * App. A at 10 (Sept. 2001) (listing Wisconsin among states that used revised prices for pharmacy and physician-administered drugs) (Defs. App. Ex. 8). As Wisconsin DHFS explained in August 2000, Wisconsin began utilizing the DOJ pricing figures in order to "more accurately reflect the acquisition cost of these drugs." DHFS, *Medicaid and BadgerCare Update* (August 2000) (Defs. App. Ex. 30).

Because these drugs are not reimbursed based upon published AWPs, the State's claims simply do not apply to them. Equally important, the State's own explanation as to why it adopted the DOJ pricing data reflects its awareness that AWP exceeds acquisition costs.

**MAC Pricing For Multi-source Drugs.** The State's theory of relief is equally unavailing as to approximately 1000 generic, multi-source medicines. As Wisconsin DHFS recently reported, the Wisconsin Medicaid Maximum Allowable Cost ("MAC") Program, which started in the 1970s, "establishes maximum allowable reimbursement for generic drugs with multiple sources." DHCF Current Policy, Brand Medically Necessary and Medicaid Maximum Allowable Cost List (April 2004) (Defs. App. Ex. 5) (http://www.pac.wisconsin.gov/pdf/PAApril20pharmBMNMACcurrent%20policy_final.pdf). Thus, for the "over 1,000 [generic/multi-source] drugs" on the Wisconsin MAC list, reimbursement is calculated based on MAC prices, not on AWP or any discount off AWP. *Id.* Indeed, DHFS estimates that "Wisconsin MAC prices are, on average, approximately 65% below AWP" for such generic/multi-source drugs. *Id.* The State thus cannot "rely" on AWP, regardless of its meaning, for such generic-drug reimbursement, because AWP is not used by the State for these drugs.[13]

[13] MAC prices are determined by Wisconsin through an elaborate process that includes a survey by a State representative of "actual wholesale prices to pharmacies from drug wholesalers and

A copy of Wisconsin's current MAC list, effective 1/1/05, is included in Defendants' Appendix. (Def. App. Ex. 5).

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With this background, it is not surprising that the State fails to allege that anyone – whether it be the State, private insurers, or private consumers – relied on AWP being an accurate record of actual acquisition costs for prescription medicines. Without well-pleaded allegations of such an understanding, however, there is no foundation for claims that the alleged misconduct caused any of the damages claimed in any Count. For this reason alone, the Amended Complaint should be dismissed.

## III. THE ATTORNEY GENERAL LACKS AUTHORITY TO PURSUE SOME OF THE CLAIMS ASSERTED.

As the Wisconsin Supreme Court long ago recognized, "the powers of the attorney general are strictly limited" by the Wisconsin Constitution, such that the Attorney General may maintain a legal action only if there is "some statute authorizing it." *State v. Milwaukee Elec. Ry. & Light Co.*, 136 Wis. 179, 190, 116 N.W. 900 (1908) (citing Wis. Const. art. VI, § 3.); *see also In re Estate of Sharp*, 63 Wis. 2d 254, 260-61, 217 N.W.2d 258 (1974) (same). Thus, "'[u]nless the power to [bring] a specific action is granted by law, the office of the attorney general is powerless to act.'" *State v. City of Oak Creek*, 2000 WI 9, ¶ 22, 232 Wis. 2d 672, 605 N.W.2d 526. The Attorney General lacks such authority "to initiate and prosecute litigation" absent specific statutory authority even where the action is "intended to protect or promote the interests of the state or its citizens." *Id.* at ¶ 50 (internal quotation omitted).

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buying groups." DHCF Current Policy, Brand Medically Necessary and Medicaid Maximum Allowable Cost List (April 2004) (Defs. App. Ex. 5).

Here, no statutory authority exists for the Attorney General to bring a number of the claims the State identifies in the Amended Complaint. First, and most broadly, no statutory authority exists for the Attorney General to represent Wisconsin citizens in pursuing any of the statutory claims identified in the Amended Complaint or to recover damages on their behalf. The State's general assertion of *parens patriae* authority in the Amended Complaint (Am. Cmplt. ¶ 1), is contrary to well-settled Wisconsin law. *See Estate of Sharp*, 63 Wis. 2d 254, 260-61, 217 N.W.2d 258 (1974) ("attorney general ... cannot act for the state as *parens patriae*.").

The Attorney General thus has no authority to pursue claims or recover damages on behalf of Wisconsin citizens under False Advertising statute (Counts I & II, Wis. Stat. § 100.18),[14] or under the Trusts and Monopolies Act (Count III, Wis. Stat. § 133.05), or for Medical Assistance Fraud (Count IV, Wis. Stat. § 49.49). Nor has any case held that the Attorney General has such authority.

In addition, no statutory authority exists that authorizes the Attorney General to maintain a claim for unjust enrichment against the Defendants as alleged in Count V, whether on behalf of the State or on behalf of Wisconsin citizens. The Attorney General does not cite any authority to support such an action.

Finally, although the Attorney General has limited authority to seek injunctive relief for false advertising under Wis. Stat. § 100.18(11)(d), that authority does not extend to authorize the Attorney General to seek penalties under Wis. Stat. § 100.262(2), as alleged in

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[14] Although the Attorney General authority under § 100.18 is limited to seeking injunctive relief, the Court separately has authority, once a violation of the statute has been established, to "make such orders or judgments as may be necessary to restore any person any pecuniary loss suffered" because of such violations. *See State v. Excel Mgmt. Servs.*, 111 Wis. 2d 479, 486-87, 331 N.W.2d 312 (1983).

Count II. Again, the State cites no statutory provision or other authority authorizing the Attorney General to pursue this claim.

Accordingly, the unjust enrichment claim in Count V should be dismissed in its entirety on this ground alone. The remaining claims should be dismissed to the extent the Attorney General purports to pursue claims for damages on behalf of any third party.

## IV. THE STATE FAILS ADEQUATELY TO ALLEGE A VIOLATION OF KEY ELEMENTS OF THE CLAIMS ASSERTED.

Besides failing to plead fraud with any of the particularity required by Wis. Stat. § 802.03(2) or alleging facts to support any link between the identified misconduct and the alleged damages, the Amended Complaint also fails adequately to allege, as required, a violation of each element of the claims asserted.

### A. The State Fails to Plead a Claim for False Advertising (Counts I and II).

The Amended Complaint fails adequately to allege each of the required elements of false advertising under Wis. Stat. § 100.18 (Counts I and II). First, the Amended Complaint does not adequately allege reliance and causation. Second, the Amended Complaint does not adequately allege how the published AWPs – in light of the indisputable public record – were false or misleading. Third, the State's repeated allegation that Defendants kept the actual drug acquisition costs for pharmacies and doctors "secret," and "concealed," fails to state a cognizable claim because Wis. Stat. § 100.18 does not impose any duty to disclose, but rather prohibits only affirmative misrepresentations.

### 1. The State Has Not Adequately Alleged Causation and Reliance.

Wisconsin courts have long recognized that false advertising claims under Wis. Stat. § 100.18 require a showing that plaintiffs relied on the accuracy of the allegedly false advertising and that plaintiffs suffered pecuniary loss as a result. *Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis. 2d 56, 68-74, 416 N.W.2d. 670 (Ct. App. 1987); *see Werner v. Pittway Corp.*, 90 F. Supp. 2d 1018, 1033-34 (W.D. Wis. 2000).[15]

#### a. The State Alleges No Reliance or Causation As to Any Consumer or Insurer.

Critically, the Amended Complaint does not allege that *any recipient* of the allegedly "false" AWP or WAC information understood that information to reflect actual commercial acquisition prices of medicines purchased by pharmacies or doctors or relied on any such understanding to its detriment. With regard to private consumers, the Amended Complaint does not allege that they relied on AWP or WAC at all, or that they believed these benchmark prices reflected actual acquisition costs when they made their purchasing decisions. (*See* Am. Cmplt. ¶¶ 62-66.) With regard to private insurers, the Amended Complaint again does not allege that they relied on AWPs or WACs as reflecting actual acquisition costs for pharmacies or doctors in setting the reimbursement rates for pharmaceuticals in privately-negotiated agreements with PBMs. Indeed, the Amended Complaint demonstrates the opposite, alleging that such private insurers typically reimburse PBMs at significant discounts off AWP. (Am. Cmplt. ¶ 71.)

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[15] Thus, the standard Wisconsin jury instruction for such a claim provides that the plaintiff must allege and prove that "it sustained a monetary loss as a result of the [representation]," and that the representation was a "significant factor contributing to [plaintiff's] decision" to buy or use the relevant product. Wis. JI-Civil 2418 (2002).

Likewise, the State makes no allegation that *any* purchasing decision was driven by an understanding that AWPs reflected an average of actual acquisition costs for pharmacies and doctors. A critical component of any false advertising claim is the showing that "defendants intentionally induced the public to purchase merchandise, either directly or indirectly, by an announcement, statement or representation" containing an untrue statement of fact. *Valente v. Sofamor*, 48 F. Supp. 2d 862, 874 (E.D. Wis. 1999). Unless reliance on the allegedly false AWPs is connected with the decision to purchase prescription medicines – which is not alleged here – there is no "requisite causal link between the supposedly misleading statements and plaintiffs' losses." *Werner v. Pittway Corp.*, 90 F. Supp. 2d 1018, 1033 (W.D. Wis. 2000) (consumer's failure to observe allegedly fraudulent statement precluded false advertising claim).

**b. The State Alleges No Basis for Finding That It Relied On Or Was Injured By Any False Representation by Any Defendant.**

Although the Amended Complaint frequently invokes the term "reliance" in reference to the State, it never pleads the only form of reliance that could sustain its case. Specifically, the Amended Complaint alleges that Wisconsin "relies" on AWP in making Medicaid reimbursements (*e.g.*, Am. Cmplt. ¶¶ 33, 35) – and it is of course true that the State has adopted AWP minus a percentage as a reimbursement benchmark. However, the State studiously avoids alleging that it ever relied on any assertion by any Defendant that AWP (or WAC) reflects actual acquisition costs of the pharmacies and physicians who dispense drugs to Medicaid recipients.[16] Nor could the State plausibly make any such allegation. As discussed

[16] The closest the Amended Complaint comes to such an assertion is the allegation that "by using the term 'average wholesale price,' *defendants convey* that term's commonly understood meaning – that the price is an average of actual prices that are charged by wholesalers." (Am. Cmplt. ¶ 35 (emphasis added.)) But this claim, besides being carefully crafted to avoid alleging what the *State understood* AWP to mean, is contradicted by other allegations in the Amended

above, AWP has been repeatedly identified, by federal and state governments alike, as a benchmark price that typically exceeds actual acquisition prices by substantial percentages.

Moreover, the State's claims do not even purport to apply to the hundreds of drugs for which AWP plays no part in the reimbursement formula, such as the approximately 400 drugs for which Wisconsin had adopted DOJ-sponsored reimbursement levels, *supra* at 23, or the over 1000 multi-source drugs where Wisconsin uses MAC, not AWP, to figure the appropriate reimbursement level. *Supra* at 24.

**2. The State Fails Adequately to Allege That Published AWPs or WACs Are False.**

No claim of fraudulent advertising can be maintained under Wis. Stat. § 100.18 (1) (Count I) without adequate allegations that the statements at issue were, in fact, false or misleading. *Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶¶ 39-48, 270 Wis. 2d 146, 677 N.W.2d 233. The State's repeated assertion, without explanation or elaboration, that the published AWPs were false does not satisfy this requirement. As established above, AWP has been for decades understood and identified as a benchmark price. *Supra* at 18-24. Despite this background, the State nowhere explains how such AWPs are "false" or "misleading." It is no answer to point to the frequent allegations that these AWPs were falsely "inflated." Sticker prices by their nature exceed market prices, but that does not make them false or misleading, any more than the sticker price for a car can be deemed misleading simply because the negotiated market prices are typically a good amount lower.

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Complaint (*e.g.*, Am. Cmplt. ¶ 58), which alleges that Medicaid reimbursements are set at AWP minus 12 percent) as well as by the public documents handled by the State itself, which show that it understood AWP *not* to reflect actual acquisition costs.

Significantly, the State does not allege that Defendants made any representations that mischaracterized the published AWPs or falsely described their relationship with WACs or with actual acquisition costs. Under these circumstances, the State has not adequately alleged the false or misleading character of the AWPs and the false advertising claims should be dismissed.

**3. Non-Disclosure Of Prices Does Not Support A Section 100.18 Claim.**

Given the undisputed public record that AWPs were understood to be benchmark prices that exceed actual acquisition costs, the core of the State's false advertising claims appears to be that Defendants failed to report actual acquisition costs for their medicines, instead of the list prices reflected by these published AWPs. Indeed, the State specifically alleges that Defendants wrongly concealed the actual sale prices of their medicines. (Am. Cmplt. ¶¶ 47-54.) However, the Wisconsin Supreme Court recently made clear that Wis. Stat. § 100.18 "does not purport to impose a duty to disclose, but, rather, prohibits only affirmative assertions, representations, or statements of fact that are false, deceptive, or misleading." *Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶ 40, 270 Wis. 2d 146, 677 N.W. 2d 233. Thus, "[s]ilence – an omission to speak – is insufficient to support a claim under Wis. Stat. § 100.18(1)." *Id.* Indeed, the Wisconsin Supreme Court in *Tiestworth* noted that it had "identified no appellate decision [under Wis. Stat. § 100.18 that] was allowed to go forward on the basis of anything other than an affirmative statement or representation." *Id.* at ¶ 40 n.4.[17]

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[17] Other courts have similarly held that manufacturers and retailers have no duty to disclose pricing structures to consumers. *See, e.g.*, *Langford v. Rite Aid of Alabama, Inc.*, 231 F.3d 1308 (11th Cir. 2000) (finding pharmacy had no duty to disclose its pricing structure for prescription drugs); *Katzman v. Victoria's Secret Catalogue*, 167 F.R.D. 649, 656 (S.D.N.Y. 1996), *aff'd*, 113 F.3d 1229 (2d Cir. 1997) (dismissing complaint where plaintiffs did not "identify any basis in

Defendants are and were under no legal duty to disclose information concerning the actual sales prices of their prescription medicines to wholesalers, pharmacies or doctors. Indeed, the federal law on Medicaid rebates prohibits the federal government from disclosing this type of information to the states. *See supra* at 6. The State's fraudulent advertising claims, which are premised on an alleged failure to disclose such prices, should be dismissed.

**B. The State Fails to Plead a Valid "Secret Rebates" Claim (Count III).**

Count III of the Amended Complaint alleges that the Defendants have violated Wisconsin's "secret rebate" statute, which provides:

> The secret payment or allowance of rebates, refunds, commissions or unearned discounts ... injuring or tending to injure a competitor or destroying or tending to destroy competition, is an unfair trade practice and is prohibited.

Wis. Stat. § 133.05. The State alleges that Defendants have extended "secret discounts" to drug purchasers (physicians, wholesalers, and pharmacies), and seeks injunctive relief and an award of treble damages on behalf of "Wisconsin and those [citizens and private payers] injured by defendants' conduct." (Am. Cmplt. ¶¶ 85, 88.)

This claim is defective for two independent reasons. First, the Attorney General lacks authority to bring this action to recover damages, *see supra* at 25-27. Second, the State has failed adequately to allege either the existence of "secret and unearned" discounts or any injury to competition.

**1. The State Claims No Injury to Competition.**

Injury to competition is an essential element of a claim under the secret rebate statute. Wis. Stat. § 133.05(1); *Obstetrical & Gynecological Assocs. of Neenah, S.C. v. Landig,*

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federal or state statutes or the common law for imposing on the Defendants a duty to disclose" the decision to sell goods at different prices).

129 Wis. 2d 362, 384 N.W.2d 719 (Ct. App. 1986). The State baldly asserts that Defendants' discounts to physicians "injur[e] competition and creat[e] artificially inflated markets and market prices for their products," and that discounts to PBMs "artificially inflat[e] the private payer market for their products." However, no facts are alleged that even attempt to show how these alleged price discounts operate to restrain price competition for drug sales. *Roux Lab., Inc. v. Beauty Franchises, Inc.*, 60 Wis. 2d 427, 429, 210 N.W.2d 441 (1973) (dismissing secret rebate claim where "no facts are alleged which show how these [discounts] operate to restrain price competition.").

Moreover, the State's conclusory allegations on this point contradict the underlying premise of the Amended Complaint. The State theorizes that each Defendant vigorously discounts its prices to physicians and PBMs in order to *compete against the other Defendants*, not to reduce competition. (*See* Am. Cmplt. ¶ 38 (alleging that defendants discount drugs and market that "their drug's spread is higher than a competing drug's,") and ¶ 71 (alleging that defendants discount to PBMs in order to get their drugs on formularies at the expense of their competitors.)) In light of the State's apparent theory of fraud, its allegation of harm to competition is conclusory and unfounded.

**2. The State Alleges No Secret Unearned Discounts.**

Count III should also be dismissed because the alleged "discounts, rebates, and other economic benefits" given by "defendants" (Am. Cmplt. ¶ 85) to physicians and PBMs are not adequately alleged to have been secret, unearned, or otherwise improper.

First, the statute applies only where discounts are provided to one purchaser and are kept secret from other purchasers. *Jauquet Lumber Co. v. Kolbe & Kolbe Millwork Co.,* 164 Wis. 2d 689, 699, 476 N.W.2d 305 (Ct. App. 1991). As recognized by the Amended Complaint,

the "purchasers" of drugs from the Defendant manufacturers are physicians, wholesalers, and pharmacies, *not the State*. The State does not allege that Defendants extend discounts to some of these purchasers, but not to others, or that these discounts are kept "secret."[18] To the contrary, the State characterizes the practice of discounting as widespread and pervasive. (*See* Am. Cmplt. ¶ 40 (describing discounting off of AWP as "industry practice.")) Moreover, in light of the extensive public record recounted above in part, *see supra* at 18-24, no reasonable claim could be made that such drug discounting is kept a "secret" from drug purchasers (doctors, pharmacies, and wholesalers).

Second, "the unambiguous language of this statute requires that a discount be both secret *and unearned* before a statutory violation can be found." *Jauquet Lumber*, 164 Wis. 2d at 700 (emphasis added). Yet the State has not alleged anywhere in the Amended Complaint that the discounts offered to drug purchasers were "unearned." *Cf. Jauquet Lumber*, 164 Wis. 2d at 699-700 (recognizing that discount may be "earned" within meaning of statute based on role purchaser plays in supplier's distribution system). Indeed, although the State provides a list of allegedly improper "inducements" (e.g., grants, free samples, research fees, and rebates, Am. Cmplt. ¶¶ 51, 71), it does not even attempt to identify which of these "inducements" constitute "discounts" or "rebates" under the statute. *See Tele-Port, Inc. v.*

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[18] Plaintiff's contentions that unspecified Defendants bestowed other economic incentives on drug purchasers (Am. Cmplt. ¶¶ 51, 85) are insufficient for the same reason. Where a secret rebate claim is premised on the provision of "special services or privileges," the plaintiff must allege that such services or privileges "were not extended to all purchasers purchasing on like terms and conditions." Wis. Stat. § 133.05(1); *Jauquet Lumber*, 164 Wis. 2d at 699. Plaintiff does not allege that any "special services or privileges" were awarded discriminatorily, but rather that such economic benefits are rampant in the industry. (*See* Am. Cmplt. ¶ 71 (alleging that "the four major PBMs, as well as many smaller ones," receive financial incentives from manufacturers.)) Indeed, the State itself receives similar economic benefits through the Medicaid rebates paid to it by drug manufacturers. *See supra* at 6.

*Ameritech Mobile Comm., Inc.,* 2001 WI App. 261, ¶ 17, 248 Wis. 2d 846, 637 N.W.2d 782 (Ct. App. 2001) (summary judgment granted where "development funds" were deemed not to be discounts). The State thus does not allege that any of the unspecified discounts provided by unspecified Defendants were "unearned" by the unspecified recipient.

For all these reasons, Count III should be dismissed.

**C. The State Fails to Plead a Claim of Medical Assistance Fraud (Count IV).**

Count IV alleges that the Defendants have violated the provision of the Public Assistance Act that makes it unlawful to "[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." Wis. Stat. § 49.49(4m)(a)(2). The State does not identify a particular "false statement or representation," or any Defendant that made such a representation. Rather, the State alleges in conclusory fashion that "[e]ach of the defendants used a variety of schemes, devices, agreements and false statements, and misrepresentations that had the effect of increasing the amount the Wisconsin Medicaid Program paid" for drugs. (Am. Cmplt. ¶ 92.)

Initially, this claim should be dismissed because, as shown above, the State's sweeping and unspecific allegations of fraud are insufficient under Wis. Stat. § 802.03(2). The State does not identify a single claim for benefits at issue, a single false statement, a single misrepresentation, or which Defendant(s) made any such statement or representation. These are the basic "who, what, when, how, and why" allegations without which a fraud claim cannot survive. *See supra* at 9-15.

In addition, as with the false advertising claims, the State does not adequately allege what is "false" about the published AWPs or which drugs are subject to these claims. *See supra* at 30-31.

Finally, the State has not adequately alleged, as required, that the alleged false statements were "material" to the determination of the rights to a benefit or payment under the medical assistance program. *State v. Williams*, 179 Wis. 2d 80, 87, 505 N.W.2d 468 (Ct. App. 1993). Nor can it do so. As established above, Wisconsin has long known that AWPs typically exceed actual acquisition costs for pharmaceuticals by substantial percentages. *Supra* at 18-24. Moreover, AWP does not even play a role for the reimbursement payments for the over 1000 generic/multi-source drugs where MAC prices dictate reimbursement, or for the hundreds of drugs for which Wisconsin has used drug pricing provided by the DOJ for determining reimbursement. *Supra* at 23-24. This Count thus should be dismissed.

**D. The State Fails To State A Claim for Unjust Enrichment (Count V).**

As an initial matter, this unjust enrichment claim fails because the Attorney General has no statutory authority to maintain such an action, *see supra* at 25-27. But even if the Attorney General had authority to bring an unjust enrichment claim, Count V fails adequately to allege each of the essential elements of that cause of action. A claim for unjust enrichment requires that the State allege: (1) that a benefit was conferred upon the defendant *by the plaintiff*, (2) an appreciation or knowledge by the defendant of the benefit; and (3) that the acceptance or retention by the defendant of the benefit under the circumstances would be inequitable. *Tri-State Mechanical, Inc. v. Northland College*, 2004 WI App. 100, ¶ 14, 273 Wis. 2d 471, 681 N.W.2d 302.

The State fails to allege any one of these elements, even in cursory fashion. (Am. Cmplt. ¶¶ 94-97.) Moreover, the allegations that are made contradict any claim of unjust enrichment against Defendants. The State does not allege that it, consumers, or private insurance companies directly conferred *any* benefit on any Defendant. Instead, the Amended Complaint

alleges that Defendants sell their products to pharmaceutical providers ("physicians, hospitals, and pharmacies.") (Am. Cmplt. ¶ 28.) The State, consumers, and/or private payers reimburse those retailers, not the Defendants, for prescription drug costs. None of the payments for prescription medicines that allegedly were based on AWPs, therefore, can be traced to the Defendants, and the Amended Complaint does not allege otherwise. Because any alleged "overpayments" were made to the providers and pharmacies that received Medicaid or Medicare reimbursements, the State did not confer any benefit on Defendants that could be recognized by Defendants under circumstances that could be deemed inequitable. The unjust enrichment claim, therefore, should be dismissed.

## V. THE CLAIMS ARE BARRED BY THE FILED RATE DOCTRINE.

As recognized in the Amended Complaint, the reimbursement levels to pharmacies and doctors for their sales of prescription drugs are set by statute and regulation. (Am. Cmplt. ¶ 57-58, 63-66.) While the state and federal governments may use AWP as a starting point for their rate-setting for pharmacists or doctors under Medicaid or Medicare, the amount actually paid to these medical providers is a government-determined rate. *See supra* at 4-7 & n.5. Indeed, the Wisconsin legislature has changed Medicaid reimbursement rates at least four times over the past five years, from AWP minus 10% (2001 and before), to AWP minus 11.25% (2002), to AWP minus 12% (2003), and to AWP minus 13% (2004). *See* n.5 *supra*. Under such circumstances, the State's claims for recovery of alleged "overpayments" by Wisconsin and by private insurers and consumers under the Medicaid and Medicare programs are barred by the "filed rate doctrine."

The filed rate doctrine, as interpreted by the Wisconsin Supreme Court, provides that a rate that has been set by a government body, that is, a "filed rate,"[19] may not be retroactively challenged in judicial proceedings. *Prentice v. Title Ins. Co. of Minnesota*, 176 Wis. 2d 714, 500 N.W.2d 658 (1993). "Courts have adopted this doctrine because 'allowing a state court to award damages based on a hypothetical rate lower than the filed rate would undermine the regulatory scheme ... .'" *CenturyTel of the Midwest-Kendall, Inc. v. PSC of Wisconsin*, 2002 WI App 236, ¶ 24, 257 Wis. 2d 837, 653 N.W.2d 130; *see also Sun City Taxpayers' Ass'n v. Citizens Utils. Co.*, 45 F.3d 58, 62 (2d Cir. 1995) (same). The doctrine thus applies to preclude damages claims that hinge on allegations that government-set rates are too high, and which ask a court to determine what the approved government rate would have been but for the alleged misconduct.

Here, the reimbursement rates set for Wisconsin's Medicaid program and Medicare Part B are lawful, government-set rates. The State's claim for damages would require that the Court decide that the discounts paid off AWP would stay the same even if the AWPs themselves were different – an exercise in "second guessing" precluded by the filed rate doctrine. *Servais v. Kraft Foods, Inc.*, 2001 WI App 165, ¶ 17, 246 Wis. 2d 920, 631 N.W.2d 629 ("[T]he filed rate doctrine precludes suits for damages developed through attacks on such lawful rates ... ."), *aff'd*, 2002 WI 421, 252 Wis. 2d 145, 643 N.W.2d 92.

The Wisconsin Court of Appeals' decision in *Servais*, 2001 WI App 165, is controlling here. In *Servais*, milk producers brought state law antitrust claims against cheese

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[19] The word "filed" in the filed rate doctrine is an historical anachronism based on its original formulation in cases involving common carriers, which filed their tariffs with government agencies. The doctrine is today broadly applied to any rate "approved by the governing regulatory agency." *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17, 18 (2d Cir. 1994).

manufacturers for manipulating prices on the National Cheese Exchange, an independent private commodities exchange. To show damages, plaintiffs claimed that these illegally-manipulated prices were used by the U.S. Department of Agriculture ("USDA") as a factor in calculating minimum milk prices through "milk orders." *Id.* at ¶¶ 2, 17. Accepting those allegations, the court dismissed the claims, holding:

> [A] court would have to conclude that the USDA minimum pay price is not reasonable and *to speculate what price the USDA would have set . . . if the alleged price manipulation at the National Cheese Exchange had not occurred.* However, because the milk orders at issue are federally established rates, such speculation would undermine a congressional scheme of uniform rate regulation and award as damages a dollar amount based on a new milk price never established by the USDA. This cannot occur because the filed rate doctrine precludes substituting the judgment of a court for the judgment of the USDA as to what constitutes a reasonable minimum pay price . . . .

*Id.* at ¶ 14 (emphasis added). Responding to allegations that defendants' illegal price-manipulation scheme caused the government to set lower minimum milk prices than it would have otherwise, the court stated: "we cannot look underneath the minimum pay prices set in the milk orders, *regardless of the acts alleged to have caused an invalid price.*" *Id.* n.5. (emphasis added).

Here, the State asks this Court to substitute its judgment of what the Wisconsin legislature and federal government would have set as proper reimbursement levels for pharmacies and physicians to receive if the alleged price inflation of AWPs had not occurred. (*E.g.* Am. Cmplt. ¶ 75, 79, 83, 88, 92, 97.) This Court is in no position, however, any more than the court in *Servais*, to calculate "true" AWPs or to second-guess what the Wisconsin legislature, DHFS, the U.S. Congress, or CMS had in mind when they decided to utilize the AWPs listed in the trade publications in reimbursement formulas for the Medicaid and Medicare programs instead of estimating actual acquisition costs through other means (such as Wisconsin does for

the MAC program and generic drugs). The filed rate doctrine precludes just this type of retroactive rate setting by the judiciary. *See Montana-Dakota Utilities v. Northwestern Pub. Serv. Co.*, 341 U.S. 246, 251 (1951) ("[T]he problem is whether it is open to the courts to determine what the reasonable rates during the past should have been.").[20]

Nor is this result changed by the fact that the Attorney General is pursuing this action not only on behalf of private consumers and insurers but also on behalf of the State. It is the nature of the relief sought, not the status of the plaintiff, that governs the application of the filed rate doctrine. *See Sun City Taxpayers' Ass'n v. Citizens Utils. Co.*, 45 F.3d 58, 62 (2d Cir. 1995) ("[T]he filed rate doctrine exists for reasons independent of the type of plaintiff maintaining the action."). Thus, although the doctrine may not preclude the State from seeking injunctive relief or statutory-authorized penalties (neither of which requires the Court to determine what an appropriate reimbursement rate should have been), it does preclude any claims for damages that are tied to a re-determination of lawful reimbursement rates.[21] *See Chandler v. Anthem Ins. Companies, Inc.*, 8 S.W.3d 48, 54-55 (Ky. Ct. App. 1999) (holding that filed rate doctrine barred Kentucky Attorney General from seeking damages "for approved but

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[20] The *Servais* decision also distinguishes Judge Saris' cursory rejection of a filed-rate doctrine challenge in *In re Pharmaceutical Industry AWP Litig.*, 263 F. Supp. 2d 172, 192 (D. Mass. 2003), which held that the doctrine did not apply because drug manufacturers do not "'file' their AWPs with any regulatory agency." In *Servais*, however, the Wisconsin Court of Appeals held that the filed rate doctrine applied to bar price manipulation claims against cheese manufacturers despite the fact that such allegedly manipulated prices were not "filed" as rates with any state or federal regulator. 2001 WI App 165, ¶¶ 7-9, ¶14. So too here, the Defendants' allegedly inflated AWPs are not themselves "filed rates," but, as in *Servais*, have been used by the government as a factor in calculating reimbursement rates for doctors and pharmacists, which *are* filed rates.

[21] The filed rate doctrine bars the Attorney General from seeking *any* relief, including injunctive relief, with regard to claims that private consumers overpaid for drugs covered by Medicare Part B. Reimbursement rates under Medicare Part B are the exclusive lawful rates set by the United States and must be given binding effect on state regulators "as a matter of federal

allegedly improper insurance rates," but allowing Attorney General to pursue prospective injunctive relief and civil penalties); *see also Prentice v. Title Ins. Co. of Minnesota*, 176 Wis. 2d 714, 726-727 & n.7, 500 N.W.2d 658 (1993) (recognizing that filed rate doctrine does not bar Insurance Commissioner from pursuing certain statutory remedies and suits "which do not seek rate-related damages").

The filed rate doctrine thus requires dismissal of all of the Amended Complaint's claims for damages arising from alleged "overpayments" under the Wisconsin Medicaid program or under Medicare Part B.

## VI. THE CLAIMS ARE BARRED BY THE APPLICABLE STATUTES OF LIMITATIONS.

The State's action purports to stretch back to 1992. (Am. Cmplt. ¶ 33.) Each of the claims asserted in the Amended Complaint, however, is barred entirely or in substantial part by the applicable statutes of limitations.

First, both of the fraudulent advertising claims under Wis. Stat. § 100.18 have a statute of limitations of three years. Wis. Stat. § 100.18(11)(b)(3); *Staudt v. Artifex Ltd.* 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998). This limitations period "is a statute of repose" that begins to run at the time the claim arises, regardless of the date of discovery by the plaintiff. *Staudt*, 16 F. Supp. 2d at 1031; *Skrupky v. Elbert*, 189 Wis. 2d 31, 526 N.W. 2d 264, 273-74 (Ct. App. 1994).

The original complaint in this action was filed on June 16, 2004, and thus the fraudulent advertising claim in Counts I and II are time barred to the extent they arose prior to

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pre-emption through the Supremacy Clause." *Entergy Louisiana, Inc. v. Louisiana PSC*, 539 U.S. 39, 47 (2003).

June 16, 2001.[22] The face of the Amended Complaint establishes that the alleged factual basis for the claims arose well before June 16, 2001, and were well known to the State. For example, the Amended Complaint relies upon and attaches an HCFA report from almost a year earlier, dated September 8, 2000, which the State acknowledges made clear that actual acquisition prices for prescription medicines were significantly less than the published AWPs. (Am. Cmplt. at Ex. A.) The Amended Complaint alleges that this alleged fraudulent conduct began as far back as 1992. (Am. Cmplt. ¶ 33.) Moreover, the only specific examples of allegedly fraudulently "inflated" AWPs provided by the State all date from before June 2001. (Am. Cmplt. ¶¶ 39, 42, Ex. B.) In addition, as was detailed above, the September 2000 HCFA report attached to the Amended Complaint echoes other government reports and publications from well into the 1990s. As a result, the claims presented by the State in Counts I and II were available to the State substantially before June 2001. These claims thus are time barred by the applicable three-year statute of limitations.

Each of the remaining claims are governed by a six-year limitations period. *See* Wis. Stat. § 133.18 (Secret Rebate action under § 133.05); *Boldt v. State*, 101 Wis. 2d 566, 305 N.W.2d 133 (1981) (unjust enrichment governed by six-year limitations period applicable to contract claims under predecessor to § 893.43); Wis. Stat. § 893.93 (six year limitations period applies for all statutory claims that do not otherwise provide a limitations period). Counts III through V thus should be dismissed, at a minimum, as to all claims arising before June 16, 1998.

[22] For seventeen Defendants who were newly added to this action by the Amended Complaint, the limitation period would be calculated from no earlier than the date of the Amended Complaint, November 1, 2004.

Nor may the State contend that it should be allowed to pursue the pre-1998 claims because it only recently discovered the alleged AWP "inflation." Even if such a "discovery rule" applies,[23] the public record establishes the State's knowledge that AWP exceeded actual acquisition costs well before 1998, *see supra* at 18-24. In any event, Wisconsin law recognizes that plaintiffs have a duty to "exercise reasonable diligence" to inquire about potential claims, and "'may not ignore means of information reasonably available to them, but must in good faith apply their attention to those particulars which may be inferred to be within their reach.'" *Tele-Port, Inc. v. Ameritech Mobile Comms., Inc.*, 2001 WI App 261 ¶ 11, 248 Wis. 2d 846, 637 N.W.2d 782, quoting *Doe v. Archdiocese of Milwaukee*, 211 Wis. 2d 312, 319, 565 N.W.2d 94 (1997). The State cannot plausibly contend, based on the available public record, that it could not have discovered long ago, through the exercise of even the most minimal of diligence, the claims it now asserts.

## CONCLUSION

For the foregoing reasons, the Amended Complaint should be dismissed in its entirety with prejudice.

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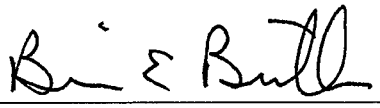
[23] An unjust enrichment claim, which is based on the doctrine of quasi-contract, accrues for purposes of the 6-year limitations period on the date the alleged misconduct giving rise to the cause of action occurs, regardless of the date of discovery of such facts. *See Watts v. Watts,* 137 Wis. 2d 506, 530, 405 N.W. 2d 303 (1987); *Segall v. Hurwitz*, 114 Wis. 2d 471, 491-92, 339 N.W.2d 333, 343 (Ct. App. 1983).

Dated: January 20, 2005

Respectfully submitted,

By: 

Brian E. Butler
State Bar No.: 1011871
Joseph P. Wright
State Bar No.: 1001904
Barbara A. Neider
State Bar No.: 1006157
STAFFORD ROSENBAUM, LLP
3 South Pinckney Street, Suite 1000
Madison, WI 53703
Tele: (608) 256-0226
Fax: (608) 259-2600

D. Scott Wise
Michael S. Flynn
Carlos M. Pelayo
DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, NY 10017
Tele: (212) 450-4000
Fax: (212) 450-3800
***Attorneys for Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP,***
**and signing on behalf of all moving Defendants**

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# Attachment A

# Selected Public Record Excerpts Reflecting Knowledge of State of Wisconsin of the Meaning of AWP

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| **Wisconsin Government Materials** | | | |
| Wisconsin Dept. of Health and Family Services ("DHFS"), Joint Committee on Finance, Paper # 479, ¶ 4 at 3-4, ¶ 7 at 4-5 (June 1, 1999). | June-1999 | "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. . . . As a result, 44 of 45 states that use the AWP as the basis for [medical assistance] drug reimbursement discount the AWP by a specified amount." The DHFS went on to discuss federal studies that confirmed that AWP substantially exceeded actual drug acquisition costs. | 2 |
| Wisconsin DHFS, *Medicaid and BadgerCare Update* (August 2000). | Aug-2000 | Wisconsin began utilizing the DOJ pricing figures in order to "more accurately reflect the acquisition cost of these drugs." | 30 |
| Wisconsin DHFS, Joint Committee on Finance, Reimbursement Rates for Prescription Drugs, Paper 474, ¶ 11, at 3-4, ¶ 13, at 4 (June 4, 2001). | June-2001 | Acknowledging that "[t]wo studies, one by the U.S. Department of Health and Human Services, office of the Inspector General and another study of the Kentucky Department of Medicaid Services found that pharmacies' average acquisition cost for most brand name drugs is approximately AWP-18%." Further discussing the Governor's proposal to increase the discount rate for Medicaid reimbursement for brand name drugs from AWP minus 10% to AWP minus 15%, and noting such a discount increase would still provide pharmacies with payments that exceeded their drug acquisition costs. Also acknowledging that "[t]he margin between the acquisition cost and the reimbursement rate, together with the dispensing fee, represents the pharmacies' total reimbursement for service costs." | 28 |
| Wisconsin DHFS, Memo to In-State Wisconsin Medicaid Certified Pharmacists, Changes in HIRSP's Drug Coinsurance Provisions and Reimbursement Rate Effective January 1, 2002, at 2 (Dec. 3, 2001). | Dec-2001 | Announcing that "the reimbursement rate for prescription drugs not on the Maximum Allowable Cost (MAC) list will be at AWP less 11.25 percent.") | 3 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| Wisconsin DHFS, Drug Reimbursement (Feb. 27, 2003). | Feb-2003 | Recognizing another federal study that had concluded that AWPs for brand name drugs typically exceeded actual acquisition costs by over 20%. Also noting that Medicaid reimbursement for brand name products set at AWP minus 11.25 % while acquisition costs averaged about AWP minus 21.84 %. | 29 |
| Wisconsin Medicaid & BadgerCare Update, No. 2003-142, PHC 1135 at 1 (August 2003). | Aug-2003 | Announcing that the "Medicaid Average Wholesale Pricing (AWP) reimbursement rate for brand name legend drugs change to AWP minus 12%," and "will change to AWP minus 13% as of July 1, 2004." | 4 |
| Wisconsin DHFS Current Policy, Brand Medically Necessary and Medicaid Maximum Allowable Cost List (April 2004). | Apr-2004 | Publishing the Maximum Allowable Costs ("MACs") for payment of generic drugs for Medicaid participants. | 5 |
| **Federal Agency Materials** | | | |
| 39 Fed. Reg. 41,480 (Nov. 27, 1974). | Nov-1974 | "Most States use average wholesale price, . . . Such standard prices are frequently in excess of actual acquisition costs to the retail pharmacist." | 31 |
| HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, Medicaid—Formula For Determining EAC For Drugs, reprinted in *Medicare and Medicaid Guide* (CCH) ¶ 28,714. | Dec-1977 | "In order to set estimated acquisition costs which come close to [actual acquisition costs], some states, for example, begin with AWP prices but apply a percentage markdown to determine acquisition costs." States that reimburse at AWP without discounting have not "made a real effort to approach [actual acquisition costs]." | 9 |
| GAO Report On Effect Of MAC Program On Prescription Drug Costs, reprinted in *Medicare and Medicaid Guide* (CCH) ¶ 30,907. | Dec-1980 | "The EAC [estimated acquisition cost] program was designed to move the states away from using Average Whole Prices (AWPs) as a basis for establishing drug reimbursement limits," because "HHS had estimated that AWPs typically were 15 to 18 percent higher than the prices at which pharmacists could obtain drugs." | 33 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| Department of Health and Human Services, Office of Inspector General, *Medicare Action Transmittal No. 84-12*, (Sept. 1, 1984), at 3, 16 (enclosing HHS-OIG, "Changes to the Medicaid Prescription Drug Program Could Save Millions."). | Sep-1984 | "AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, … rebates, or free goods that do not appear on the pharmacists' invoices," and recommends that State agencies be precluded from using AWP without a discount in determining reimbursement amounts. The report found that 99.6% of pharmacy drug purchases were made at prices averaging approximately 15.93% below AWP, with some at 42% below AWP. | 1 |
| HHS-OIG, "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program," (Oct. 1989), at 5. | Oct-1989 | "[W]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs. When AWP is used, we believe it should be discounted." | 10 |
| HHS-OIG, "Physicians' Costs for Chemotherapy Drugs (Nov. 6, 1992), at 2, 5, Appendix III. | Nov-1992 | A study of 13 physician-administered chemotherapy drugs which showed that the physicians' actual costs were as much as 83% lower than AWPs for those drugs and concluded that "AWP is not a reliable indicator of the cost of a drug to a physician." | 11 |
| HHS-OIG, Reviews of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Departments of Health for Ten States and the District of Columbia. | May-1996 – Jan-1997 | Reporting that "[t]he overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices" nationally was "18.3 percent [for brand name drugs] and 42.5 percent [for generics]." | 12-22 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| HHS-OIG, "Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs" at 1, 5 (April, 1997). | Apr-1997 | "Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP." "Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP." | 23 |
| HHS-OIG, "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" at 5, (August, 1997). | Aug-1997 | "Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP." | 24 |
| HHS-OIG, "Excessive Medicare Payments for Prescription Drugs," at ii (December, 1997. | Dec-1997 | "The published AWPs . . . bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." | 26 |
| CMS, State Medicaid Manual at §6305.1(B), *available at* http://www.cms.hhs.gov/manuals/45_smm/sm_06_6000_to_6400.3.asp#_Toc490464489 (2005). | Apr-2000 | "[T]here is a preponderance of evidence that demonstrates that . . . AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc. Consequently, without valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices <u>generally</u> and <u>currently</u> paid by providers." | 34 |
| HCFA Transmittal Mem. AB-00-86 (Sept. 8, 2000). | Sep-2000 | Transmitting alternative average wholesale price data from the United States DOJ, and stating "that because purchasers often receive further discounts below the advertised wholesale catalog price, . . . actual acquisition costs may be lower." | 35 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| OIG, "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products." *Department of Health and Human Servs.*, A-06-00-00023, Aug. 2001, i. | Aug-2001 | "We estimated that the actual acquisition cost for brand name drugs was a national average of 21.84 percent below AWP." | 36 |
| Department of Health and Human Services, Office of Inspector General, *Medicaid's Use of Revised Average Wholesale Prices*, 1-4, App. A (Sept, 2001). | Sep-2001 | Listing Wisconsin as among the states that relied not on published AWPs, but on alternative pricing data supplied by the United States Department of Justice. | 8 |
| *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO Report to Congressional Committees*, at 25. | Sep-2001 | "Medicare's AWP-based methodology does not incorporate information on actual transaction prices." | 37 |
| OIG, "Excessive Medicare Reimbursement for Ipratropium Bromide." *Dept. of Health and Human Servs.*, OEI-03-01-00411, 12 (March, 2002). | Mar-2002 | "The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices to wholesale distributors; these prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts." | 38 |
| 42 CFR 447.332. | Oct-2002 | Granting states discretion as to whether to include prescription drugs in their Medicaid programs, and latitude in determining the reimbursement formula used for such prescriptions. | 39 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| Abt Assocs. Inc., Report to CMS, "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices," at 15-16 (June 21, 2004). | Jun-2004 | Defining AWP as "a *list price* used for *invoices between drug wholesalers and pharmacies or other appropriate drug purchasers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration" that is "typically 20% to 25% above the WAC for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for generic drugs." Further defining WAC as "a *list price* used for *invoices between drug manufacturers and wholesalers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration." | 6 |
| **U.S. Congressional and Executive Materials** | | | |
| *Prescription Drug Prices: Are We Getting Our Money's Worth?*, Majority Staff Report, Special Comm. on Aging, United States Senate, S. Rep. 101-49 at 11 (1989). | Aug-1989 | "Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% off the manufacturers published "Average Wholesale Price" (AWP), even for brand name products." | 41 |
| *Balanced Budget Act of 1997: Report of the House Comm. on the Budget*, H. Rep. No. 105-149 at 1354 (1997). | 1997 | "[T]he Office of Inspector General reports that [AWP-based] Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." | 25 |
| *President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare, hearings Before the Senate Committee on Finance*, 105th Cong., at 265 (1997). | Feb/Mar-1997 | Reporting the Congressional testimony, that "Medicare pays the "average wholesale price" (AWP) for covered drugs. However, the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a "sticker" price set by drug manufacturers and published in several commercial catalogs." | 27 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| White House Office of the Press Secretary, *"Remarks by the President in Radio Address to the Nation,"* 1997 WL 76741, at *1-2 (Dec. 13, 1997). | Dec-1997 | President Clinton, addressing the Medicare program, stated that: "[s]ometimes . . . waste and abuses aren't even illegal; they're just embedded in the practices of the system. Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs-overpayments that cost taxpayers hundreds of millions of dollars . . . . Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price-the so-called sticker price-for the drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price." | 42 |
| *Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost*, Report to Congressional Committees, GAO-01-1118, September, 2001, 4. | Sep-2001 | "For most physician administered drugs, the average discount from AWP ranged from 13 percent to 34 percent; two physician-administered drugs had discounts of 65 percent and 86 percent." | 43 |
| *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers*, House Comm. on Energy and Commerce, Subcomm. on Health, 107th Cong., at 3 (2001). | Sep-2001 | Reporting the Congressional testimony, that AWP "could also be an acronym for 'ain't what's paid.' It is quite clear that despite its name, AWP is not the average wholesale price at which these drugs are sold to health care providers or anything close to it." | 44 |
| *Reimbursement and Access to Prescription Drugs Under Medicare Part B.* Subcomm. on Health Care of the Senate Comm. on Finance, 2 (2002). | Mar-2002 | "So the AWP, . . . is a little bit like sticker price on a car. You have your suggested retail price, but very few people pay the sticker price on a car and no physicians or suppliers are paying for the AWP, the average wholesale price, for drugs." | 45 |

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| *Hearing on Medicare Payments for Currently Covered Prescription Drugs, Centers for Medicare and Medicaid Audits*, Subcomm. on Health of the House Comm. on Ways and Means, 1, 3 (Oct. 3, 2002). | Oct-2002 | Reporting testimony that "the published AWPs that Medicare and Medicaid use to establish drug reimbursement bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers. . . . there is a significant difference between pharmacy acquisition costs for both brand and generic drugs and the basis for most states' reimbursement for drugs – the average wholesale price (AWP)." | 40 |
| **Litigation Materials** | | | |
| *Louisiana v. Dept of Health & Human Services*, 905 F.2d 877, 879-881 (5th Cir. 1990). | Jan-1990 | Recounting rejection by HCFA in 1987 of Louisiana's proposed Medicaid reimbursement rate set at AWP without any discount, because AWPs "are significantly higher than the prices pharmacies generally pay for their drugs." | 46 |
| *United States v. MacKenzie*, Crim. No. 01-CR-10350-DPW, Remarks of Michael K. Louks, Hearing Transcript at 68 (D. Mass. June 24, 2004). | Jun-2004 | A federal prosecutor, in an AWP case involving a brand name drug, stating that it was an "historical fact" that there was a 25% difference between AWP and "list price," (sometimes called "Wholesale Acquisition Cost." or "WAC") and that the government understood and expected such a differential. | 47 |
| **Media Materials** | | | |
| Elizabeth Sanger, *No Rx for Plans; Drug Plans Draw Pharmacists' Ire*, Newsday, Feb. 24, 1989. | Feb-1989 | "Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price." | 48 |

**Attachment A**

| Source | Date | Excerpt | Defs. App. Ex. No. |
|---|---|---|---|
| Professor David H. Kreling, University of Wisconsin, School of Pharmacy, *Assessing potential prescription reimbursement changes: Estimated acquisition costs in Wisconsin*, 10 Health Care Financing Review, No. 3 (Spring 1989). | Spring-1989 | Noting that "there is considerable evidence that pharmacists' actual purchase costs usually differ from AWP," and that "it is apparent that AWPs are not the best estimates of pharmacists' purchase costs." | 49 |
| Eric D. Randall & Michael Clements, *Drug Firms Handle Stress: Companies Breaking Out Batch of Deals*, USA Today, May 4, 1994. | May-1994 | "[D]iscounts offered to large buyers can be as much as 70% off the average wholesale price." | 50 |
| Bill Alpert, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices For Pharmaceuticals?*, Barron's, June 10, 1996. | Jun-1996 | Describing AWP as "Ain't What's Paid." "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices [to manufacturers] that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims." | 51 |
| Spencer Rich, *Battling the High Prices Medicare Pays for Drugs*, The Washington Post, Jan. 2, 1997. | Jan-1997 | AWP is "like the sticker price of an automobile;" "most doctors buy at a substantial discount and bill Medicare for a price based on AWP." | 52 |