

STATE OF WISCONSIN  
COURT OF APPEALS  
DISTRICT II

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OF WISCONSIN**

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STATE OF WISCONSIN,

Plaintiff-Respondent-Cross-Appellant,

v.

ABBOTT LABORATORIES, ASTRAZENECA  
LP, ASTRAZENECA PHARMACEUTICALS LP,  
AVENTIS BEHRING, LLC f/k/a ZLB  
BEHRING, LLC, AVENTIS  
PHARMACEUTICALS, INC., BEN VENUE  
LABORATORIES, INC., BOEHRINGER  
INGELHEIM PHARMACEUTICALS, INC.,  
BOEHRINGER INGELHEIM ROXANE, INC.,  
BRISTOL-MYERS SQUIBB CO., DEY, INC.,  
IVAX CORPORATION, IVAX  
PHARMACEUTICALS, INC., JANSSEN LP  
F/K/A JANSSEN PHARMACEUTICAL  
PRODUCTS, LP, JOHNSON & JOHNSON,  
INC., McNEIL-PPC, INC., MERCK & CO. f/k/a  
SCHERING – PLOUGH CORPORATION,  
MERCK SHARP & DOHME CORP. f/k/a  
MERCK & COMPANY, INC., MYLAN  
PHARMACEUTICALS, INC., MYLAN, INC.  
f/k/a MYLAN LABORATORIES, INC.,  
NOVARTIS PHARMACEUTICALS CORP.,  
ORTHO BIOTECH PRODUCTS, LP, ORTHO-  
McNEIL PHARMACEUTICAL, INC., PFIZER  
INC., ROXANE LABORATORIES, INC.,  
SANDOZ, INC. f/k/a GENEVA  
PHARMACEUTICALS, INC., SICOR, INC. f/k/a  
GENSIA SICOR PHARMACEUTICALS, INC.,  
SMITHKLINE BEECHAM CORP. d/b/a  
GLAXOSMITHKLINE, INC., TAP  
PHARMACEUTICAL PRODUCTS, INC., TEVA  
PHARMACEUTICALS USA, INC., WARRICK

Appeal No.  
2010AP232-  
AC

PHARMACEUTICALS CORPORATION,  
WATSON PHARMA, INC. f/k/a SCHEIN  
PHARMACEUTICALS, INC., and WATSON  
PHARMACEUTICALS, INC.,

Defendants,

PHARMACIA CORPORATION,

Defendant-Appellant-Cross-Respondent.

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On Appeal from the Dane County Circuit Court  
The Honorable Richard G. Niess Presiding  
Circuit Court Case No. 04-CV-1709

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**THE NON-PHARMACIA BRAND DEFENDANTS’  
AMENDED  
AMICUS CURIAE BRIEF**

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November 22, 2010

Donald K. Schott  
Freya K. Bowen  
Matthew J. Splitek  
QUARLES & BRADY LLP  
33 East Main Street  
Suite 900  
Madison, WI 53703

Andrew D. Schau  
COVINGTON & BURLING LLP  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018

William F. Cavanaugh, Jr.  
Peter C. Harvey  
Adeel A. Mangi  
PATTERSON BELKNAP  
WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, NY 10036-6710

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## SUMMARY OF ARGUMENT

For brand-name drugs, AWP represents a formulaic markup of typically 20 or 25 percent over the drug's wholesale acquisition cost (WAC), which is the invoice price manufacturers charge to wholesalers. (AWPs play a different role in the market for generic drugs.) Because AWP's have a predictable relationship to the marketplace prices for brand drugs, many state Medicaid agencies and private insurers use AWP's as a starting point to which a percentage reduction is applied to arrive at a desired reimbursement amount. The term was actually coined by a California Medicaid official in the 1970's "because they needed a *methodology* to pay all of the different pharmacies that existed in California at the time." (R434/74:12-75:6,<sup>1</sup> Br. App. 175<sup>2</sup>) (emphasis added). Although nominally an acronym for "average wholesale price," the term has never referred to an actual average of the prices retailers pay to wholesalers for drugs.

The fact that AWP is not an actual average of wholesale prices has for many years been well known to participants in the

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<sup>1</sup> Citations to the record for appeal are to the Clerk's Document Number/Page:Line. For example, R434/74:12-75:6 means Clerk's Document No. 434, page 74 ,line 12 through page 75, line 6.

<sup>2</sup> Citations to the Appendix to The Non-Pharmacia Brand Defendants' Amended *Amicus Curie* Brief, filed concurrently herewith, are designated as "Br. App. \_\_\_."

health care industry, including pharmaceutical manufacturers, wholesalers, retail pharmacists, private insurance companies, state Medicaid agencies and the federal government. For many years, Wisconsin, like many states, has chosen to use AWP in its formula for determining how much to reimburse pharmacists who dispense brand-name drugs to Medicaid patients. But, because the State knows that AWP is not an actual average of wholesale prices, and that pharmacists typically pay wholesalers much less than AWP, the State reimburses pharmacists at a deep discount from AWP.

In 2004, after decades of using AWP with the understanding that it does not refer to actual wholesale prices, the State sued nearly every drug manufacturer on the ground that AWP's are "untrue, deceptive [and] misleading" under Wis. Stat. § 100.18 and "false" under Wis. Stat. § 49.49. Yet, in the six years since it filed the lawsuit, Wisconsin has continued to use an "AWP minus" formula to reimburse pharmacists for brand drugs. This is akin to the Fox television network, which for years has broadcast a sporting event known as the "World Series," suing Major League Baseball on the grounds that the term "World Series" is "untrue, deceptive or misleading" because the event is not truly a world-wide sporting

event—while at the same time continuing to use the phrase “World Series” in its own promotion of the event.

The circuit court correctly rejected the State’s argument that the fact that the State knows that AWP’s are not actual averages of wholesale prices is irrelevant to determining whether Defendants’ use of the term is “untrue, deceptive or misleading.” As the court explained, if two parties knowingly use the term “cat” to refer to an animal the dictionary refers to as a “dog,” neither party can claim, years later, that a statement calling the animal a “cat” is false or deceptive because it is inconsistent with the dictionary definition of “cat.” (R169/6, Br. App. 162). However, the circuit court erred in not dismissing the State’s § 100.18 and § 49.49 claims against Pharmacia and the other Defendants in light of the undisputed evidence that the State used AWP’s knowing that they are not actual averages of wholesale prices.

Likewise, the circuit court erred in accepting the State’s flawed argument that it is the Defendants’ AWP’s that “cause” the State to reimburse pharmacists above their actual acquisition costs for brand-name drugs. The State intentionally chose to reimburse pharmacists more than their actual acquisition cost as the result of deliberate policy and political decisions, and continues to do so

today. For this reason also, the State’s § 100.18 and § 49.49 claims should have been dismissed.

Finally, the circuit court also erred in holding that the State was entitled to a jury trial on its § 100.18 and § 49.49 claims. The Wisconsin Supreme Court’s recent decision in *Harvot v. Solo Cup Co.*, 2009 WI 85, 320 Wis. 2d 1, 768 N.W.2d 176, confirms that a party has a constitutional right to a jury trial on statutory claims only when the statute shares a “similar purpose” with a cause of action that existed at common law when the Wisconsin Constitution was adopted. Because § 100.18 does not share a similar purpose with the common law offense of “cheating”—its alleged common law counterpart—the State is not entitled to a jury trial on that claim. Likewise, § 49.49, enacted as part of the statutory scheme governing Wisconsin’s Medical Assistance program, does not share a similar purpose with nineteenth-century common law fraud.

#### **WHAT “AWP” IS, AND IS NOT**

The AWP for a drug is not, and is not understood to be, an actual average of the prices that pharmacists pay to acquire the drug from wholesalers. Since the term was invented by California Medicaid in the 1970s, AWPs for brand-name drugs have typically been set at a formulaic 20 or 25 percent markup above a published

list price known as Wholesale Acquisition Cost (“WAC”).

*AstraZeneca v. Alabama*, 41 So. 3d 15,24 (Ala. 2009) (Br. App. 193) (“AWP was calculated by adding 20% or 25% to the reported WAC and thus bore a consistent formulaic relationship to WAC” (internal quotation marks and citations omitted)); (R434/238:19-20, Br. App. 176) (“Every company has a 20 or 25 percent markup”). As the State’s own expert testified, there is a “standard relationship” between the WAC and the AWP reported by FirstData Bank for brand-name drugs. (R437/37:9-11, A. Ap. 764<sup>3</sup>).

Brand manufacturers typically sell their drugs to wholesalers or large retail chains at WAC. (R439/17:15-19:3, Br. App. 182-83). Wholesalers can earn a small prompt-pay discount of approximately 2 percent if they pay within 30 days, but WAC is the price charged and invoiced at the time of sale. (R439/17:20-22 & 18:23-19:1, Br. App. 182-83).<sup>4</sup> Wholesalers in turn sell brand-name drugs to retail pharmacists at a markup determined by the wholesalers without input from the brand manufacturers. (R439/19:7-15, Br. App. 183.)

The evidence in this litigation shows that this markup averages

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<sup>3</sup> Citations to the Appendix to Appellant’s Brief are designated “A. Ap. \_\_\_.”

<sup>4</sup> A federal statute defines WAC as an undiscounted list price. *See* 42 U.S.C. 1395w-3a(c)(6)(B).

about 2 percent over the amount the wholesaler pays to acquire the brand drug from the manufacturer. (R437/37:1-7, A. Ap. 764).

## STANDARD OF REVIEW

Every issue addressed in this brief is subject to this Court’s independent, *de novo*, review. Interpreting and applying a statute to undisputed facts are questions of law that appellate courts review *de novo*. *Bank Mutual v. S.J. Boyer Constr.*, 2010 WI 74, ¶ 21, \_\_ Wis. 2d \_\_, 785 N.W.2d 462 (citation omitted). Appellate courts also interpret the Wisconsin Constitution independently of the circuit court. *Harvot v. Solo Cup Co.*, 2009 WI 85, ¶ 32, 320 Wis. 2d 1, 768 N.W.2d 176.

## ARGUMENT

### I. AWPs Are Not “False” Or “Misleading” Because The Parties Understood That The Term “AWP” Does Not Refer To An Actual Average Of Wholesale Prices.

Satisfying the first element of the State’s § 100.18 and § 49.49 claims requires proof that Defendants made a statement that is false or misleading. Yet it is undisputed that, while the term “AWP” nominally derives from the words “average wholesale price,” the Defendants, the State and others in the Medicaid reimbursement community all understand that AWP does not represent an actual average of the prices that retailers pay for drugs. It is also beyond

dispute that the State chooses to use AWP's in its Medicaid reimbursement formula, and makes its policy-based judgments about what discount to apply to AWP, with full knowledge of that fact. Therefore, the circuit court should have dismissed the State's claims.

**A. *AWP's Used As Understood By All Of The Parties—Including The State—Cannot Be “False.”***

The linchpin of the State's liability case is that the published figures called AWP's are false because they are not, as a dictionary definition of the individual words would suggest, actual averages of wholesale prices. This argument fails where, because of history, custom or otherwise, actors in an industry have a practice of using words in a way that does not conform to the dictionary definition of those words.

AWP is not defined in any Wisconsin or federal Medicaid statute or regulation. Thus, its meaning derives from the common understanding of the parties using the term. The undisputed evidence demonstrates that *all* participants in Wisconsin's Medicaid reimbursement program understand that AWP's are not actual averages of wholesale prices paid by pharmacists for prescription

drugs. For instance, the chairman of a federal task force appointed to study state Medicaid reimbursement explained:

In the 1980s, it was well known among federal policy makers at [Health & Human Services] and among state Medicaid agencies that AWP did not reflect actual sales prices for drugs from wholesalers or pharmacies. Rather, AWP was a misnomer and actual prices paid by pharmacies to wholesalers were substantially below AWP. This was well understood and accounted for in Medicaid reimbursement practices.

(R135/Ex. 5/2,<sup>5</sup> Br. App. 140). Indeed, as early as 1974, the U.S. Department of Health and Human Services told the states in a Notice of Proposed Rulemaking that AWP's "are frequently in excess of actual acquisition costs to the retail pharmacist." Reimbursement of Drug Cost—Medical Assistance Program, 39 Fed. Reg. 41480 (Nov. 27, 1974) (to be codified at 45 C.F.R. pt. 250).

Wisconsin cannot claim to have been ignorant of these facts; the undisputed record demonstrates that it has understood for decades that pharmacists purchase drugs well below published AWP's. (*See, e.g.*, R135/Ex. 29/3, Br. App. 12; R135/Ex. 30/4, Br. App. 4; R135/Ex. 31/1-2, Br. App. 15-16; R135/Ex. 32/3-4, Br. App. 21-22). Since 1984, DHFS has received, reviewed, and distributed at

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<sup>5</sup> Citations to the exhibits to R135 (Defs.' Joint Resp. to Pltf.'s Partial Mots. For Summ. J.) are to R135/Exhibit Number/Page:Line. The exhibits to R135, although part of the record in this case, are not included in the abbreviated record for appeal adopted by the parties. The Brand Defendants cite to these exhibits pursuant to the Court's order restricting the Brand Defendants to addressing factual information that "was . . . part of the record before the circuit court." Order (Nov. 10, 2010) at 4.

least a dozen federal reports stating that AWP does not represent an actual average of wholesale prices. (R135/Ex. 1/474:2-515:10, Br. App. 112-23). In 1995, Wisconsin's Department of Agriculture, Trade and Consumer Protection concluded that:

Wholesalers often start their price negotiations with retailers at the Average Wholesale Price (AWP). The AWP is the manufacturer's suggested selling price for wholesalers to use. The "Actual Acquisition Cost" is the true cost that retailers pay. *This amount may, and does, differ significantly from AWP.*

(R135/Ex. 36/21, Br. App. 29) (emphasis added). Moreover, since the late 1990s numerous Defendants have informed Wisconsin that the AWP's published by the pricing compendia do not represent actual prices paid to wholesalers for prescription drugs. (R135/Ex. 40/112:7-114:10, 116:20-117:20, 127:10-133:19 & 134:16-137, Br. App. 132-33 & 136-38). Indeed, Wisconsin Medicaid has commonly referred to AWP as "ain't what's paid." (R135/Ex. 37/164:12-165:21, Br. App. 126).

Because the State knows that AWP's are not an actual average of wholesale prices it has, for the past two decades, reimbursed pharmacists using a formula based on a discount off of AWP. In 1990, Wisconsin changed its reimbursement formula for brand drugs from 100% of AWP to AWP minus 10%. (R135/Ex. 1/392:18-394:21, Br. App. 107). In 2001, it changed to AWP minus

11.25%. (R135/Ex. 69/5, Br. App. 35). In 2003, it changed to AWP minus 12%, and, in 2004, it changed to AWP minus 13%. (R135/Ex. 1/435:20-436:13, Br. App. 110).

If AWPs had represented a true average of wholesale prices, then Wisconsin pharmacists would have lost money on every Medicaid prescription they filled. As the Alabama Supreme court observed in rejecting similar AWP claims, perhaps “the most irrefutable evidence of the State’s actual understanding of WAC and AWP is the reimbursement methodology itself. . . . In truth, the State—as do all the states—takes a discount from AWP to compensate for the fact that AWP is *not a net figure*.” *AstraZeneca*, 41 So.3d at 31-32 (Br. App. 200) (emphasis in original).

Because it cannot deny that it knows, and has known, that AWPs are not actual averages of wholesale prices, the State argues instead that its knowledge is irrelevant to determining whether the published AWPs are “false.” (Resp. Br., p. 36). According to the State, if the number published as an AWP for a drug is something other than a number that meets the dictionary definition of “average wholesale price” for that drug, the AWP is “false” even though everyone involved in reimbursing for drugs understands that AWP does not refer to a dictionary definition of average

wholesale price. The State's position is untenable and, if accepted, would wreak havoc in the marketplace. For example, under the State's theory it could seek millions of dollars in forfeitures for the tickets sold for "Big Ten" football games because the "Big Ten" does not have 10 teams. Moreover, the fact that the public at large is not generally familiar with parlance used in a particular industry does not render a statement using industry parlance "false." Otherwise, a lumber store would be liable for "falsely" advertising the sale of 2 x 4's even though, as every builder knows, 2 x 4's actually measure  $1\frac{3}{4}$  x  $3\frac{1}{2}$  inches.

The State's next argument is that even though it knows the number published as the AWP for a drug is not an actual average of the wholesale prices paid for that drug, the number should still be considered "false" because the State does not know what the actual average wholesale price is. This is an ultimately unsuccessful twist of logic. As noted above, the number published as the AWP for a brand drug is calculated as a formulaic 20 or 25 percent mark-up from the manufacturer's WAC price. There is nothing false or "wrong" about the number, which the State concedes is simply the product of a standard mathematical calculation. (R437/37:8-18, A. Ap. 764). And, because the State knows that the number is not an

actual average of wholesale prices, there is nothing false about using the term AWP to describe the number. The fact that a reported AWP for a drug does not tell a payor what the actual average of wholesale prices for that drug is does not change this analysis. Nor does it matter if the State may not always have understood the precise mathematical relationship between WAC and AWP for brand drugs. What matters is that throughout the relevant time the State chose to use AWP's knowing that they did not represent actual averages of wholesale prices.

***B. The State's Misguided Effort To Apply Section 100.18(10)(b) To The Use Of AWP's Is Meritless And Should Be Rejected.***

The State cannot avoid these dispositive issues based on § 100.18(10)(b). This provision does not apply here.<sup>6</sup>

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<sup>6</sup> The Brand Defendants are permitted to address the issue whether § 100.18(10)(b) is applicable in this case. The Court's November 10 order disallowed the Brand Defendants from discussing "issues from the trial that the appellant has not addressed in its brief." Order (Nov. 10, 2010) at 4. Pharmacia addressed the issue whether § 100.18(10)(b) is applicable in its opening brief. (See App. Br., pp. 25-27; see also Resp. Br., pp. 39-41 (arguing in response that § 100.18(10)(b) is applicable)).

The Brand Defendants have deleted the single argument that the State objected to in its motion to strike. The State contended that the Brand Defendants cannot "argue that it was improper for the circuit court to quote from [§ 100.18(10)(b)] in its instructions to the jury," because Pharmacia has not challenged the jury instructions on appeal. State's Motion (Oct. 26, 2009) at 8-9 (internal quotation marks omitted). The Brand Defendants have eliminated any reference to the circuit court's jury instructions in this amended brief.

First, this provision is one statutory specification of what should be considered deceptive under the Deceptive Trade Practices Act, which generally proscribes statements to the public that are “untrue, deceptive or misleading,” and that are made “with the intent to induce an obligation.” *K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 2007 WI 70, ¶ 19, 301 Wis. 2d 109, 732 N.W.2d 792. The Supreme Court has clearly stated that “[w]e think by this amendment that the legislature intended to protect the residents of Wisconsin from any untrue, deceptive or misleading representation made to promote the sale of a product.” *State v. Automatic Merchs. of Am., Inc.*, 64 Wis. 2d 659, 663, 221 N.W.2d 683 (1974) (emphasis added). The State’s reliance on these statutes to hold pharmaceutical manufacturers liable for AWP is entirely misplaced.

The AWP that are alleged to have injured Wisconsin are the AWP that the State used to set reimbursement rates for individual drugs. These AWP cannot in any sense be understood to be (i) representations (ii) to the public (iii) to promote the sale of product. The State does not rely on any general circulation publication for the AWP used to calculate reimbursements to pharmacies. Instead, Wisconsin Medicaid contracts with Electronic Data Service

(“EDS”) to act as the State’s fiscal agent and process claims. (R435/137:11-138:6, C. Resp. Ap. 280-281<sup>7</sup>). EDS, in turn, contracts with First DataBank to supply AWP pricing data. (R435/137:7-17, C. Resp. Ap. 280). These are the AWP’s that are used in the reimbursement process. (Resp. Br., p. 6.) The contract between First DataBank and EDS is a license for “drug pricing fixed in computer data bases” that include “Blue Book” AWP’s. (R304/DX-490,<sup>8</sup> C. Resp. Ap. 155 & 168). There is no “book”, however; the AWP’s are conveyed to EDS on a computer tape. (R304/DX-490, C. Resp. Ap. 168). Rather than being a statement to the public, these tapes and the data they contain are subject to strict confidentiality provisions. (R304/DX-490, C. Resp. Ap. 168). Nor are AWP’s in any way representations “made to promote the sale of a product” to the State. AWP’s are themselves a product owned by First DataBank that First DataBank conveys, via confidential contract, to EDS. (*Id.*). In *K&S Tool & Die Corp.*, the Court held that when a buyer enters into a contract with a seller, the buyer is no longer a member of the public. 2007 WI 70, ¶ 26. The contract between EDS and First DataBank removes the relevant AWP’s—the ones used to

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<sup>7</sup> Citations to the Appendix to Combined Brief of Appellant and Cross-Respondent are designated as “C. Resp. Ap. \_\_\_\_.”

<sup>8</sup> Citations to the trial exhibits are to the Clerk’s Document Number/Exhibit Number.

process reimbursement claims—from the realm of statements to the public.

Confidential computer tapes containing AWP information received by a sophisticated data processing company pursuant to a two-party licensing agreement cannot reasonably be deemed to be representations to the public under any familiar construction of that term. The state’s invocation of a consumer protection statute—and specifically a proscription of representing retail prices as a manufacturer’s or a wholesaler’s prices—to apply to confidential computer tapes licensed and used to generate reimbursement payments is an exercise in fitting a square peg into a round hole.

Moreover, § 100.18(10)(b) plainly was intended to prevent consumer deception, yet no consumer purchases or could purchase prescription drugs based on representations about AWP. Section 100.18(10)(b) should not be construed to invalidate national practices—here, the reporting of AWPs—when it is well-understood that the AWPs are not actual wholesale prices but are benchmarks which must be adjusted when used in reimbursement formulae by a state or other sophisticated payor.

**II. Wisconsin Has Set Its Reimbursement Rates By Deliberate Choice, Not Because It Was Misled About What AWP Means.**

It is undisputed that Wisconsin reimburses pharmacists who dispense drugs to Medicaid patients at a rate that pays them a profit margin in addition to the cost of what they pay to acquire drugs from wholesalers. But, in order for the State to prevail on its two causes of action, it must prove that it is the Defendants who *caused* the State to pay this profit margin because the AWPs published for the Defendants' drugs are not actual averages of wholesale prices. The State cannot make this showing. Instead, the evidence demonstrates that the State intentionally built a profit margin into the reimbursement rate as a result of a political process driven by the express goal of paying pharmacists an amount sufficient to incentivize them to participate in the Medicaid program and to serve Medicaid patients.

The State confuses the causation analysis by constructing an argument that goes as follows: *if* the State had been told the actual acquisition costs paid by pharmacists, the court must assume the Legislature would have authorized funds sufficient to pay pharmacists only their acquisition cost because that is what federal

law requires. There are several flaws in this argument, and each flaw is fatal to the State's claims.

**A. *The State's Causation Theory Fails Because Wisconsin Did Not Intend To Set The Reimbursement Rate At Actual Cost.***

Perhaps the clearest example of both the political nature of the reimbursement setting process, and the State's intent to pay pharmacists more than acquisition cost, comes from the 2005-07 biennial budget process. In 2005, after the State started this lawsuit alleging that AWP's are false and are causing it to overpay pharmacists, Governor Doyle proposed that the reimbursement rate for brand-name drugs be reduced from AWP minus 13% to AWP minus 16%. (R123/6, A. App. 12; R135/Ex. 66/2, Br. App. 43; R135/Ex. 139/1, Br. App. 68). According to a Department of Health and Family Services paper published to support that proposal, even with this reduction "most pharmacies acquisition costs would still be lower than the reimbursement rate proposed" by the Governor, because pharmacy acquisition costs averaged AWP minus 21%, with a range of AWP minus 17% to AWP minus 24%,. (R135/Ex. 139/1, Br. App. 68; R135/Ex. 33/2, Br. App. 40). The Wisconsin Joint Committee on Finance estimated that if the Governor's proposed reduction were enacted, pharmacists would still earn a

profit of \$1.59 to \$6.37 on each Medicaid transaction for a brand-name prescription. (R135/Ex. 66/5, Br. App. 46). In other words, the Governor proposed a reimbursement formula that would lower payments to pharmacists but continue to pay them a modest profit, not reimburse them at actual cost.

The Legislature rejected the Governor's proposal, and kept the reimbursement rate at AWP minus 13%. (R123/6, A. App. 12.) Governor Doyle then used his line-item veto power to change the rate to AWP minus 16%—a rate DHSS acknowledged would still pay pharmacists a profit. (R123/6, A. App. 12; R135/Ex. 152, Br. App. 55; R135/Ex. 160/4-5, Br. App. 66-67). However, in the face of political opposition from pharmacists, Governor Doyle suspended the reimbursement reduction called for by his veto and appointed a commission to find equivalent savings elsewhere, while still “compensating pharmacies fairly and protecting benefits to Wisconsin’s most vulnerable residents.” (R135/Ex. 80/3, Br. App. 80; R135/Ex. 1/154:2-157:21, Br. App. 102; R135/Exs. 153-59, Br. App. 56-62).

The Governor's Commission on Pharmacy Reimbursement proposed reducing payment for brand drugs to AWP minus 15% instead of AWP minus 16%. (R135/Ex. 80/30, Br. App. 84). This

recommendation also contemplated a profit margin for pharmacists, because the Commission found that drug acquisition costs generally fall within a range “between 15% and 22% less than AWP.” (R135/Ex. 80/4, Br. App. 81). Indeed, the Commission explicitly recognized and accounted for the interest of pharmacists in receiving “sufficient reimbursement to cover their costs of doing business, *i.e.*, the cost of the drug (ingredient cost), and the costs of dispensing *and some profit margin.*” (R135/Ex. 80/7, Br. App. 83) (emphasis added). Wisconsin did not adopt the Commission’s proposal but instead left the reimbursement rate for brand-name drugs at AWP minus 13%—a *higher* rate than the Commission concluded was needed to provide pharmacists with a sufficient profit margin on Medicaid transactions. (R135/Ex. 1/158:4-15, Br. App. 103).

These events amply demonstrate that the State set its Medicaid reimbursement formula for brand drugs at a rate which paid pharmacists a profit *not* because it believed that published AWP’s for brand drugs represented an actual average of wholesale prices, or because it did not know what actual acquisition costs were, but because it wanted pharmacists to earn a profit margin. As the circuit court recognized, “[t]he evidence is compelling that a

political tug-of-war between various interest groups spanning a number of successive biennial budget sessions resulted in the adoption of reimbursement formulas that were known to overcompensate participating Wisconsin pharmacies.” (R376/8, A. Ap. 169). As the court aptly put it, “plaintiff’s case has a Captain Renault quality to it, insofar as the plaintiff professes to be ‘shocked- shocked’ that the AWP system has resulted in overpayments to pharmacies.” (*Id.*). The State should not be allowed to use this lawsuit to recover from Defendants the profit margin that the Legislature knowingly decided to pay local pharmacists.

The State’s theory on liability was resoundingly rejected by the only other state supreme court to have considered an AWP case on the merits. In *AstraZeneca LP v. Alabama*, 41 So.3d 15 (Ala. 2009), the Alabama Supreme Court ruled, as a matter of law, that Alabama neither relied, nor reasonably could have relied, on published AWP figures as representing actual prices when the evidence demonstrated that Alabama—like Wisconsin—knew that the published AWPs were higher than the prices paid to wholesalers when it established its Medicaid reimbursement rates. *Id.* at 29-33 (setting aside AWP jury awards and ordering judgment for the Defendants) (Br. App. 198-202).

The State dismisses *AstraZeneca*, claiming that it addressed solely the issue of “reasonable reliance,” not whether the AWP were false. (Resp. Br., p. 38). But the reason that Alabama could not reasonably rely on AWP as “Average” “Wholesale” “Prices” was because it had “actual knowledge of a different meaning.” *AstraZeneca*, 41 So.3d at 30 n.9 (Brand App. 199). Wisconsin similarly was not deceived by the so-called “plain meaning” of AWP because it—like all other states—knew that AWP are not intended to reflect prices paid by pharmacists for drugs. That is why every state that uses AWP in its reimbursement formula applies a deep discount to calculate the reimbursement amount.

**B. *The State’s Causation Theory Also Fails Because It Improperly Imposes Upon Defendants An Affirmative Duty To Report An Actual Average Of Prices Paid By Retailers To Wholesalers—A Transaction To Which The Defendants Typically Are Not Parties.***

Section 100.18 requires a “causal connection between the practices found illegal and the pecuniary losses suffered.” *Tim Torres Enterprises v. Linscott*, 142 Wis. 2d 56, 70, 416 N.W.2d 670 (Ct. App. 1987). In this case, establishing that causal connection requires the State to prove what the Legislature would have done if the numbers published by the pricing compendia were not “falsely”

labeled as AWP. But, as is shown above, the State cannot establish that it would have acted any differently if the numbers had been labeled something else (for example, “WAC plus 20%” or even “not AWP”), because the State in fact knew that the numbers were not an actual average of wholesale prices.

The State attempts to subtly alter the causation analysis by changing the question from “What would the State have done if Defendants had ‘correctly’ labeled the AWP numbers?” to “What would the State have done *if the numbers had been changed* to ‘correctly’ fit the State’s redefinition of what AWP should mean?” In other words, the State’s causation theory rests *not* on showing that it would have acted differently if the AWP numbers provided had been accompanied by a description the State views as accurate, but instead on showing what it allegedly would have done had Defendants provided totally different figures—figures the Defendants have no legal obligation to provide and which are based on transactions between wholesalers and pharmacists to which Defendants were not even parties.

The State’s novel causation twist is contrary to Wisconsin law. The Supreme Court has made clear that a failure to disclose information cannot itself be an actionable misrepresentation under

the false advertising statute. “A non-disclosure does not constitute an ‘assertion, representation or statement of fact’ under Wis. Stat. § 100.18(1).” *Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶ 4, 270 Wis. 2d 146, 677 N.W.2d 233. Thus any injury the State allegedly suffered because Defendants failed to disclose information is not actionable under § 100.18.

Nor has the State cited any authority, and Defendants are aware of none, importing a duty of disclosure into the Medicaid fraud statute. A defendant can be liable under these statutes only for causing damage with an untrue representation—not for failing to benefit the plaintiff with a separate, “true” representation on the same subject. Thus, the State’s claims fail as a matter of law.

***C. The State’s Causation Theory Relies On An Incorrect View Of Federal Law.***

The State insists we must assume that if the Legislature knew actual acquisition costs it would use those costs as the reimbursement rate, because that is what federal Medicaid regulations require. (Resp. Br., pp. 25-26). The State misreads the regulations, which actually say that reimbursement for brand-name drugs may not exceed, *in the aggregate*, the lower of: (1) providers’ estimated acquisition costs (“EAC”) *plus* reasonable dispensing fees;

or (2) the providers' usual and customary charges to the general public. 42 C.F.R. § 447.512(b) (emphasis added). Nothing in the regulations requires that the profit component be confined to the dispensing fee as opposed to the ingredient reimbursement, as long as the formula complies with the regulation "in the aggregate." In fact, the Department of Health and Human Services Departmental Appeals Board—HHS's final authority on whether agency action with respect to Medicaid reimbursement is lawful—ruled that states "could offset a lower than reasonable dispensing fee with ingredient costs which were higher than HCFA's specific limits as well as higher than the costs to the pharmacies themselves." *See Pennsylvania Dep't of Public Welfare, D.A.B. No. 1315 (1992) (Br. App. 225); see also id. n.9* ("The regulation can reasonably be read to permit states to pay more than an appropriately determined EAC for drug ingredient cost, but less than a reasonable dispensing fee, so long as the payments did not, in the aggregate, exceed the upper limit") (*quoting* Reconsideration ruling on DAB 1271) (Br. App. 229). Indeed, the law of at least one state—approved by federal Medicaid under the same law that Wisconsin claims prohibits it from paying a profit to pharmacists—expressly *requires* that state's Medicaid agency to pay pharmacists a dispensing fee plus "the net

cost of the drug *and a reasonable operating margin.*” Idaho Admin. Code § 16.03.09.665.02.d.iii (2007-09) (emphasis added); Idaho Admin. Code § 16.03.09.817.04.c (2001-06).

Moreover, federal Medicaid regulations require that the State set its reimbursement rates sufficiently high “to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” 42 U.S.C. § 1396a(a)(30)(A); *see also* 42 C.F.R. § 447.204. Wisconsin legislators were keenly aware of the need to reimburse pharmacists at a sufficient level to ensure their continued participation in the Medicaid program.<sup>9</sup>

**D. *The State’s Causation Theory Requires The Courts To Violate The Separation Of Powers And Political Question Doctrines.***

Another fatal flaw in the State’s causation argument is that it impermissibly requires the Court to dictate the answer to a

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<sup>9</sup> For instance, in 2001 State Senator Dave Hansen issued a press release opposing a reimbursement rate cut, stating “I think there is a real risk of pharmacies closing, particularly in smaller, more rural communities. I don’t want anyone to be denied access to life- or health-saving prescriptions because the state forced their pharmacist out of business.” (R135/Ex. 78, Br. App. 30). In 2005, State Representative Albers wrote a letter to a Wisconsin pharmacist, noting that the Legislature “saw the importance of maintaining reimbursement rates for pharmacists,” recognized the inability of pharmacists to serve citizens enrolled in the Medical Assistance program without “sufficient reimbursement rates,” and had restored \$17 million towards reimbursement rates that otherwise would have been cut. (R135/Ex. 65d, Br. App. 156).

question of public policy: “What *should* the Legislature establish as the reimbursement rate for pharmacists?” This question arises because the State claims as damages the difference between (1) what it reimbursed to pharmacists for drug costs and (2) the actual average costs those pharmacists paid to buy those drugs. (Resp. Br., p. 25). This damage calculation assumes that if the Legislature knew a drug’s actual acquisition cost it would have directed Wisconsin Medicaid to pay pharmacists no more than that amount, with no profit margin. This causation theory requires the judicial branch to determine what decision the legislative branch should have made when setting the reimbursement rate. Second guessing legislative judgments in this manner is prohibited by both the separation of powers and political question doctrines.

The question of what reimbursement rate to set under the State’s Medicaid program falls squarely within the core, constitutionally exclusive authority of the Legislature. The Wisconsin Supreme Court “has long held that it is the province of the legislature, not the courts, to determine public policy” and that “[s]pecifically regarding appropriations, Wis. Const. art. VIII, §§ 2 and 5 empower the legislature, not the judiciary, to make policy decisions regarding taxing and spending.” *Flynn v. Dep’t of Admin.*,

216 Wis. 2d 521, 539-40, 576 N.W.2d 245 (1998). How much to pay as reimbursement to pharmacists who participate in the Medicaid program, including the appropriate amount to ensure continued participation by pharmacists, is exactly the type of policy decision regarding taxing and spending exclusively committed to the Legislature by the Wisconsin Constitution. Because it is within the “core area” of the Legislature’s authority, it is constitutionally impermissible, under the separation of powers doctrine, for the courts to intrude upon—and second-guess—the Legislature’s deliberate policy decisions regarding reimbursements to pharmacists. *See State ex rel. Friedrich v. Dane County Circuit Court*, 192 Wis. 2d 1, 13, 531 N.W. 2d 32 (1995) (“Each branch [of government] has a core zone of exclusive authority into which the other branches may not intrude.”).

The political question doctrine provides an independent, but related, reason why the courts should not second-guess the Legislature’s spending decisions in this case. Wisconsin has adopted the formulation of the political question doctrine articulated by the United States Supreme Court in *Baker v. Carr*, 369 U.S. 186, 209 (1962). *See State v. Jensen*, 2004 WI App 89, ¶ 48, 272 Wis. 2d 707, 681 N.W. 230, *aff’d per curiam*, 2005 WI 31, 279 Wis. 2d 220, 694

N.W.2d 56. Thus a non-justiciable political question exists under Wisconsin law if, “prominent on the surface of the issue to be adjudicated,” the court finds any of the following: “(1) a textually demonstrable constitutional commitment of the issue to a coordinate political department; or (2) a lack of judicially discoverable and manageable standards for resolving it; or (3) the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion . . . .” *Id.*

Each of these factors applies here. First, the policy decision regarding the appropriate spending under a governmental program is exclusively committed to the legislative branch by the Wisconsin constitution. Second, a court or jury also lacks any manageable standard to use when determining how to strike the right balance between saving taxpayer money and ensuring that reimbursements are sufficient to persuade enough pharmacists across the state to participate in the Medicaid program. Finally, balancing these competing policies requires a policy determination that neither a court nor a jury is competent to make.

The State’s theory of causation demands that a judge or jury substitute its judgment about the appropriate Medicaid reimbursement rate for the judgment of the Legislature. This is

precisely the type of judicial incursion into the core, exclusive, domain of the legislative branch that the separation of powers and political question doctrines expressly forbid.

### **III. The State Is Not Entitled To A Jury Trial On Its Claims.**

The circuit court ruled that the State was entitled to a jury trial on its § 100.18 and § 49.49 claims. In so doing, it relied upon the Wisconsin Supreme Court's decision in *Village Food*, which held that a right to a jury trial arises only when a cause of action created by statute "existed, was known, or was recognized at common law at the time of the adoption of the Wisconsin Constitution in 1848." *Village Food & Liquor Mart v. H & S Petroleum, Inc.*, 2002 WI 92, ¶ 11, 254 Wis. 2d 478, 647 N.W.2d 177; (R216/1-6, Br. App. 165-70). Although the court expressed doubts about how to apply the *Village Food* test in this case, it ultimately concluded that the State was entitled to a jury trial on its § 100.18 claim because the statute has "an analogous forerunner" in the common law offense of "cheating," which the court found to be "similar inasmuch as both are aimed at protecting the public from the misrepresentations of merchants engaged in trade." (R216/2-4, Br. App. 166-68). The court likewise concluded that the State was entitled to a jury trial on its § 49.49 claim, believing that cause of action "can best be characterized as a

statutory sub-species of common law fraud, with the medical assistance benefit program serving merely as the stage for its performance.” (R216/5-6, Br. App. 169-70). However, the Wisconsin Supreme Court’s decision in *Harvot v. Solo Cup*, 2009 WI 85, 320 Wis. 2d 1, 768 N.W.2d 176, issued after the Pharmacia trial, clarifies the application of the *Village Food* test, and makes clear that the circuit court’s application of the test in this case was erroneous.<sup>10</sup>

In *Solo Cup*, the Court considered whether there is a constitutional right to a jury trial for claims under the Wisconsin Family and Medical Leave Act (“WFMLA”). The Court explained that the appropriate inquiry when applying the *Village Food* test is whether a statute and its proffered common law counterpart “share a similar purpose.” *Solo Cup*, 2009 WI 85, ¶ 72. The Court determined that there was no constitutional right to a jury trial

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<sup>10</sup> This court may appropriately reverse the circuit court on the basis of *Solo Cup*, even though *Solo Cup* was decided after the circuit court had issued its decision. See *Zak v. Zifferblatt*, 2006 WI App 79, ¶¶ 17 & 18, 292 Wis. 2d 502, 715 N.W. 2d 739 (appellate court should apply decision of Supreme Court on constitutional issue to circuit court decision previously issued when appellants “raised their constitutional challenge in the circuit court and preserved it for appellate review”); see also *Olson v. Augsberger*, 18 Wis. 2d 197, 201, 118 N.W. 2d 194 (1962) (judgment under attack at time controlling decision was rendered should be reviewed under new rule announced in decision).

under the WFMLA, because it is “modern social legislation” of a type that “was quite unheard of in 1848.” *Id.* at ¶ 80.

The Court rejected, as “too broad to be meaningful,” the plaintiff’s claim that the WFMLA is analogous to common law causes of action concerning labor standards that have existed for centuries, including, specifically, an action for breach of a retainer agreement. *Id.* at ¶ 81. The Court explained that while that cause of action was “superficially” the most analogous to the WFMLA, its purpose was to “ensure that the servant (employee), who could be criminally prosecuted for departing before his term of employment was complete, was cared for and compensated as promised.” *Id.* at ¶¶ 85-86. Because “[a]ssisting an employee to balance work and family demands was not a purpose of this common law cause of action,” the Court determined that it did not share a similar purpose with the WFMLA, was not a counterpart, and therefore failed the *Village Food* test. *Id.* at ¶ 86.

**A. Section 100.18 And Common Law “Cheating” Do Not Share A Similar Purpose.**

The key to applying the *Village Food* test is determining “how narrowly to draw the analogy between the claims at issue and the causes of action at statehood.” *State v. Schweda*, 2007 WI 100, ¶ 29,

303 Wis. 2d 353, 736 N.W.2d 49. Courts must “narrowly construe” the statutory causes of action analogized to pre-1848 common law claims, lest they “render the *Village Food* test a nullity.” *Id.* at ¶ 40. Having “doctrinal roots” in a pre-statehood cause of action does not make a modern statute a “counterpart” for purposes of the *Village Food* test.” *Id.* at ¶ 34.

Here, the analogy between § 100.18 and the proffered pre-statehood common law counterpart of “cheating” is “too broad to be meaningful.” *See Solo Cup*, 2009 WI 85, ¶ 81. “Cheating” encompasses an extremely broad range of unsavory activity, including using false weights and measures, putting sawdust in bread, pawning another’s goods, playing with false dice, and the modern tort of misrepresentation.<sup>11</sup> By contrast, § 100.18 created a cause of action for false advertising that did not exist at common law in 1848, and is not simply a codification of common law misrepresentation. *See Kailin v. Armstrong*, 2002 WI App 70, ¶ 40, 252 Wis. 2d 676, 643 N.W.2d 132 (Section 100.18 creates “a distinct statutory cause of action,” separate from common law misrepresentation claims.). The common law tort of “cheating” also

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<sup>11</sup> 4 William Blackstone, COMMENTARIES ON THE LAWS OF ENGLAND, ch. 12, at 1556 & n.12 & 15 (1897) (Br. App. 213).

includes a scienter requirement, while § 100.18 imposes liability even if there is no intent to deceive. *See id.* Even if §100.18 had “doctrinal roots” in cheating, *Schweda* and *Solo Cup* make clear that such roots are not enough to satisfy *Village Food*. Accordingly, the State is not entitled to a jury trial on its § 100.18 claims.

**B. Section 49.49 And Common Law Fraud Do Not Share A Similar Purpose.**

*Solo Cup* instructs that courts should not look to the broad purpose of a modern statute—*e.g.*, protecting workers from discharge on the basis of illness or injury—but should instead focus on the specific purpose of the statute in the historical context in which it was enacted. *See Solo Cup*, 2009 WI 85, ¶¶ 79-80. In this case, comparing nineteenth-century common law fraud and § 49.49 in the manner *Solo Cup* directs reveals that despite their broad similarities—both guard against fraud—§ 49.49 was enacted for a very different purpose.

Section 49.49 is part of the statutory scheme governing Wisconsin’s Medical Assistance program. *See Wis. Stat.* §§ 49.43–49.499. “Medical assistance is a joint federal and state program aimed at ensuring medical care for the poor and needy.” *Tannler v. Dep’t of Health & Soc. Servs.*, 211 Wis. 2d 179, 190, 564 N.W.2d

735, 741 (1997). The federal portion of the program was enacted in 1965 in response to a growing elderly population, rising medical costs, and “a general lack of affordable health insurance and health care options.”<sup>12</sup> Thus Wisconsin’s Medicaid program, which went into effect on July 1, 1966, is “modern social legislation” of a type “quite unheard of in 1848.” *Solo Cup*, 2009 WI 85, ¶ 80.

As with the WFMLA, “it would be hard to imagine” that the State’s § 49.49 claim “existed, was known, or was recognized at common law...in 1848.” Although § 49.49 protects against fraud, it is specifically limited to fraud “in connection with a medical assistance program,” and is part of the extensive statutory scheme creating Wisconsin’s Medical Assistance program. Wis. Stat. § 49.49(1)(a); Wis. Stat. §§ 49.43–49.499. Under *Solo Cup*, a simple comparison of the statute to common law fraud, without considering the specific purpose and historical context of the legislation, is “too broad to be meaningful.” *Solo Cup*, 2009 WI 85, ¶ 81. Because common law fraud does not have a similar purpose to a statute addressing fraud in connection with the state’s modern medical

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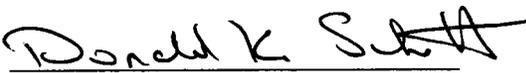
<sup>12</sup> Judith D. Moore & David G. Smith, *Legislating Medicaid: Considering Medicaid and Its Origins*, 27 HEALTH CARE FINANCING REVIEW 45, 47 (Winter 2005-06) (Br. App. 73).

assistance program, the State is not entitled to a jury trial on its § 49.49 claim.

### CONCLUSION

This Court should dismiss the State's §100.18 and § 49.49 claims. If the State's claims are not dismissed, this Court should determine that the State is not entitled to a jury trial on its claims.

Dated this 22nd day of November, 2010.

By:   
Donald K. Schott  
Freya K. Bowen  
Matthew J. Splitek  
QUARLES & BRADY LLP  
33 East Main Street  
Suite 900  
Madison, WI 53703

Andrew D. Schau  
COVINGTON & BURLING LLP  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018

William F. Cavanaugh, Jr.  
Peter C. Harvey  
Adeel A. Mangi  
PATTERSON BELKNAP  
WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, NY 10036-6710

*Attorneys for Johnson &  
Johnson, Janssen LP,  
McNeil-PPC, Ortho Biotech  
Products, LP, and Ortho-  
McNeil Pharmaceutical, Inc.)*

Submitted on Behalf of all  
Non-Pharmacia Brand  
Defendants

## CERTIFICATION REGARDING FORM AND LENGTH

I hereby certify that this brief complies with the Court's Order of August 19, 2010 granting leave to file non-party briefs in that it does not exceed 35 pages.

I further certify that this brief conforms to the rules contained in Wis. Stats. §§ 809.19(8)(b) as to form where proportional serif font is used.

This brief contains 7,455 words.

Dated this 22nd day of November, 2010.

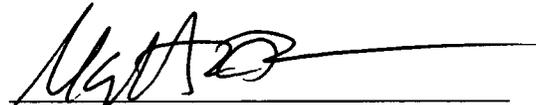


Matthew J. Splittek

**CERTIFICATION REGARDING ELECTRONIC  
BRIEF AND APPENDIX**

I hereby certify that I have submitted an electronic copy of this brief, including the appendix, which complies with the requirements of Wis. Stat. § 809.19(12) and (13). I further certify that the electronic brief is identical in content and format to the printed form of the brief filed as of this date.

Dated this 22nd day of November, 2010.

  
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Matthew J. Splitek

## CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 22nd day of November, 2010, I caused to be served a copy of the foregoing Non-Pharmacia Brand Defendants' Amicus Curiae Brief on all counsel of record via Lexis Nexis File and Serve®.

  
Xavier Santistevan

## APPENDIX CERTIFICATION

I hereby certify that filed with this brief, either as a separate document or as a part of this brief, is an appendix that complies with Wis. Stat. § 809.19(2)(a) and that contains, at a minimum: (1) a table of contents; (2) the findings or opinion of the circuit court; and (3) portions of the record essential to an understanding of the issues raised, including oral or written rulings or decisions showing the circuit court's reasoning regarding those issues.

I further certify that if the record is required by law to be confidential, the portions of the record included in the appendix are reproduced using first names and last initials instead of full names of persons, specifically including juveniles and parents of juveniles, with a notation that the portions of the record have been so reproduced to preserve confidentiality and with appropriate references to the record.

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Matthew J. Splitek