

STATE OF WISCONSIN	CIRCUIT COURT	DANE COUNTY
	Branch 9	
STATE OF WISCONSIN,	)	
Plaintiff,	)	
v.	)	Case No. 04-CV-1709
	)	Unclassified – Civil: 30703
AMGEN INC., et al.,	)	
Defendants.	)	

**PLAINTIFF’S REPLY BRIEF IN SUPPORT OF PROTECTIVE ORDER  
BARRING DEFENDANTS FROM REQUIRING WISCONSIN  
TO SEARCH ELECTRONIC FILES FOR WHAT DEFENDANTS  
CALL GOVERNMENT KNOWLEDGE DOCUMENTS**

The issue on the present motion is whether the defendants can force the State to conduct an exhaustive and expensive search of the e-mails of its Medicaid employees in the hope of finding documents that would support a legally impermissible defense. The State’s opening brief showed that the answer is no. Despite the length of their Opposition – which would have run to at least 70 pages had it not shoved most of its material into 104 footnotes in microscopic type – defendants offer no convincing case to the contrary.

Section I below will answer defendants’ insinuation that the State has stonewalled them in discovery. Section II will answer their efforts to explain away the law that rejects their “government knowledge” defense, the predicate for their proposed discovery. Section III will answer their remaining arguments. Section IV addresses Johnson & Johnson’s separate response to the motion.

**I. DEFENDANTS’ INSINUATION THAT THE STATE IS STONEWALLING THEIR DISCOVERY IS FALSE.**

Defendants open their brief by accusing the State of trying to “thwart Defendants [*sic*] discovery efforts.” Defendants’ Opposition To Plaintiffs’ Motion For Protective Order (hereafter cited “Defs. Opp.”) at 2 n. 3. The truth is different. With little objection

from the State, defendants have taken and continue to take sweeping documentary and depositional discovery. The State has already produced more than 189,000 pages of documents to defendants, some of which appear as exhibits to the Opposition.

Defendants have already deposed eight present or former Wisconsin State officials associated with Medicaid drug reimbursement. One of these depositions (James Vavra) took four days. What defendants call an attempt to “thwart” their discovery turns out to be nothing more than the related group of well-founded motions and objections presently pending before the Court.

Defendants likewise hurt their credibility by asserting that that the State “has not asserted *in its present motion* that Defendants’ requests are overly-burdensome.” Defs. Opp. at 3 n. 3 (emphasis added). As defendants know, the State *does* argue, vigorously, that the electronic discovery defendants demand to take will place an enormous and undue burden on the State. *See* State’s Brief In Response to Defendants’ Motion To Compel Production Of E-mail, pp. 17-18. Having laid out its case for burdensomeness in that response, the State chose not repeat it in its own motion for protective order.

## **II. DEFENDANTS’ PROPOSED ELECTRONIC DISCOVERY RESTS ON AN INVALID “GOVERNMENT KNOWLEDGE” DEFENSE.**

As the State has shown in its pending Motion for Partial Summary Judgment, and as it reiterated in its opening brief on the present motion, defendants’ hopes of escaping liability for inflating their AWP data and thereby inflating State Medicaid payments to providers rest principally on their “Government Knowledge” defense. This defense asserts that the State knew what the defendants were doing, and looked the other way, because the State *wanted* to inflate payments on account of providers’ drug acquisition costs in order to give them a “profit” on dispensing prescriptions to Medicaid patients.

Defendants’ latest brief tries to “spin” that defense to make it more palatable. First, they give it a new name: “Government Choice.” Second, in referring to crucial allegations of the complaint, the defendants substitute the words “Wisconsin Medicaid”

for the complaint's "State of Wisconsin." See, e.g., Defs. Opp., at 1, 6 (purporting to quote Second Amended Complaint, ¶¶ 34, 36, 59). Third, defendants assert that officials within "Wisconsin Medicaid," and therefore the "State of Wisconsin," made a "conscious, informed and intentional decision to reimburse providers participating in its Medicaid program not only at a rate that covers providers' costs, but further provides them a profit, in order to ensure their continued participation in the Medicaid program so that Medicaid recipients can receive federally mandated equal access to care." Defs. Opp. at 1. Specifically, as will be seen, defendants accuse the State of making a conscious choice to provide this profit by knowingly using defendants' inflated AWP's to inflate the ingredient cost component of drug reimbursements to providers to levels that the State knew were far higher than providers' actual ingredient costs.

This argument has no merit. As Section A will show, defendants do not rebut the State's showing that if employees of the State had made the "choice" defendants claim they made, those employees would have violated the law. As Section B will show, the evidence cited by defendants to insinuate the existence of this illegal "choice," and thereby to get their foot in the door to argue for sweeping further electronic discovery on this subject, shows no such "choice." As Section C will discuss, defendants have no persuasive response to the State's showing that proving such an illegal "choice," even if it had been made, would not provide a defense to the State's claims.

**A. Defendants Do Not Dispute That The "Choice" They Claim Wisconsin Medicaid Employees Made Would Have Been Unlawful.**

Nowhere does defendants' massive Opposition dispute that the "choice" they claim "Wisconsin Medicaid" made – to give providers a "profit" through inflating the ingredient-cost component of Medicaid drug reimbursements to levels far in excess of what providers actually paid to acquire the drugs -- would have been unlawful.

Specifically, as the State showed, pursuant to federal law, the State reimburses most "brand" prescription drugs by a payment that consists of two parts: a payment for

ingredient cost and a “reasonable dispensing fee.” 42 C.F.R. § 447.512 (recently renumbered from 42 C.F.R. § 447.331). The “ingredient cost” is set by determining the “Estimated Acquisition Cost” (EAC) incurred by providers to acquire the drug. Federal regulations require States to make their best efforts to set EAC at the *actual prices providers pay to acquire the drugs*. See 42 CFR § 447.502 (recently renumbered from § 447.301), which provides: “Estimated acquisition cost means the agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.” Defendants do not dispute that the State, having chosen to participate in the Medicaid program, must abide by these regulations. *Pennsylvania Pharm. Ass’n v. Dept. of Public Welfare of Comm. of Pennsylvania*, 542 F. Supp. 1349, 1352 (W.D.Pa. 1982); *J. K. Dillenberg*, 836 F. Supp. 694, 696 (D.Ariz. 1993).

For drugs it reimburses on the basis of AWP (which include almost all “brand name” drugs), the State uses AWP *solely in fixing the EAC component of reimbursement*. It arrives at EAC through a formula which currently is AWP (as published by First DataBank) minus 13%. The AWP’s are provided by defendants to First DataBank. As Judge Saris recently remarked, this system puts “the proverbial pharmaceutical fox in charge of the reimbursement chicken coop. The different pharmaceutical companies unfairly took advantage of the system by setting sky high prices with no relation to the marketplace.” *In re Pharmaceutical Industry AWP Litigation*, 491 F.Supp.2d 20, 95 (D.Mass. 2007). If defendants were to report lower, more accurate AWP’s to First DataBank, the level of payment by the State for estimated acquisition cost would go down, as a matter of simple arithmetic.

The State is not required by federal statute or regulations to provide a “profit” as an incentive to providers under its Medicaid program, whether pharmacists, doctors, or hospitals. Defendants cite the statutory provision requiring a State’s reimbursement levels to be “sufficient to enlist enough providers so that care and services are available

to the general population in the geographic area.” Defs. Opp. at 1 n. 1, *quoting* 42 U.S.C. § 1396(a)(3))A). But this provision does not require States to provide a profit. It is a matter of common knowledge that States often set Medicaid reimbursement rates at levels that do not fully cover provider costs, and courts have turned back legal challenges by providers who claim that they are losing money on Medicaid business. *See, e.g., Pennsylvania Pharm. Ass’n v. Dept. of Public Welfare of Comm. of Pennsylvania, supra*, 542 F. Supp. at 1349-1352 (W.D.Pa. 1982). As the materials supplied by defendants’ Opposition illustrate, providers (particularly pharmacists) endlessly complain about supposedly low Medicaid reimbursement rates (particularly the dispensing fees), but keep dispensing drugs to Medicaid patients anyway.<sup>1</sup>

Moreover, even if State Medicaid authorities decide that it is necessary to provide some level of “profit” on Medicaid business in order to induce prescription drug providers to serve Medicaid patients, federal law, by defining EAC in terms of providers’ actual acquisition prices, forbids the State from inflating EAC to provide that profit. A State that wants to provide any level of profit to providers of drugs to Medicaid patients must provide it through the dispensing fee, not through inflating “Estimated Acquisition Cost.” There has been controversy over the years as to whether the State of Wisconsin’s dispensing fee provides such profit. As the State will prove at trial, it has set that fee higher than analogous dispensing fees paid by private insurance payers. In recent years, a majority of members of the Governor’s Pharmacy Advisory Commission (half of which consists of representatives of the Pharmacy industry) have recommended big increases in

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<sup>1</sup> Another example: many States’ reimbursements to hospitals for hospital services to Medicaid patients are lower than the hospitals’ costs of serving those patients, yet hospitals continue to serve Medicaid patients. In Illinois, for example, hospitals lose so much money on Medicaid patients that a bill recently introduced in the Illinois legislature would allow hospitals to claim those losses as “charity care.” *See* H.B 5000, available at <http://ilga.gov/legislation/billstatus.asp?DocNum=5000&GAID=8&GA=94&DocTypeID=HB&LegID=24242&SessionID=50>.

the dispensing fee. Year after year, the State has declined to do so. *See, e.g.*, Defs. Opp., Ex. 5, p. 1; Ex. 6, p. 1.

In short, defendants do not dispute that if “Wisconsin Medicaid” employees were doing what the defendants’ Government Choice theory alleges, they would be acting in violation of the law, because they would be knowingly setting their reimbursements for “Estimated Acquisition Cost” at levels that were systematically higher than providers’ actual costs for acquiring the drugs.

**B. The “Government Choice Evidence Collected To Date” Cited By Defendants Shows No Such “Choice.”**

In seeking electronic discovery on their “Government Choice” theory, defendants use a “foot in the door” strategy. Under the rubric of “Government Choice Evidence collected to date,” defendants cite documents and deposition testimony which, they claim, shows that such a choice was made. Defs. Opp. at 7-9, nn. 19-31. On the basis of this characterization, they argue that they are entitled to discover Wisconsin Medicaid officials’ e-mails. However, the evidence they cite shows no such “choice.” Consider the following examples.

1. No State official whose deposition testimony defendants quote has even hinted at what defendants charge – that the State intended to give pharmacists a profit by illegally inflating the ingredient-cost component of reimbursements to levels far beyond providers’ actual costs to acquire the drugs. Defendants cite to James Vavra’s testimony, but that testimony makes clear that the State intended to adhere to “the Federal principle of estimated acquisition cost close to what the pharmacists obtained the [drugs] at” and that any profit the pharmacists would earn had to come through the dispensing fee. Defs. Opp. Ex. 4, at 77:5-14.

2. Defendants suggest that they disclosed that “[First Data Bank’s] AWP’s did not represent actual prices.” Defs. Opp. at 9 and n. 31, *citing* Ex. 14. Exhibit 14 is a letter from defendant Novartis to a Wisconsin Medicaid official named Roma Rowlands,

announcing a change in the AWP of a drug called COMTAN®. The letter includes a disclaimer saying that AWP, “in keeping with current industry practices, is set as a percentage above the price at which each product is offered generally to wholesalers. Notwithstanding the inclusion of the term price, in Average Wholesaler Price, AWP is not intended to be a price charged by Novartis for any product to any customer.” This disclaimer is meaningless, because the name “average wholesale price” does not *imply* that it is the price charged to wholesalers or to customers of Novartis. Rather, the plain meaning of the words is the price charged by *wholesalers* when they resell Novartis’s drugs to *providers*. Thus, Novartis’s disclaimer told Wisconsin Medicaid nothing of value, and nothing that it would not have already assumed from the plain meaning of the term “AWP.” The other disclaimers defendants cite are of the same ilk. Amgen, like Novartis, said that AWP is not the price at which Amgen sell its drugs. Defs. Opp. Ex. 16. Schering professed not even to know the average wholesale price of its drugs (but now contends Wisconsin should have). Defs. Opp. Ex. 17.

3. Defendants cite various reports from an advisory commission called the Governor’s Pharmacy Commission. Those reports are filled with material that supports the State’s position that it never intended to pay more than providers’ acquisition costs. For example, the Commission’s “Medicaid Briefing Papers” for 2005 assume that defendants’ AWP’s mean what the name implies: “AWP represents the package price reported by the manufacturer or based on surveys of drug wholesalers and drug manufacturer-supplied information for a drug product.” Defs. Opp. Ex. 8, p. 5.

4. Similarly, the Commission’s 2006 report asserts that one of the Commission’s guiding principles is that “Payment to pharmacists should cover the reasonable operational cost of the services they provide, *with ingredient costs reimbursed as close to actual costs as can reasonably be determined.*” Defs. Opp. Ex. 5, p. 7 (emphasis added). This principle is at war with defendants’ assertion that the State

knowingly uses inflated AWP's to inflate the ingredient cost component of reimbursements to providers.

5. Defendants' material frequently documents how impossible it was for the State, in the face of defendants' false announced AWP's, to figure out what real provider acquisition costs were. For example, in its 2006 report, the Pharmacy Commission admitted that its members had not been able to "reach agreement on what it costs pharmacies to acquire the brand drugs they are dispensing." Defs. Opp. Ex. 5, p. 4.

6. Far from showing an intent by Wisconsin officials to violate federal cost-control regulations by using ingredient cost to provide pharmacists a profit, the evidence cited by defendants is filled with references to Wisconsin having one of the most aggressive programs in the country to control Medicaid drug costs. For example, as discussed above, Wisconsin has resisted pharmacists' pressure to raise the dispensing fee. Moreover, the State has been a leader in setting its own "Maximum Allowable Cost" (MAC) limits for "generic" multisource drugs. Defs. Opp. Ex. 8, p. 5.

7. Defendants never suggest *why* "Wisconsin Medicaid" would make a choice to provide pharmacists a profit by deliberately inflating the ingredient cost component of drug reimbursements beyond the limit allowed by law. If Wisconsin wants to provide pharmacists a profit, it can do so through the separate dispensing fee.

In short, defendants' "Government Choice Evidence collected to date" in no way shows the unlawful "choice" defendants claim, and provides no support for the burdensome and expensive electronic discovery defendants want to take.

**C. The "Government Choice" Claimed By Defendants Would Not Be A Defense In This Case Even If It Had Been Made.**

Defendants' Opposition fails to rebut the State's showing that an unlawful choice by Wisconsin officials to inflate the ingredient cost of Medicaid drug reimbursements, even if it had been made, would be no defense to the State's claims in this case.

**1. Other AWP Decisions Have Barred The “Government Choice” Defense.**

As the State showed, courts of three other States have rejected identical “government knowledge” defenses in AWP cases. Defendants do not mention these decisions until deep in their brief, and then only in a footnote. They distinguish the New Jersey ruling, *Walker v. TAP Pharm. Prods. Inc.*, No. CPM L 682-01 (Super. Ct. N. J. 2005) (Ex. F to the State’s opening brief) on the ground that “it involved a motion *in limine* to preclude defendants from presenting government knowledge evidence at trial.” Defs. Opp., at 22, n. 75. However, if government knowledge evidence is so clearly irrelevant as to be declared inadmissible *in limine*, there is no persuasive reason to allow it to serve as the predicate for expensive and time-consuming electronic discovery. Such discovery cannot possibly lead to the discovery of *admissible* evidence.

As for the Texas decision, *Texas ex rel. Ven-A-Care v. Roxane Laboratories, Inc.*, No. GV-002327 (Dist. Ct. Travis Cty., Tex. 2003) (Ex. G to the State’s opening brief), defendants argue that it “never suggested, much less ruled, that government knowledge was irrelevant.” Defs. Opp. at 22 n. 75. But that was the necessary implication of the Court’s summary judgment ruling for Texas, which ruled that knowledge by Texas government officials of the inflated level of AWPs could not prevent summary judgment on the issue of liability.

Even weaker is the defendants’ attempt to distinguish *People v. Pharmacia Corp.*, 835 N.Y.S.2d 486 (App. Div. 2007) (Ex. H to the State’s opening brief), which affirmed an order barring “government knowledge” discovery. According to defendants, in New York, the legislature sets reimbursement rates, whereas in Wisconsin, “it is not the legislature, but DHFS, along with the governor’s office, which formulates Plaintiff’s drug reimbursement methodology.” Defs. Opp. at 23 n. 76. Defendants further claim that the Appellate Division relied on the fact that information about the legislature’s intent “could be culled from legislative history.” *Id.* This argument is mistaken. First, as explained in

more detail in the State's Motion To Quash Defendants' Notice Of Deposition Of Wisconsin Legislature's Fiscal Bureau Budget Analysts, while executive-branch employees propose a Medicaid budget based, among other factors, on a proposed formula for reimbursing providers for drugs, it is the legislature that has the final say on the budget, subject to the Governor's veto power. Second, nothing in the New York court's decision mentions "legislative history," much less denies the requested discovery because of the availability of "legislative history."

Aside from failing to distinguish these three AWP decisions rejecting the "Government Knowledge" defense, defendants cite no decision that *supports* that defense. The closest they come to citing any specific ruling is to invoke a comment in Judge Saris's recent ruling on the merits in a class action filed by private payers. In that case, Judge Saris stated that "the [federal] government and industry were well aware by the late 1990's that there was a 20 to 25% spread." Defs. Opp. at 22, *quoting In re Pharm. Ind. Average Wholesale Price Litigation, supra*, 460 F. Supp.2d at 32. On the basis of this finding, she declined to hold that it was a *per se* violation of the Massachusetts consumer protection statute to report false AWPs. (She found three of the defendants liable in any event.) This conclusion is irrelevant to the present issue. Judge Saris was not considering and could not have considered the validity of a "Government Choice" defense. The plaintiffs in the trial before her were private payers, not governments, and the trial did not involve any state's Medicaid program. The choice these payers made to pay on the basis of AWP was a private choice, unconstrained by Medicaid regulations. Thus, the case did not present the legal issue presented by the "Government Choice" defense in the present case – whether a government plaintiff can be estopped from recovering on account of a purported "choice" by its employees which, if made, would have been unlawful.

**2. The Strong Presumption Against Estopping The Government Bars The Government Choice Defense.**

As discussed in the State's opening brief, defendants' "government knowledge" defense asserts that the State of Wisconsin can be estopped from pursuing relief for defendants' behavior because employees of the State made a "conscious choice" to do something that was barred by law. As the State showed, the law of Wisconsin and all other states holds that such estoppel, where allowed at all, is only allowable under conditions that the defendants cannot conceivably satisfy. Defendants' arguments to the contrary have no merit.

**a. The "we might argue for an exception" argument.**

Defendants assert that that they should be allowed "Government Choice" discovery because it will help them whether to argue for one of the exceptions to the rule against estopping the government. They write:

In the present case, Defendants *may* argue that (a) severe injustice would be caused if Plaintiff were allowed to recoup money that was voluntarily paid under a reimbursement scheme created by Plaintiff with full knowledge of the relationship between AWP and acquisition cost, and in furtherance of the goals of the State Medicaid program, whereas (b) application of estoppel would cause no harm to the public interest because Plaintiff has reimbursed providers in accordance with its determined methodology. The important point for purposes of this Motion is that the Court should not have to conduct this balancing in an evidentiary vacuum.

Defs. Opp. at 24 (emphasis added).

This argument has no value. No matter how much electronic "Government Choice" discovery they take, and no matter what that discovery reveals, defendants have no prospect of proving even the elements that must be proved to estop *non-governmental* parties, much less the heightened requirements needed to estop governmental parties.

The basics of proving estoppel against any party, whether governmental or non-governmental, were set forth in *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51 (1984), which happened to be a suit for overpayment by the federal government in connection with the Medicare program. The recipient of the overpayment

claimed estoppel. The Supreme Court quoted Restatement (Second) of Torts § 894(1) (1979), which sets forth the traditional test of what a defendant must show to prove an estoppel claim, regardless of the identity of the plaintiff:

If one person makes a definite misrepresentation of fact to another person having reason to believe that the other will rely upon it and the other in reasonable reliance upon it does an act ... the first person is not entitled

\* \* \* (b) to regain property or its value that the other acquired by the act, if the other in reliance upon the misrepresentation and before discovery of the truth has so changed his position that it would be unjust to deprive him of that which he thus acquired.

Thus, the party claiming the estoppel must have relied on its adversary's conduct "in such a manner as to change his position for the worse." And the reliance must have been reasonable in that the party claiming the estoppel did not know nor should it have known that its adversary's conduct was misleading. *Heckler*, 467 U. S. at 59. Wisconsin has required the same showing in other contexts. *See State v. City of Green Bay*, 96 Wis.2d 195, 202-203 (1980), which also added the requirement that "the proof of estoppel must be clear and convincing and may not rest on conjecture."

It is obvious, without any discovery whatsoever, that defendants cannot prove these basic estoppel requirements. Defendants do not and cannot assert that any State employee has led any defendant to believe anything. Defendants do not and cannot assert that anyone in the State – Governor, legislator, or Medicaid bureaucrat -- ever told any of them that he or she approved of defendants providing false AWP data to First DataBank, much less that defendants could continue with that practice without worrying about legal repercussions from the resulting inflation in ingredient cost reimbursements to providers. Hence, defendants point to nothing the State said or did to them on which defendants would have had any reason to rely. Had any representative of the State done or said something of the kind, defendants would not only know it already, but would have

featured such evidence prominently in its Opposition brief. Their failure to do so speaks volumes. Indeed, as defendants emphasized in unsuccessfully moving to dismiss, they had no dealings with the State, which paid the providers, not defendants. A provider might – with great difficulty – fashion an estoppel argument on the basis of the State’s paying its claim, but defendants are not in a position to do so.

It is likewise obvious, without any discovery whatsoever, that defendants could never prove that any reliance they might choose to allege was *reasonable*. Defendants seem to be saying that for many years the State never told them that their inflated AWP were a problem; that instead the State continued to reimburse providers on the basis of those inflated AWP; and that hence defendants “relied” on this continuing conduct by the State by continuing to provide inflated rather than true AWP data to First Data Bank. If that continuation is the “reliance” which defendants invoke to estop the State, it cannot amount to “reasonable” reliance. As shown above, the defendants do not and cannot dispute that deliberately inflating “ingredient cost” payments to far more than providers’ actual acquisition costs would have violated the law. “[T]he general rule [is] that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.” *Heckler, supra*, 467 U.S. at 63.

Wisconsin law is the same. In *Westgate Hotel, Inc. v. E.R. Krumbiegel*, 39 Wis.2d 108 (S. Ct. 1968), the Court rejected the argument that because the City of Milwaukee had not enforced an ordinance for nine years and, indeed, had appeared to approve defendants’ violations of a city ordinance, the defendant had been lulled into thinking that his conduct was lawful, and the City was therefore barred from proceeding. *Id.* at 113.

In short, no amount of Government Choice discovery could help defendants prove even the basic requirements of estoppel that must be proved against any defendant.

It is just as clear that no amount of discovery can help defendants prove the *heightened* requirements for estopping the *government*. In Wisconsin, defendants must prove that “the government’s conduct would work a serious injustice and . . . the public’s

interest would not be unduly harmed by the imposition of estoppel.” *City of Green Bay, supra*, 96 Wis.2d at 201. There is no prospect for defendants to prove that it would cause them “serious injustice” unless they can assert the “Government Choice” defense. That defense asserts that “even if we announced false AWP’s that are not prices at all, and even if those phony prices got plugged into a formula which thereby increased your ingredient costs over what federal law permitted, you knew what we were doing and shouldn’t recover.” Refusing to allow this ugly argument cannot conceivably produce “injustice,” much less “serious injustice.”

Likewise, defendants have no hope of proving *City of Green Bay*’s requirement that “the public’s interest would not be unduly harmed by the imposition of estoppel.” Allowing defendants to estop the State in these circumstances would mean tolerating a violation of federal law through the deliberate inflation of the ingredient-cost component of drug reimbursements. Such a violation of a law intended to control costs is a *per se*, and very serious, “harm to the public interest.”

In particular, defendants can never prove that the State made these overpayments “in furtherance of the goals of the State Medicaid program,” to use their words. Whatever that program’s goals may be, its first goal is to comply with binding federal law imposing limits on costs. As shown above, it would have been illegal under federal law to inflate the ingredient-cost component of drug reimbursements in order to provide a “profit” to providers.

To sum up: the “we might decide to argue for an exception” argument – the argument that defendants might decide, on the basis of “Government Choice” discovery, to advocate an exception to the presumption against estopping the State -- cannot justify that discovery. Regardless of how much “Government Choice” discovery is allowed, defendants have no prospect of proving the elements for estopping any defendant, much less the heightened requirements for estopping the State.

**b. The attempt to distinguish between the “State” and its “employees.”**

Defendants’ second argument to escape from the presumption against estopping the State is to argue that the rule only applies when it is State officials, as opposed to the “State itself,” who engage in the activity that defendants invoke as an estoppel.

Defendants claim that here “the State of Wisconsin, as opposed to a few, individual employees, made an informed and conscious decision to reimburse Medicaid providers as it did.” Defs. Opp. at 24-25. For three reasons, this argument is without merit.

First, even if defendants were correct that at some point actions by officials in violation of controlling law become the actions of the “State itself,” they still must prove that these actions of the “State itself” satisfy the elements of estoppel. But as the previous section shows, defendants can never prove those elements. Even if the purported “Government Choice” had really happened, and were considered to be the choice of the “State itself”, this purported choice still was a violation of federal law, and did not involve making any representation to defendants, much less one on which they could reasonably rely.

Second, defendants offer no convincing argument that the illegal “choice” they hypothesize could be attributed to the “State itself” as opposed to officials of the State. They offer no legal criterion for distinguishing these two situations. But the two cases defendants cite for their argument (Defs. Opp. at 25, n. 84), do suggest such a criterion, and it defeats defendants’ argument. In *Dept. of Revenue v. Family Hosp., Inc., supra*, the Supreme Court estopped the Department of Revenue from reversing its past practice and collecting a sales tax on a not-for-profit hospital’s parking receipts, because the Department had issued an official “Technical Information Memorandum” which stated “that at all times relevant to this dispute the department's published interpretation of the tax laws held that the hospital parking receipts were tax exempt.” 105 Wis.2d at 254. In *Libby, McNeill & Libby v. Wisconsin Dept. of Taxation*, 260 Wis. 551 (Wis. 1952), the

Court estopped the Department of Revenue from collecting a tax which the taxpayer had failed to pay in reliance on a published Wisconsin Supreme Court decision which the Court later overruled.

Taken together, *Libby* and *Family Hospital* suggest that where State officials act contrary to law, the action can be considered the action of the “State of Wisconsin” only when officials with authority to issue interpretations of the law openly and expressly approve the position in question and do so in a way upon which the defendant would reasonably rely. Any lesser standard would in effect dismantle the principle, discussed above, which discourages the application of estoppel against the State.

This standard defeats the “Government Choice” theory. Defendants do not claim that anyone in Wisconsin Medicaid, or any court, or the legislature, or the Governor, ever issued any kind of statement, written or otherwise, stating that defendants were entitled to inflate their AWP.

Third, the ultimate decision on how Wisconsin chooses to reimburse prescription drug providers under the Medicaid program is not made by Wisconsin Medicaid officials. It is ultimately made by the Wisconsin legislature (subject to the Governor’s veto), through the budget process that is described in more detail in the State’s brief in support of its motion to quash the depositions of certain Fiscal Bureau Budget Analysts.

No amount of electronic discovery from Wisconsin Medicaid employees will help defendants prove that the Wisconsin legislature (or the Governor) intended for the State to inflate providers’ ingredient costs in violation of federal law. Mid-level Medicaid employees may not testify about the intentions of the Legislature. Indeed, even a state legislator may not testify about the intent of a Legislative Act. *State v. Consolidated Freightways Corporation*, 72 Wis.2d 727, 738 (S. Ct. 1976). “[N]either a legislator, nor a private citizen, is permitted to testify as to what the intent of the Legislature was in the passage of a particular statute.” *Moorman Mfg. Co. v. Industrial Commission*, 241 Wis. 200, 208 (S. Ct. 1942). The e-mails of Wisconsin Medicaid officials are precisely the

sort of “non-public or informal understandings of agency officials” that are irrelevant to prove the intent of legislative action. *United States v. Lachman*, 387 F.3d 42, 54 (1<sup>st</sup> Cir. 2004).

**c. The attempt to distinguish the “public health, safety and welfare” cases.**

As the State’s opening brief showed, estoppel is never applied in cases where the Attorney General is seeking to protect the public health, safety or welfare. *State v. City of Green Bay supra*, 96 Wis.2d at 201-02. Defendants do not dispute this principle. But they claim that this is not such a case. How can this not be? Here the Attorney General is bringing a law enforcement action to enjoin an ongoing fraud on Wisconsin’s taxpayers and Medicaid and Medicare recipients, brought under some of Wisconsin’s most important statutes for protection of the public. It is hard to imagine an action more clearly seeking to protect the public welfare.

Defendants argue that *City of Green Bay* recognizes a distinction between cases where the City is trying to enforce laws enacted for public health and cases where the State seeks “forfeitures.” Defs. Opp. at 25, n. 96. But the State is not seeking forfeitures from defendants. It did not pay defendants; it paid providers on the basis of defendants’ conduct. It is seeking injunctive and damage relief from defendants.

To sum up: defendants’ “Government Choice” defense seeks to estop the State on the basis of conduct which, had it occurred, would have been unlawful. Defendants cannot prove such an estoppel no matter how much Government Choice discovery they take. For that reason, the burdensome and expensive electronic discovery they seek to take to establish this non-existent defense should not be allowed.

### III. DEFENDANTS' REMAINING ARGUMENTS FOR "GOVERNMENT CHOICE" ELECTRONIC DISCOVERY HAVE NO MERIT.

#### A. The "Allegations Of The Complaint" Argument.

The Second Amended Complaint alleges that "It has never been Wisconsin's intention to pay more for a drug than the cost of that drug to a provider." Defs. Opp. at 6, *quoting* Compl. ¶36. Defendants substitute the words "Wisconsin Medicaid" for "Wisconsin" in this allegation, then argue that they need "Government Choice" electronic discovery to help rebut it. Defs. Opp. at 6. As shown in Section II, defendants cannot establish the intent of the State of Wisconsin by showing the intent of "Wisconsin Medicaid" officials who, had they made the choice defendants claim, would have been violating the law.

Defendants also argue that they need this discovery to disprove a supposed allegation of the Complaint that "it [Wisconsin Medicaid] understood the published AWP for drugs to reflect the actual average prices that providers paid to wholesalers." Defs. Opp. at 6, *citing* Compl. ¶¶ 36, 59. Neither of these cited paragraphs makes this allegation. Paragraph 36 reads:

Because Wisconsin, like most states, has no consistent source of systematic information about providers' acquisition cost for the drugs that it reimburses, Wisconsin has relied on the prices reported to First DataBank by defendants and published by First DataBank, to estimate the acquisition cost of most of its drugs. Consistent with the explanation of AWP by First DataBank that some providers pay less than the published AWP and some more – that the AWP is only an average of wholesale prices – Wisconsin set its reimbursement rate at AWP minus 10% for most of the relevant period. Wisconsin also pays the provider a dispensing fee. It has never been Wisconsin's intention to pay more for a drug than the cost of that drug to a provider.

And paragraph 59 reads:

Defendants have themselves continuously concealed the true price of their drugs and continued to publish deceptive AWP and WACs as if they were real, representative prices. Indeed, in the 2000 edition of Novartis' Pharmacy Benefit Report, an industry trade publication, the glossary defines AWP as follows:

Average wholesale price (AWP) – A published suggested wholesale price for a drug, based on the average cost of the drug to a pharmacy from representative sample of drug wholesalers. There are many AWP's available within the industry, AWP is often used by pharmacies to price prescriptions. Health plans also use AWP – usually discounted – as the basis for reimbursement of covered medications.

*Novartis Pharmacy Benefit Report: Facts and Figures*, 2000 Edition, East Hanover, NJ, Novartis Pharmaceuticals Corporation, p. 43.

Defendants also argue that they need this discovery to disprove the allegation that the false AWP's that defendants caused to be published "deprived it [Wisconsin Medicaid] of pricing information it needed to estimate accurately the acquisition costs of Defendants' drugs." Defs. Opp. at 6, *citing* Compl. ¶ 34. No far-flung electronic "Government Choice" evidence can disprove this self-evident proposition. Had the defendants published honest prices, the State would have had, for every one of the many thousands of drugs that the State might be called upon to reimburse, the best available current estimates, from the parties in the best position to know them, of what the average wholesale price was. Defendants cannot claim that the State did assemble or could have assembled that sort of current, accurate, and detailed information from any other source. The "Government Choice Evidence assembled to date" cited by defendants shows the contrary. *See, e.g.*, Defs. Opp. Ex. 11, pp. 51, where Carrie L. Gray, a policy analyst in the Wisconsin Medicaid bureaucracy, testified that "First DataBank provides us with our pricing information." Beyond that, she said, "we don't have the resources" to collect information about actual pharmacy acquisition prices. *Id.*, p. 52. When defendants showed her various other possible documents, such as wholesaler data from Cardinal, a wholesaler, she made clear that this information could not be relied on to show the real prices that pharmacies were paying. *Id.* at 54-55.

**B. The "Reliance" Argument Under § 100.18(1).**

Defendants argue that under the State's Deceptive Trade Practice Claim (Wis. Stat. § 100.18(1)), the State must prove "among other things, that it relied on Defendants'

representations.” Defs. Opp. at 10. This year, the Wisconsin Supreme Court held to the contrary: “A plaintiff does not have the burden of proving reasonable reliance.” *K&S Tool & Die Corporation v. Perfection Machinery Sales, Inc.*, 301 Wis.2d 109 (S. Ct. 2007) at ¶35. All a plaintiff must prove is a “causal connection between the untrue, deceptive, or misleading representation and the pecuniary loss.” *Id.* The causal connection the State will prove is simple. The State sets ingredient cost reimbursement for brand name drugs at AWP minus a percentage, and First DataBank gets its AWP information from defendants. If defendants inflate the AWP, then the amount the State pays will be likewise inflated, as a matter of simple arithmetic.

Defendants argue that perhaps this “reliance” rule will change, because the Supreme Court recently accepted review of the unpublished opinion in *Novell v. Migliacco*, No. 2005AP2852 (Wis. Ct. App. October 17, 2006). Defs. Opp. at 11. The Supreme Court does not say why it accepts review of any case, but one can be confident that it did not accept review of *Novell* to consider whether to overturn the holding of a unanimous decision of a few months earlier.

Defendants also grasp at the statement in *K&S* that the reasonableness of a plaintiff’s reliance may be relevant in considering whether a defendant’s false statements were a substantial factor in a plaintiff’s loss. Defs. Opp. at 10 & n. 33, *quoting K&S* at ¶ 36. For two reasons, this statement provides no warrant for defendants’ proposed “Government Choice” discovery. First, as stated above, there is an immediate, automatic, and arithmetic causal mechanism at work. If defendants inflate their AWP, the AWP-based formula the State uses for calculating reimbursements for ingredient costs will produce inflated ingredient costs. Second, the argument is just another version of an argument to estop the State. Like all states, Wisconsin has no practical alternative to basing much of its drug reimbursements on formulas depending on AWP as a way of estimating provider ingredient costs. And Wisconsin is barred by federal law from using a formula that it knows to be paying inflated ingredient costs.

**C. The “Secret Rebate” Argument Under Wis. Stat. § 133.05.**

Defendants assert that they need to discover whether Wisconsin Medicaid employees knew that defendants were paying “secret” discounts within the meaning of Wis. Stat. § 133.05. This argument comes oddly from defendants who are fighting tooth and nail to keep their discounting policies of ten years ago secret. In any event, the argument affords no basis for seeking the e-mails of Wisconsin Medicaid employees. Whether discounts were “secret” within the meaning of the statute depends on the conduct of the *defendants*. If evidence existed (and it does not) that defendants informed the State of these discounts, it would be in defendants’ files. In contrast, defendants cannot destroy the secret rebate claim by showing that Wisconsin Medicaid employees learned from sources other than defendants about these discounts and then made a choice to violate the law. That is the invalid “Government Choice” theory in another guise.

**D. The Argument About “Falsity” Under Wis. Stat. § 49.49.**

Defendants argue that electronic “Government Choice” discovery may reveal State employees’ understanding of the term “average wholesale price.” They argue that if employees regarded it as a vague, indefinite term, it cannot be “false” within the meaning of the Medicaid Fraud Statute, Wis. Stat. § 49.49. Defs. Opp. at 13.

This argument has no merit. First, as discussed above, it is the legislature whose intentions are relevant here. Non-public or informal opinions of mid-level executive employees about the meaning of the term AWP are not admissible to prove that intention.

Second, defendants merely rehash an argument they have lost on motions to dismiss in virtually all AWP cases. The argument is that names – in this case, the name “average wholesale price” – carry no meaning, despite their plain language, and hence are not statements at all. Judge Saris explained in detail why this argument is wrong. The MDL defendants moved for summary judgment, arguing that the term “average wholesale price” in the federal Medicare statute had no established meaning and hence they were free to report any prices they wanted as “average wholesale prices” without

violating that statute. Judge Saris disagreed. She held that the words “average wholesale price” in the statute would be given their plain meaning, which is “the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies.” *In re Pharmaceutical Industry AWP Litigation*, 460 F.Supp.2d 277, 278, 284-288 (D. Mass. 2006). *See also Federated Nationwide Wholesalers Service v. FTC*, 398 F.2d 253, 257, n.3 (2d Cir. 1968): “The term ‘wholesale price’ is generally defined as the price which a retailer pays to its sources of supply when purchasing goods for resale to the ultimate consumer.”

The same result follows under Wisconsin law. A statement is “untrue” when it “does not express things exactly as they are.” *Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis.2d 56, 65 n.3 (Ct. App. 1987). *See also* Wisconsin Pattern Jury Instruction (Civil), § 2418 (1998), which tells juries that a statement is untrue “if it is false, erroneous, or does not state or represent things as they are.” Giving price data the name “average wholesale price,” when the data do not represent prices at all, much less averages of prices to wholesalers, does not represent things as they are, and therefore makes a false statement about those data.

#### **E. The “Unjust Enrichment” Argument.**

According to defendants, electronic discovery of Medicaid employees might help them prove that allowing defendants to retain any increase in profits or market share that resulted from their practice of announcing false AWPs would not be “unjust.” Defs. Opp. at 14-15. The argument is that (1) the State made a choice to violate the law and to incur inflated ingredient costs by using defendants’ false prices in its reimbursement formula, and (2) the State’s choice to violate the law makes it “just” to allow defendants to retain the fruits of their practice. This argument amounts to asserting that two wrongs make a right. It has no merit, because it is just another version of the “Government Choice” defense – trying to hold the State responsible for the actions of its officials.

**F. The “Limitations” Argument.**

Defendants’ “limitations” argument pertains to a single claim of the State: its claim for violation of the Medicaid Fraud Statute. The parties dispute which statute of limitations applies to this claim. The State asserts that it is the ten-year statute of Wis. Stat. 893.87.<sup>2</sup> Defendants assert that it is the six-year statute of Wis. Stat. § 893.93 (1)(b). Defs. Opp. at 16-17. But under either statute, it is undisputed that there is a “discovery rule” under which a cause of action for fraud cannot accrue “until the plaintiff knows objectively, the cause of the injury and defendant’s part in that cause.” *Kolpin v. Pioneer Power & Light Company, Inc.*, 162 Wis.2d 1, 22-23 (Sup. Ct. 1991). The existence of the discovery rule means that the State may be able to recover on this claim for conduct occurring before the beginning of the statutory limitations period – i.e., for conduct before June 3, 1998 (if defendants are right about the governing limitations statute) or before June 3, 1994 (if the State is right).

Defendants argue that they need electronic discovery to determine whether, before June 3, 1998, the State had “discovered” its cause of action within the *Kolpin* test. The argument is unpersuasive. First, as the State’s opening brief discussed, e-mail is a recent technology. Defendants do not contend that the State was using e-mail to any significant degree prior to June 3, 1998. Defendants argue that perhaps subsequent e-mails from the “modern period” refer to the State’s knowledge at earlier times. Defs. Opp. at 18 n. 62. This unlikely possibility cannot in itself justify the expensive and burdensome discovery sought by defendants. To bolster their case that something like this might turn up, defendants cite two post-1998 documents alluding to a 1997 OIG

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<sup>2</sup> That section provides: “Any action in favor of the state, if no other limitation is prescribed in this chapter, shall be commenced within 10 years after the cause of action accrues or be barred. No cause of action in favor of the state for relief on the ground of fraud shall be deemed to have accrued until discovery on the part of the state of the facts constituting the fraud.” Clearly fraud against the State is embraced in this provision. The six-year fraud general statute of § 893.93(1)(b) does not mention the State, whereas § 893.87 specifically discusses fraud claims against the State.

Report stating that pharmacies could obtain brand-name drugs at less than AWP. *Id.* But no draconian e-mail search is necessary to show the undisputed fact that Wisconsin received such reports.

Second, what matters under *Kolpin* is that the State discovers the *defendants'* part in any Medicaid fraud. Defendants have pointed to no evidence anywhere, at any time, that would have told the State, or anyone else, of defendants' role in the fraud alleged by this claim.

Third, as the State's opening brief showed, the case for ordering a vast e-mail search is weakened still further by the fact that the "continuing violation" doctrine will apply, rendering the discovery rule irrelevant. "A cause of action accrues only when the cause of action is complete; and where, as here, it is averred in the affidavits that the negligent acts of malpractice were continuous, the cause of action is not complete until the last date on which the malpractice occurred. If an action is timely brought in relationship to that last date, the entire cause of action is within the jurisdiction of the court." *Kolpin, supra*, 162 Wis.2d at 22. Defendants argue that the doctrine should apply only to negligent acts, not fraudulent ones. Neither *Koplin* nor any other Wisconsin case imposes such a restriction. Fraud is more culpable than negligence, and there is less, not more, reason to excuse a fraud defendant from the continuing violation doctrine than a negligence defendant. The State alleges, and will prove, a cause of conduct which continues even today. Thus, this cause of action, as in *Kolpin*, has not yet been completed.

In short, any limitations issues presented by the § 49.49 claim cannot justify defendants' proposed electronic discovery blitzkrieg. Nor does the defendants' claim that they need this discovery for a laches defense. As plaintiffs' opening brief remarked, a laches defense is unavailable against the State in this case. Defendants argue otherwise, citing cases from Illinois which allowed laches claims against the State under certain limited circumstances. Defs. Opp. at 27 & n. 95. These cases are not inconsistent with

Wisconsin's rule, which is that where an action is "brought by the State in its sovereign capacity to protect a public right," laches cannot apply. *State v. Josefsberg*, 275 Wis. 142, 81 N.W.2d 735 (S. Ct. 1957); accord, *State v. Chippewa Cable Co.*, 21 Wis.2d 598, 124 N.W.2d 616 (S. Ct. 1963); *Stein v. State Psychology Examining Bd.*, 265 Wis.2d 781, 668 N.W.2d 112 (Ct. App. 2003). This is a lawsuit brought by the Attorney General under an important group of statutes for the protection of the public. Laches is therefore unavailable as a defense.

**G. The "Amount Reasonably Necessary" Argument Under Wis. Stat. § 49.49.**

Defendants offer another argument related to the Medicaid Fraud claim under § 49.49. According to defendants, that statute limits damages to amounts "reasonably necessary to remedy the harmful effects of the violation." Defs. Opp. at 19 & n. 63, quoting Wis. Stat. § 49.49(6). Defendants then construct a complicated argument by analogy to the federal False Claims Act to the effect that damages are to be measured by reference to the amount the State would have paid had it known the "true facts." Defendants then claim that electronic discovery is required to determine what "true facts" were known to the "State." *Id.* This argument is yet another repackaging of the argument for estopping the State on the basis of Medicaid officials' knowledge.

Moreover, guidance on the allowable damages is provided by § 49.49(1)(c), which gives the State an action for damages in the event of a criminal conviction under the statute. Subsection 1(c) reads, in relevant part:

- (c) *Damages.* If any person is convicted under this subsection, the state shall have a cause of action for relief against such person in an amount 3 times the amount of actual damages sustained as a result of any excess payments made in connection with the offense for which the conviction was obtained . . . *Actual damages shall consist of the total amount of excess payments, any part of which is paid by state funds.* [Emphasis added.]

It does not make sense that the State's "actual damages" would differ, as defendants imply, in a civil action brought by the Attorney General in the absence of a criminal

conviction. Actual damages are actual damages, period. Accordingly, if the State proves its Medicaid fraud case under §49.49, its basic damages will have to be the “total amount of excess payments,” a figure that will arithmetically from the formula for reimbursing ingredient cost and the amount of the inflation in defendants’ AWP. As already discussed, no electronic “Government Choice” discovery can be relevant to that calculation.

#### **H. The “Failure To Mitigate” Argument.**

Defendants argue that they have a “potential” defense of failure to mitigate and that electronic discovery of Medicaid officials could help them prove it if they decide to make it. Defs. Opp. at 19. The argument is empty. As defendants admit, none of the statutes under which Wisconsin sues mentions a failure-to-mitigate defense. *Id.* at 20. And they can cite no Wisconsin statute that has allowed such a defense under any of them. More importantly, defendants can cite no case from anywhere in the country where any court has imposed an obligation on a *government* to mitigate damages suffered through deceptive conduct. There is much law to the contrary. In *United States v. Aging Care Home Health Inc.*, 2006 WL 2915674 (W.D.La. 2006), the Court wrote:

Defendants argue the government’s alleged fault in not discovering defendants’ alleged wrongdoing earlier and argues that had the government intervened earlier, defendants would not have continued what the government now claims was improper billing. This argument does not raise an issue of mitigation, but is essentially, as defendants’ counsel admitted in the hearing, more in the nature of an attempt to assert the government’s fault, which is not relevant to the issues in the lawsuit and is not the defense stated in paragraph 149. Further, as to the fraud claims under the False Claims Act, *the government has no duty, in any event, to mitigate its losses.*

*Id.* at \*1. Likewise, “defendant tortfeasors in failed bank litigation cannot limit their liability by attacking the conduct of the federal banking agencies.” *FDIC v. Gladstone*, 44 F.Supp.2d 81, 85 (D.Mass.1999). *See also FDIC v. Oldenburg*, 38 F.3d 1119, 1121-1122 (10th Cir.1994), *cert. denied*, 516 U.S. 861 (1995) and cases there cited; *FDIC v.*

*Mijalis*, 15 F.3d 1314, 1324-1325 (5th Cir.1994); *FDIC v. Bierman*, 2 F.3d 1424, 1438-1441 (7th Cir.1993); *RTC v. Hecht*, 818 F. Supp. 894 (D.Md.1992).

There are good reasons for not allowing the mitigation defense in such circumstances. First, governments do not act, and cannot be expected to act, like private persons. By their nature, governments are lumbering. They cannot turn on a dime upon discovering fraud, as the present case demonstrates. It can take years to put a reimbursement structure into place, and powerful interest groups (such as drug manufacturers and pharmacists) are always ready to fight tooth and nail against changing them. Judge Saris rightly found that even after certain defendants' conduct in reporting grossly inflated AWP prices was known by the federal government, that conduct was still "egregious" and hence unlawful under the Massachusetts consumer protection statute because the federal government could not move quickly to fix the problem. *In Re Pharmaceutical Average Wholesale Price Litigation, supra*, 491 F.Supp.2d at 95. State governments are no more agile.

Second, to allow the defense would amount to circumventing the rule limiting estoppel against the State.

Moreover, Wisconsin is mitigating by bringing this lawsuit. The State rightly believes that the easiest and cheapest way to right the system for reimbursing prescription drugs under Medicaid is for defendants to report true AWP prices, to demand that the publishers publish those prices, and to hold accountable those defendants who continue not to do so. The State is not required to further distort its drug reimbursement formulas in order to counteract the defendants' continuing reporting of false prices. To impose that requirement, as defendants' "mitigation" argument urges, is to have the fraudulent tail wag the honest dog.

#### **I. The Argument Analogizing § 49.49 to the False Claims Act.**

Defendants analogize the State's Medicaid Fraud claim under Wis. Stat. § 49.49 to a claim under the federal False Claims Act (FCA). Defendants then argue that in

claims under the FCA, “government knowledge can be a defense.” Defs. Opp. at 26. Hence, they argue, “Government Choice” electronic discovery should be allowed to help them disprove the § 49.49 claim. *Id.* The argument has no merit.

Section 49.49 is not the False Claims Act, and no Wisconsin case has turned to the FCA for guidance in interpreting it. To the contrary, interpretations of the Medicaid Fraud statute have opted for simplicity, rather than the complications of FCA caselaw. For example, the only *scienter* requirement under § 49.49 is the intentional making of a false statement. *State v. Williams*, 179 Wis.2d 80, 88-89 (Ct. App. 1993).

But in any case, using FCA caselaw as a guide to interpreting § 49.49 would hurt defendants badly. That caselaw provides yet another argument for disallowing the “Government Choice” defense, and hence for quashing electronic discovery designed to pursue that defense.

Cases under the False Claims Act in fact disfavor a “government knowledge” defense. In the MDL litigation, in denying a motion to dismiss California’s AWP claim under the federal False Claims Act, Judge Saris reviewed the status of “government knowledge” defenses to FCA cases:

Some courts have held that governmental knowledge will vitiate a possible FCA claim where “the government knows *and approves* of the particulars of a claim for payment before that claim is presented.” *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7<sup>th</sup> Cir. 1999) (emphasis added). In these instances, “the presenter cannot be said to have knowingly presented a fraudulent or false claim.” *Id.* Thus, there may be “occasions when the government’s knowledge of or cooperation with a contractor’s actions is so extensive that the contractor could not as a matter of law possess the requisite state of mind to be liable under the FCA.” *Id.*; see also *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9<sup>th</sup> Cir. 1991) (holding that knowledge by federal officials may “show that the defendant did not submit its claim in deliberate ignorance or reckless disregard of the truth”). However, government knowledge is not an automatic bar to suit under the FCA. *United States ex rel. Butler v. Hughes*, 71 F.3d 321, 327 (9<sup>th</sup> Cir. 1995); *Shaw v. AAA Eng’g & Drafting, Inc.*, 213 F.3d 519, 534-535 (10<sup>th</sup> Cir. 2000).

As California alleges it did not know the extent of false drug prices, or approve them, dismissal is inappropriate.

*In re Pharmaceutical Industry Average Wholesale Price Litiga.*, *supra*, 478 F.Supp.2d at 174. *See also Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp.2d 719, 730 (N.D. Ill. 2007), which reiterated that “mere acquiescence (rather than approval) by government employees is not sufficient to avoid liability, as requiring mere acquiescence would preclude FCA liability any time a government employee and a defendant were in cahoots.”

Judge Saris’s analysis is consistent with a large body of FCA caselaw that imposes a heavy burden on defendants who want to negate the “falsity” or “scienter” requirements of the FCA by showing that the Government knew and approved of their actions. For example, “even a contractor who tells a government contracting officer that a claim is false still violates the statute when the false claim is submitted.” *United States ex rel. Mayman v. Martin Marietta Corp.*, 894 F. Supp. 218, 223 (D. Md. 1995). To show that its *scienter* was negated, the defendant must offer credible evidence of a meeting of the minds between a defendant and the government such that the defendant reasonably believed that its representations were accurate and its conduct was permissible. To show such, courts have required that the defendant (1) prove that it identified a problem with performance under a contract, (2) disclose the problem to the government, and (3) cooperate with the government to resolve the problem. *See, e.g., United States ex rel. Costner v. URS Consultants, et al.*, 317 F.3d 883, 888 (8<sup>th</sup> Cir. 2003) (defendants’ “openness with the EPA about [problems in the cleanup of a hazardous size] and their close working relationship in solving the problems negated the required scienter” under the FCA); *Shaw, supra*, 213 F.3d at 534 (defendant’s knowledge was not negated where defendant was not forthcoming about its conduct and “repeatedly evaded government employees’ questions” about its failures to recover silver from photo lab chemicals); *Butler, supra*, 71 F.3d at 327-29 (9<sup>th</sup> Cir. 1995) (defendant “completely cooperated and shared all information” during the testing of Apache helicopters); *Wang*

*ex rel. United States v. FMC Corp.* 975 F.2d 1412, 1421 (9<sup>th</sup> Cir. 1992) (defendant disclosed to the Army a deficiency with a howitzer and had dialogue about how to fix it).

Defendants do not argue, and cannot plausibly argue, that any amount of “Government Choice” discovery, no matter what it turned up, would show this sort of knowledge and approval by the State of what they did. Even assuming the State knew that AWPAs as announced in First DataBank were higher on average than actual provider acquisition costs, and even assuming that the State knew at all relevant times that these announced prices resulted from defendants’ supplying inflated price data to First DataBank, it is laughable to assert that anyone in the State – whether Medicaid officials, or legislators, or the Governor -- *approved* of defendants’ providing these inflated prices. Defendants suggest no reason why the State could possibly approve of such a practice. Even if the State wants to provide pharmacists a profit on Medicaid drug dispensing, the State still needs accurate information about providers’ *real* acquisition costs in order to make rational determinations about what profit it will choose to provide. The last thing in the world the State would approve of would be a practice of providing inflated price data under the guise of “Average Wholesale Price.” Such a practice can only throw obstacles in the way of the State carrying out its objective.

The FCA “government knowledge” cases cited by defendants (Defs. Opp. at 26, n. 87), to the extent they are relevant at all, only emphasize the fact that express government *approval* of the particular defendant’s conduct is necessary. For example, in *United States ex rel. Englund v. Los Angeles County*, 2006 WL 3097941 (E.D.Cal. 2006), the court denied relief because “it is undisputed that the Federal government knew what the County was doing and implicitly approved of the County’s actions.” *Id.* at \*12. In *Costner, supra*, the court merely held that “A contractor that is open with the government regarding problems and limitations and engages in a cooperative effort with the government to find a solution lacks the intent required by the Act.” 317 F.3d at 888.

To sum up: in the absence of a legally valid “Government Choice” defense, none of defendants’ other arguments for their proposed electronic discovery has merit.

#### **IV. JOHNSON & JOHNSON’S SEPARATE RESPONSE HAS NO MERIT.**

Defendant Johnson & Johnson has filed a separate response to the State’s Motion for Protective Order. Its main purpose appears to be to boast about having escaped liability (by the skin of its teeth) in the recent trial before Judge Saris. If Johnson & Johnson thinks that this decision provides additional support for defendants’ proposed electronic discovery, it is mistaken. To understand why this is so, some background on the trial before Judge Saris is necessary.

The trial before Judge Saris involved a plaintiff class consisting of *private* insurance companies and health insurance plans that asserted claims under the Massachusetts’ consumer protection statute and other state law causes of action. *In re Pharmaceutical Industry Average Wholesale Price Litigation, supra*, 491 F.Supp.2d at 30. Neither the state of Wisconsin nor any other governmental purchaser was involved in the trial. Neither the federal Medicaid program nor any state’s Medicaid program was at issue, much less the federal regulations establishing limits on reimbursement to providers in Medicaid programs at no more than the providers’ estimated acquisition costs.

In construing the Massachusetts consumer protection statute, Judge Saris determined that to be an actionable “unfair practice,” defendants’ behavior had to be “egregiously wrong.” 491 F.Supp.2d at 57, *quoting Mass. Sch. Of Law v. Am. Bar Assn.*, 142 F.3d 26, 41 (1st Cir. 1998). She then applied this “egregious misconduct” standard to determine whether defendants had violated Massachusetts law. *See, e.g.*, 491 F. Supp. 2d at 60, 68.

Plaintiffs in the case before Judge Saris chose to advance a conservative theory of liability under the Massachusetts consumer protection statute – an approach that was dictated by the fact that their clients were all private entities and included enormous and highly sophisticated insurers (like Blue Cross) who had an intimate knowledge of the marketplace for prescription drugs. Plaintiffs’ expert witness, Raymond S. Hartman, took the position that during the relevant period, the “marketplace” had an “expectation that AWP did not exceed the average sales price [the price paid by providers to obtain the drugs] by more than 30%.” 491 F.Supp.2d at 40. The plaintiffs used this opinion as an “expectations yardstick.” Under this theory, “Dr. Hartman uses the yardstick to find liability wherever a drug exceeds that threshold.” *Id.*, at n. 20. By adopting this theory, the plaintiffs in effect conceded that the announcement of AWP’s that were less than 30% above the true acquisition cost of providers did not violate Massachusetts law with respect to this class of private payers. With plaintiffs having made this concession, the liability issue was whether spreads greater than the “Hartman expectations yardstick” were unlawful under Massachusetts law.

Judge Saris found three defendants (AstraZeneca, Bristol-Myers Squibb, and Warrick (Schering-Plough) liable for drugs whose “spreads” had exceeded the Hartmann expectations yardstick. Although she found that Johnson & Johnson had published AWP’s that significantly exceeded the true acquisition costs and had marketed this spread to physicians in connection with the drug Remicade, she nevertheless found Johnson & Johnson not liable, concluding: “While Johnson & Johnson’s conduct was at times troubling, it did not rise to the level of egregious misconduct actionable under the Massachusetts Chapter 93A because its spreads never substantially exceeded the range of

what was generally expected by the industry and [federal] government.” 491 F.Supp.2d at 31.

Johnson & Johnson claims that because Judge Saris found relevant what *private* payers knew about the degree of inflation of AWP, Johnson & Johnson must be given electronic discovery into what Medicaid officials of the State of Wisconsin knew at a given time about that subject. The argument is without merit, for three reasons.

First, the present case is not brought by a private payer, but rather by a government payer (the State of Wisconsin) under the Medicaid program. The difference is critical. The private payers who brought the case before Judge Saris were free actors in terms of what they could pay providers for their acquisition costs. To the extent that those payers understood that the defendants were inflating their AWPs, but had an accurate understanding of the degree to which defendants were inflating them, they were free to set reimbursement formulas as they liked, including formulas based on AWP that provided a profit to the providers for the ingredient cost of the drugs. In that context, where the private payers were free actors, it was at least arguable that Johnson & Johnson did not act “egregiously” as long as its announced AWPs, though false, did not exceed the true AWPs by more than those private payers assumed.

But in the instant case, the State is not a free actor. As explained earlier, it is required by federal law to reimburse providers for the ingredient cost of a drug at no more than the provider’s acquisition cost for that drug. Defendants know that the State’s payments to providers are subject to this federal limit. If the defendants’ announced AWPs result in the State systematically reimbursing ingredient costs at more than the law permits, then defendants’ conduct is indefensible by any standard, whether the

Massachusetts standard of “egregiousness” or the far less demanding standard of Wisconsin law, which simply forbids making false statements, period.

Second, to apply the theory of Judge Saris to a suit by a government payer would circumvent the Wisconsin law against estopping the State on account of the knowledge of its Medicaid officials. As this brief has shown, a defendant who reports false prices that cause the State to reimburse ingredient costs at levels that violate the law cannot estop the State from recovering simply by showing that persons within the State’s bureaucracy knew the prices were false. That law prohibits the State from using “Estimated Acquisition Cost” to subsidize provider profits – much less subsidize them to the tune of the markups that would be tolerated by using the “Hartman expectations yardstick” as a threshold for liability.

Third, whatever strategic or other reasons led the private plaintiff class in the case before Judge Saris to advance an “expectations” theory of liability and a 30% yardstick, the State of Wisconsin is not proceeding under such a theory here (nor is it required to).

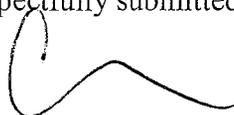
In sum, it would not be a defense even if Johnson & Johnson could show that officials of the State of Wisconsin had the same “expectation” about the inflation of AWP that Dr. Hartmann attributed to sophisticated private payers. For this reason, Judge Saris’s ruling does not justify electronic discovery of Wisconsin Medicaid officials.

## CONCLUSION

The State respectfully requests that its Motion For Protective Order Barring Defendants From Requiring Wisconsin To Search Electronic Files For What Defendants Call Government Knowledge Documents be denied.

Dated: November 30, 2007

Respectfully submitted,



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One of Plaintiff's Attorneys

CHARLES BARNHILL, SBN 1015932  
ELIZABETH J. EBERLE, SBN 1037016  
GEORGE F. GALLAND, JR. (Pro Hac Vice)  
ROBERT S. LIBMAN (Pro Hac Vice)

Miner, Barnhill & Galland, P.C.  
44 East Mifflin Street, Suite 803  
Madison, WI 53703  
(608) 255-5200

FRANK D. REMINGTON  
Assistant Attorney General, SBN 1001131  
CYNTHIA R. HIRSCH  
Assistant Attorney General, SBN1012870

Wisconsin Department of Justice  
Post Office Box 7857  
Madison, Wisconsin 53707-7857  
(608) 266-3542 (FDR)  
(608) 266-3861 (CRH)

P. Jeffrey Archibald, SBN 1006299  
Archibald Consumer Law Office  
1914 Monroe St.  
Madison, Wisconsin 53711  
(608) 661-8855

Attorneys for Plaintiff, State of Wisconsin

