

STATE OF WISCONSIN

CIRCUIT COURT
Branch 9

DANE COUNTY

STATE OF WISCONSIN,
)
)

Plaintiff,
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v.
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AMGEN INC., et al.,
)
)

Defendants.
)
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Case No. 04-CV-1709
Unclassified – Civil: 30703

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

Defendants have gone well beyond the bounds of the discovery rules (and reason for that matter) in their unsparing search (at plaintiff’s time and expense) for documents which they contend support their “government knowledge” defense. Their latest sally is to demand that Wisconsin hire an outside agency to pore through the e-mails of at least 32 past and former employees in the hope of supporting this defense.

This search is designed to uncover documents showing the slightest awareness on the part of state employees at any level that some drugs were actually sold to providers at prices below the false prices defendants’ intentionally published. Defendants hope to use such material to argue to the jury that Wisconsin employees were either negligent or wanted to overpay for defendants’ drugs and embraced defendants’ fraud as a means of doing so---and that as a result defendants’ fraudulent conduct should be exculpated.

It is time to rein this search in. Defendants’ government knowledge defense is apocryphal. Knowledge on the part of employees of the State of Wisconsin of

defendants' unlawful scheme, if any such knowledge exists, cannot exculpate defendants' conduct or limit the damages payable to Wisconsin's taxpayers. Hence, the materials defendants are seeking cannot lead to the discovery of relevant evidence, and Wisconsin should not be put to the time and expense of looking for such materials, particularly at the level defendants' now demand. Plaintiff, therefore, requests that it be protected from any further discovery by defendants the sole purpose of which is designed to support their government knowledge defense. Furthermore, because the Gebhart memo, which defendants assert as an example of an admission of government knowledge, is protected by privilege, inadmissible and irrelevant based on the law that follows, Wisconsin asks for the return of the memo.

Plaintiff begins with a look at the regulatory and factual background which controls the resolution of this issue, and then sets out the law which demonstrates why defendants' discovery demands are improper. Lastly, plaintiff explains why defendants must surrender the Gebhart memo.

I. GOVERNMENT KNOWLEDGE IS NO DEFENSE IN THIS CASE.

A. Federal and State Regulations Require Wisconsin to Pay Providers No More Than the Estimated Acquisition Cost for Medicaid Drugs.

Section 42 U.S.C. 1396(a)(30)(A) sets forth the outline of the payment structure required of each state that participates in the Medicare program: "A State plan for Medical Assistance must---(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services....as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the

extent that such care and services are available to the general population in the geographic area.”

The Secretary of the U.S. Department of Health and Human Services promulgated regulations to implement this sub-part. The Secretary explained the “Basis and purpose” of these regulations as follows: “In this subpart, secs. 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care.” 42 CFR § 447.300 (The entirety of the regulations are attached as exhibit A.) One of the central purposes of these regulations was to hold down the cost of the program (and thereby expand access to participants with the finite amount of money available) by limiting the amounts states could pay participating providers. Thus, the regulations state explicitly that “The Medicaid agency must not pay more than the upper limits described in this subpart.” 42 CFR 447.304.¹ The subpart’s upper limits are set forth in 42 CFR §§ 447.331 and 332. In essence, these regulations require that for brand name drugs, and for generic drugs for which no federal upper limit is set, states must reimburse at “the lower of the---

- 1) Estimated acquisition costs plus reasonable dispensing fees established by the agency;
- or (2) Providers usual and customary charges to the general public.”

The estimated acquisition cost is defined by regulation as 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.” 42 C.F.R. § 447.301.

¹ If the Medicaid agency pays more than this amount it may not seek reimbursement for this overage. Wisconsin sought and received reimbursement for all its Medicaid expenditures.

The Secretary has given the States more latitude in connection with multi-source drugs (generic drugs, certified by CMS, made by three or more manufacturers) mandating that states pay no more than an upper limit set by CMS, called the Federal Upper Limit (FUL), and less if the state chooses. *See* 42 C.F.R. § 447.331, 332. Wisconsin has chosen to pay less than the FUL by utilizing a formula requiring that providers of multi-source drugs be reimbursed at the lesser of the estimated acquisition cost, the provider's usual and customary charge, or the Wisconsin MAC listing (Exhibit B).

These Federal regulations control Wisconsin's reimbursement policy. They have never been altered by the Federal government during the period relevant to this case. And no Wisconsin employee is authorized to exempt the defendants from these regulations. "State participation in the Medicaid Program is optional. If a state does elect to participate, it must comply with all provisions of the federal Medicaid statute and implementing regulations..." *J.K. v. Dillenberg*, 836 F.Supp. 694, 696 (D.Az. 1993).

These rules are public, and it is defendants' obligation to know, understand and abide by these rules. "As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement." *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 64 (1984). *See, North Memorial Medical Center v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995).

B. The Factual Context of Defendants' Assertion of Their "Government Knowledge Defense."

Wisconsin accuses the defendants of purposely hijacking the principal data sources upon which Wisconsin relied to reimburse providers by filling the available medical compendiums with false average wholesale prices, and by standing by while Wisconsin overpaid for drugs based on formulas using defendants' false prices.

There is really no dispute over the fact that defendants published average wholesale prices for their drugs which were greatly in excess of their drugs actual average wholesale prices. Some defendants have admitted it (see Exhibit C, plaintiff's motion for summary judgment against Johnson & Johnson), whereas others simply plead ignorance but plead no contrary evidence. No defendant contends that the published average wholesale prices of its drugs were accurate. Moreover, plaintiff now possesses the records of the three major wholesalers which conclusively show that the published average wholesale prices of defendants' drugs---every one-- greatly exceeded the actual average wholesale prices of their drugs.

There also can be no significant argument over the fact that it is unlawful to publish a wholesale price that is greater than retailers are actually paying. This is true in Wisconsin by statute, *see, e.g.*, Wis. Stat. § 100.18(10)(b), and true through decisional authority elsewhere. See plaintiff's motion for summary judgment against Johnson & Johnson, Exhibit C.

Finally, there is no dispute that, contrary to federal regulations, Wisconsin reimbursed providers at levels far in excess of the acquisition cost of the drugs they dispensed.

That these three elements of plaintiff's case are irrefutable has left the defendants with only two arguments which are: 1) they didn't publish the false prices, someone else did; and 2) Wisconsin employees knew that at least some of the published prices for defendants' drugs were being discounted in the market place and this knowledge bars Wisconsin from recovery for defendants' unlawful conduct. The first defense is not at issue in connection with this motion, but the second defense—the so-called government

knowledge defense—is the basis of defendants’ latest document demands. Because this is not a viable defense as a matter of law, defendants should be prohibited from requiring that Wisconsin engage in a further search for such documents.

C. Defendants’ Government Knowledge Defense Is Inapplicable to This Case and Documents Supporting It Cannot Lead To Relevant Evidence.

1. Wisconsin Cannot Be Estopped From Enforcing Its Laws Against the Defendants By The Acts of Its Employees.

The central issue in this case is whether defendants’ conduct in unlawfully publishing false prices for their drugs interfered with Wisconsin’s ability to meet its federal obligation to pay only the estimated acquisition cost of the drugs used by their citizens. That it did so is virtually a tautology. Had defendants published true and correct prices, Wisconsin would have had no choice but to pay those prices—that is what federal law commands.

Defendants seek to escape this judgment by arguing that Wisconsin employees are complicit in their scheme in one way or another. On the most elemental level defendants simply argue that employees were negligent in not responding sooner to reports that some of defendants’ drugs were selling to some providers at prices lower than the published average wholesale prices. This argument takes a number of forms, all of which boil down to the charge that Medicaid employees had a duty to reformulate the program in some way to account for defendants’ fraud.

In the latest version of this theme, defendants contend that Wisconsin employees knew of defendants’ fraud and used it to intentionally over pay pharmacists on their ingredient costs for the benevolent purpose of assuring greater access. Put in a brighter spotlight, this argument posits that Wisconsin employees wanted to overpay pharmacists

for their drugs by as much as 1,000 percent, and were content to permit drug companies to market their drugs through the publication of such spreads instead of on the basis of patient efficacy and cost.

However this argument is spun, the issue presented by this motion is simple. Can defendants exculpate themselves by proving that Wisconsin employees either were negligent in reacting to their fraud or knew about defendants' fraud and used it to intentionally pay pharmacists more than federal law permits? On this issue, there is no room for debate. It is a certainty that defendants cannot escape liability for their fraudulent conduct by blaming Wisconsin's employees. It has been so for almost two hundred years. "As a general rule laches or neglect of duty on the part of officers of the Government is no defense to a suit by it to enforce a public right or protect a public interest." *FTC v. The Crescent Publishing Group, Inc.*, 129 F.Supp.2d 311, 324 (S.D.N.Y. 2001). See *Nevada v. US*, 463 U.S. 110 (1983), relying on *Utah Power & Light Co. v. US*, 243 U.S. 389, 409 (1917) where the Court rejected the argument that certain officials of the United States had granted a power company the unfettered right to utilize federal lands holding:

As presenting another ground of estoppel it is said that the agents in the forestry service and other officers and employees of the government, with knowledge of what the defendants were doing, not only did not object thereto, but impliedly acquiesced therein until after the works were completed and put in operation. This ground also must fail. As a general rule, laches or neglect of duty on the part of officers of the government is no defense to a suit by it to enforce a public right or protect a public interest.

As the Court said in *Heckler v. Community Health Services*, 467 U.S. 51, 63 (1984):

Justice Holmes wrote: ‘Men must turn square corners when they deal with the Government.’ *Rock Island, A. & L.R. Cp. V. United States*, 254 U.S. 141, 143, 41 S. Ct. 55, 56, 65 L.Ed. 188 (1920).’ This observation has its greatest force when a private party seeks to spend the Government’s money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know that law and may not rely on the conduct of Government agents contrary to law.”

Or as the Court said in *Federal Crop Insurance Corp. v. Merrill*, 332 U.S. 380, 384 (1947):

Whatever the form in which the Government functions, anyone entering into an arrangement with the Government takes the risk of having accurately ascertained that he who purports to act for the Government stays within the bounds of his authority. The scope of this authority may be explicitly defined by Congress or be limited by delegated legislation, properly exercised through the rule-making power. And this is so even though, as here, the agent himself may have been unaware of the limitations upon his authority.

See US v. Socony-Vacuum Oil Co., 310 US 150, 226 (1940): “Though employees of the government may have known of those programs and winked at them or tacitly approved them, no immunity would have been thereby obtained.”

This doctrine dates back to the infancy of the Supreme Court. *See US v. Kirkpatrick*, 22 U.S. 720, 735 (1824) and *see US v. Insley*, 130 U.S. 263, 266 (1889): “The principle that the United States are not bound by any statute of limitations, nor barred by any laches of their officers, however gross, in a suit brought by them as a sovereign government to enforce a public right or to assert a public interest, is established past all controversy or doubt.”

And this doctrine has specifically been applied in the context of the Medicare/Medicaid programs. *Heckler v. Community Health Services*, 467 U.S. 51 (1984) (holding also that companies signing on to the Medicaid program have a duty to know the regulations and may not rely on the conduct of government agents contrary to law.) Significantly, in *Heckler*, the Supreme Court rejected a health care provider's argument that the Government was estopped from recouping money furnished to the provider that it "should never have received in the first place." *Id.* at 61. The Court noted that, "When the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined." *Id.* at 60. *See also North Memorial Medical Center v. Gomez*, 59 F.3d 735 (8th Cir. 1995).

Wisconsin law is no different. The case of *City of Milwaukee v. Leavitt*, 31 Wis.2d 72, 77-79, 142 Wis.2d 169 (Sup. Ct. 1966) is directly on point. There the City of Milwaukee sued to terminate a non-conforming commercial use in a residential neighborhood. The landlord defended on the ground that commercial occupancy permits had been continuously granted him for 14 straight years, and he had expended considerable amounts of money to ready the building for such a commercial use based on conversations with building inspectors and in reliance on the occupancy permits. Thus, the landlord argued that the City was estopped from prosecuting him. The Supreme Court rejected the landlord's contention in no uncertain terms:

While municipal and other government units are not wholly immune from application of the doctrine of equitable estoppel, this court is firmly committed to the principle that estoppel 'will not lie against a municipality so as to bar it from enforcing an ordinance enacted pursuant to the police power. Thus erroneous acts of municipal officers do not afford a basis to estop the municipality

from enforcing its ordinances enacted pursuant to the police power. In Anno. I A.L.R.2d 338, the rule is well stated:

‘Ordinarily a municipality is not estopped by a mistake, unauthorized act, laches, dereliction, or wrongful conduct on the part of a public official, and no estoppel can grow out of dealings with municipal public officers of limited authority where such authority has been exceeded.’

31 Wis.2d 72, 142 N.W.2d 169 at 171-172. The principle that Wisconsin’s citizens do not lose their right to enforce laws passed for their welfare because of errors or misconduct on the part of governmental employees was reaffirmed as the policy of Wisconsin in the case *State v. City of Green Bay*, 96 Wis.2d 195, 201-02, 291 N.W.2d 508 (1980):

We have not allowed estoppel to be invoked against the government when the application of the doctrine interferes with the police power for the protection of the public health, safety or general welfare. *State v. Chippewa Cable Co.*, 21 Wis.2d 598, 608, 609, 124 N.W.2d 616 (1963); *Park Bldg. Corp. v. Ind. Comm.*, 9 Wis.2d 78, 87, 88, 100 N.W.2d 571 (1960); *Town of Richmond v. Murdock*, 70 Wis.2d 642, 653, 654, 235 N.W.2d 497 (1975); *McKenna v. State Highway Comm.*, 28 Wis.2d 179, 186, 135 N.W.2d 847 (1965); *Milwaukee v. Milwaukee Amusement, Inc.*, 22 Wis.2d 240, 252-53, 125 N.W.2d 625 (1964).

291 N.W.2d 508 at 511. In short, defendants cannot exculpate themselves by blaming Wisconsin employees and, hence, discovery in this area is precluded.

Defendants have attempted to overcome this general rule by putting different spins on their government knowledge argument designed to make it appear that their defense is more than just finger pointing. As we show below none of these attempts to bypass the uniform case law on this issue has merit.

2. Each of the Different Iterations of Defendants' Government Knowledge Defense Is Baseless.

At various points in this litigation, defendants have attempted to justify their government knowledge defense under one or more of the following theories.

- a. Defendants' theory that their conduct is exculpated by the negligence or knowledge of Medicaid employees.

Defendants' contention that Medicaid employees knew, or should have known, of defendants' fraud and did nothing about it is unavailable to the defendant. That is precisely what the case law cited above stands for. This case law disposes of, for example, any use by defendants at trial of the so-called admission of attorney Gebhart to the effect that some employees believed that the published average wholesale prices were higher than the real prices. (This memo is privileged and inadmissible in any event as plaintiff shows in Section II., *infra*.)

- b. Defendants' theory that State employees embraced their fraud because the State employees wanted to overpay for defendants' drugs.

Defendants' argue that Wisconsin's Medicaid employees, instead of being buffaloed by defendants' phony prices, used them as a vehicle to hide overpayments on the ingredient cost for "public policy and/or political considerations." The most recent sighting of this argument is in Johnson & Johnson's Supplemental Responses and Objections to Plaintiff's Third Set of Interrogatories, etc., Allegation 30, attached hereto as Exhibit D. There, J&J argues that Wisconsin employees and legislators welcomed its fraud on the basis of a *mélange* of federal reports, notes from individual state legislators to lobbyists,² and decisions by the State legislature not to further reduce its

² An individual legislator's view of legislation is inadmissible. See *Responsible Use of Rural and Agricultural Land v. Public Service Commission*, 239 Wis. 660, 688 n.20, 619 N.W. 888 (Sup. Ct. 2000).

reimbursement formula at various junctures. (The irony of relying on decisions not to reduce the reimbursement formula as a defense is inescapable. Having completely disabled Wisconsin and other states from learning of the true cost of their drugs by publishing phony prices, defendants attempt to exculpate their conduct by pointing to the confusion they created within state government over what the proper reimbursement level should be, a confusion compounded by cries of penury from pharmacy lobbyists.)

This defense has been rejected by other judges who have presided over similar cases in other jurisdictions. As Judge Stearns observed, “[t]he recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct.” *In re Lupron*, 295 F.Supp.2d 148 at 168 n.19 (D. Mass. 2003). *In re Pharm. Indus. AWP Litig.*, 263 F.Supp.2d 172, 187 (D. Mass. 2003) (“the fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWP’s cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices”); *see also In re Lupron*, 295 F.Supp.2d at 163 (rejecting notion that “Congress deliberately invited the very fraud of which defendants are accused”).

More recently in her findings in connection with the MDL trial of four of the defendants here, Judge Saris emphatically rejected the defense that slowness on the part of the government to react to defendants’ unlawful conduct equals acquiescence:

The publication of false, inflated AWP’s caused real injuries to the government, insurers, and patients who were paying grossly inflated coinsurance payments for critically important, often life-sustaining drugs. Once the mega-spreads became widely known, the conduct was still egregious under the unfairness prong of Chapter 93A because neither the third party payors nor the

government could move quickly or effectively to fix the problem. In 2003, Congress finally fixed the problem by moving to a reimbursement system not based on AWP.

In re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F.Supp.2d 20, 30-31 (D. Mass. 2007).³

Most importantly for this case, the affirmative defense that Wisconsin employees deliberately overpaid for Medicaid drugs is simply unavailable to the defendants. By Federal law, Wisconsin employees are not permitted to overpay for ingredient cost for any policy reason whatsoever. The regulations could not be clearer: “The Medicaid agency must not pay more than the upper limits described in this subpart.” 42 CFR § 447.304. Although the State Medicaid program has some latitude in setting its dispensing fee which it does separately, nothing in the Regulations permits any deviation from the clear command that a State pay no more than the lower of the estimated acquisition cost, the FUL or the provider’s usual and customary charge for the drugs it reimburses.

Defendants have sought to avoid this conclusion by suggesting that the clause in § 42 U.S.C. 1396(a)(30)(A) regarding the need to assure access to the Medicaid program provides authority for Wisconsin to unilaterally deviate from the Regulation’s payment formula. But the Regulations can be searched in vain for any such license. Plainly, the Secretary believed that reimbursing drugs at their ingredient cost would be adequate to assure access. Thus, if Wisconsin employees had used defendants’ fraudulent prices as a

³ J&J got off the hook in the MDL. Although Judge Saris found J&J guilty of marketing the spread, found that the acquisition cost of J&J’s drugs consistently exceeded the AWP, and generally found J&J’s conduct “troubling,” she concluded that because the private payers would have known of the AWP spread for J&J’s drugs, J&J’s misconduct did not reach the required Massachusetts standard of “outrageous conduct.” *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp.2d 20, 103-04 (D. Mass. 2007). In Wisconsin, of course, falsity is the standard and Judge Saris’ findings for J&J in Massachusetts are an indictment of J&J here. Moreover, the defense that Wisconsin should have known of J&J’s spreads is unavailable against a state as plaintiff shows above.

vehicle to overpay for the ingredient cost, that conduct would be unlawful and not bar the claims of Wisconsin's citizenry.

- c. The theory that knowledge possessed by State Medicaid employees of price discounting breaks the causation chain between defendants' phony prices and Wisconsin's overpayments.

In a different variant of their argument that Wisconsin Medicaid employees embraced defendants' fraud, defendants contend that their false prices were not the cause of Wisconsin's overpayment—Wisconsin's decision not to reduce the reimbursement rate was. Thus, the argument goes, there is no causal link between defendants' false prices and Wisconsin's losses. Put another way, it is defendants' contention that their false price reporting did not contribute to Wisconsin overpaying for its citizens drugs; that had defendants truthfully reported prices that were “generally and currently paid by providers” (42 C.F.R. § 447301) as commanded by Federal Regulations, Wisconsin, nevertheless, would have reimbursed providers at prices greatly in excess of these published prices—in some cases 1,000 percent or more.

Seen this way, defendants' causation argument makes no sense. It requires the Court and jury to assume that Wisconsin, in the face of accurate price reporting, would have unlawfully ignored Federal regulations, grossly inflated their drug reimbursement levels and gotten away with it! And that doing so was a practical possibility in a context where the only electronic data available for Wisconsin's Medicaid program to use reported accurate prices. No defendant is entitled to make such an argument to a jury,

nor can such a theory justify the discovery defendants are seeking.⁴ Indeed, when reviewing defendants' argument from this perspective, it is plain that defendants' false price reporting was the essential factor (not just a substantial one) in Wisconsin's overpayment. Without this unlawful conduct no state, no matter what the intentions of their civil servants, would have, or could have, overpaid for defendants' drugs.

d. Defendants' federal False Claims Act defenses are irrelevant here.

In the cases brought by the Federal Government the defendants contend that they need access to internal documents to show that the government knew of their fraud and approved of it. Under the federal False Claims Act a defendant may escape liability by showing it lacked the required scienter. To prove such a defense a defendant must show that it fully informed the Government of its misconduct and the Government approved it. Or, put another way, that it reasonably believed that its conduct was known and condoned by Federal government. Mere acquiescence will not do. *See* Exhibit E at 8 *et seq.*, the memorandum of the Department of Justice explaining this claim and what defendants must do to prevail on it. And *see U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F.Supp.2d 719, 729-30 (N.D.Ill. 2007): "...the proper test is whether "the government knows and approves of the particulars of a claim for payment before the claim is presented." *Id.* at 545. This Court has noted that mere acquiescence (rather than

⁴ Causation is sometimes confused with reliance. They are two different concepts as one court neatly describes:

Defendant mistakenly contends that the statutory requirement for a causal connection between the deceptive practice and the claimant's damages equates to a requirement that the claimant prove detrimental reliance. However, causation and reliance are distinct concepts. 'Causation requires a nexus between a defendant's conduct and a plaintiff's loss; reliance concerns the nexus between a defendant's conduct and a plaintiff's purchase or sale.' Seth William Goren, *A Pothole on the Road to Recovery; Reliance and Private Class Actions Under Pennsylvania's Unfair Trade Practices and Consumer Protection Law*, 107 Dick. L. Rev. 1, 11 (2002) (internal quotation marks and footnote omitted) [hereinafter Goren]; *see also id.* at 11 n.45 and authorities cited therein. *Smoot v. Physicians Life Insurance Company*, 135 N.M. 265, 87 P.3d 545, 550 (Ct. App. 2003). Reliance is not a required element in any of plaintiff's causes of action.

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.”

Defendants cannot use this scienter contention to rummage through the e-mails of Wisconsin employees. The argument that defendants’ believed their fraudulent price reporting was permissible because they fully disclosed what they were doing to Wisconsin employees (which they assuredly never did) is simply unavailable to the defendants at the state level. No Wisconsin employee or legislator has the power to authorize Wisconsin to deviate from the command of the Federal regulations that Wisconsin pay its providers no more than the estimated acquisition cost. Or, put another way, defendants cannot argue that it was reasonable to believe that Wisconsin employees licensed their fraud since Wisconsin employees could not do so.

- e. Defendants also contend that they need access to Wisconsin’s e-mails to support their arguments on statute of limitations.

Defendants argue that they need government knowledge documents in connection with their statute of limitations defense. This argument simply ignores the controlling case of *Kolpin v. Pioneer Power & Light Company, Inc.*, 162 Wis.2d 1, 22-23, 469 N.W.2d 595 (Sup. Ct. 1991) which describes the Wisconsin rules on statute of limitations as follows:

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. Accordingly, plaintiff’s commencement of the action was timely.

* * *

This court, in setting forth the ‘discovery rule’ and the ‘continuum of negligent acts’ doctrine did not create two discrete theories of accrual of a cause of action. Under *Tamminen* and *Robinson*, if a defendant engages in a continuum of separate negligent acts which cause the plaintiff damage, the cause of action is not complete until the last act of negligence occurs. Once the cause of action is complete, then the cause of action accrues.

Under *Hansen* and *Borello*, if a defendant engages in a negligent act (or a continuum of negligent acts such as *Tamminen* or *Robinson*) which causes the plaintiff damage, the cause of action is not complete until the plaintiff knows, objectively, the cause of the injury and the defendant’s part in that cause. Once the cause of action is complete, then the cause of action accrues.

The two lines of cases stand for the proposition that in order for a cause of action to accrue, it must be complete. It is complete when the negligent act occurs, or the last act occurs in a continuum of negligent acts, *and* when the plaintiff has a basis for objectively concluding that the defendant was the cause of the plaintiff’s injuries and damages.

This holding defeats defendants’ limitations arguments.

There are three different statutes of limitations involved in this case. The first is Wis. Stat. 100.18(11)(b)3, which is a three-year statute. This limitation has been held to be a statute of repose, barring any claim that is not brought within three years of the filing of the complaint. As a consequence no discovery is necessary to establish when it cuts off claims.

Wisconsin’s Medicaid Fraud claim and the unjust enrichment claims are governed by Wis. Stat. 893.87 which provides that in the absence of a specific statute of limitations the State has 10 years to bring its claim with the proviso that the cause of action does not accrue “until discovery on the part of the state of the facts constituting the fraud.”

Wisconsin’s secret discount claim is governed by the specific statute of limitations in Wis. Stat. 133.18(2) and (4) which contains a six year limitation period,

again with the proviso that the time period begins to run only upon discovery “of the facts constituting the cause of action.”

What this means, even before looking at the implications of the *Kolpin* opinion, is that none of defendants’ phony prices published within six years of the filing of the complaint in 2004 (the shorter of the two statutes at issue) is barred by the statute of limitations. Or, conversely, the only issue is whether Wisconsin can reach back beyond 1998 in connection with its secret discount claim or beyond ten years in connection with the Medicaid fraud claim. This means that, at most, defendants’ e-mail search must be limited to the period prior to 1998.

If that practical fact does not end the matter, *Kolpin* does. *Kolpin* says that plaintiff is entitled to damages for the entire period of a continuous tort. Defendants cannot argue in good faith that they were not publishing phony prices before 1998. And even if they could, all the evidence for such a defense is in defendant’s possession, not plaintiff’s.

Kolpin also says that a statute of limitations runs against a plaintiff only when a plaintiff can objectively conclude “that the defendant was the cause of the plaintiff’s injuries and damages.” (*Kolpin, supra*, 162 Wis.2d 1, 23.) Defendants do not contend that the plaintiff should have known that they were responsible for the phony prices prior to 1998 (the closest defendants get to making this argument is to contend that Wisconsin employees knew that the published prices were being discounted in the market place) or that defendants’ conduct led to Wisconsin’s damages. Indeed, defendants continue to deny both those things even today. Before trolling through the state’s e-mail system the defendants have to at least publicly take the position that Wisconsin employees knew that

defendants were intentionally publishing phony prices and that these same employees knew that Wisconsin was being damaged thereby—a position utterly at odds with defendants’ current denials.

In sum, the defense of governmental knowledge turns out to be a straw man and an inadequate basis for demanding an e-mail scavenger hunt. That is not to say that defendants will be unable to come up with new iterations on their government knowledge theme; big Pharma is represented by the brightest lawyers in America, but the truth is that no matter how inventive defendants’ counsel are in trying to blame Wisconsin’s employees for Wisconsin’s Medicaid overpayments it is an incontrovertible fact that if the defendants had published honest pricing, Wisconsin, by law, would have had to utilize such pricing.

D. Other Courts Have Correctly Rejected Defendants’ Government Knowledge Argument and Such Holdings are Hardly Unfair.

The courts that have directly come to grips with this issue have held that government knowledge is not a valid defense in any shape or form in three different contexts. Thus, in New Jersey the court refused to admit such evidence at trial (Exhibit F), in Texas the judge granted the state’s motion for summary judgment on the governmental knowledge defense⁵ (Exhibit G), and in New York the Appellate court affirmed a trial court’s decision to preclude discovery on the issue (Exhibit H). There is no reason for this Court to cut a new path.

Holding that defendants cannot escape the consequences of their fraud by blaming Wisconsin Medicaid employees is hardly unfair. Big Pharma consists of some of the richest companies in the world—richer than many countries. Their lawyers would not

⁵ Because the Judge who did so issued a simple one-page Order, we attach the brief of the State of Texas raising this issue as the foundation for the Order.

have missed the fact that for the last 50 years it has universally been the law that businesses cannot report prices, suggested or otherwise, that bear no relationship to the prices customers are actually paying. Nor could defendants miss the clear statutory commands to the same effect in states such as Wisconsin.

Defendants simply thumbed their collective noses at the states and the Federal government believing them too ignorant and/or cumbersome to do anything about it, or believing that their lobbying efforts combined with those of the pharmaceutical trade would shield them from any harm. More than a hint of this is reported by Judge Saris in her recent decision where she concludes:

While J&J worked to “preserve physician economics,” there was serious concern at the company that the government would find out about the spreads and take action to reduce the reimbursement amounts. (*See* PX 339 at 61805.) In 1998 Cathleen Dooley, then the Senior Director for Reimbursement and Health Policy, sent an email about Medicare’s reimbursement policy for Procrit in which she stated, “[r]ight now they do not know what the cost [of Procrit and Epogen] is for different providers.” (PX 259 at 842.) She cautioned that the fact that patients were paying a copayment of a price much higher than the acquisition cost would be a “public relations issue.” (*Id.* at 843.) She further noted that the only way that Medicare could determine Procrit’s market price was “to require an invoice be submitted with each Medicare claim that is sent in. This would be very cumbersome....” (*Id.* at 842.) Similarly, when Ortho Biotech considered taking a price increase in 1997 and 1998 it was concerned that raising the Procrit AWP above the Epogen AWP could “raise red flags” and “trigger a price survey.” (PX 262.) Ortho Biotech recognized that if a survey were taken, “the reimbursement rate would be lowered,” which would decrease the profit to providers. (PX 339 at 61805.)

491 F.Supp.2d 20, 37 (D. Mass. 2007). And see the J&J memo itself, attached as exhibit I, detailing why it is difficult for even the Federal government to obtain accurate prices and dismissively concluding that: “If they were smart, they would expand the current demonstration project...”

Although the equities are all with Wisconsin's taxpayers in this context, plaintiff is not depending on equity to prevail on this motion. The law is a bright line. Defendants cannot utilize e-mails of Medicaid employees to exculpate themselves. And any further searching for such e-mails should be barred.

II. THE GEBHART MEMO IS PRIVILEGED, IRRELEVANT AND INADMISSIBLE HEARSAY. IT SHOULD BE RETURNED TO WISCONSIN.

The Gebhart Memo was inadvertently produced to the defendants. They should return it because it is a privileged communication, inadmissible and irrelevant.

A. The Document is Privileged.

As the Gebhart memo itself shows, it is hard to conceive of a document more obviously privileged. This memo reports conversations a lawyer who is assisting Wisconsin in this case had with employees in connection with this case. Under Wis. Stat. § 905.03 this document is privileged. Wis. Stat. § 905.03 provides: "A client has a privilege to refuse to disclose and to prevent any other person from disclosing confidential communications made for the purpose of facilitating the rendition of professional legal services to the client: between the client ...and the client's lawyer..." Wis. Stat. § 905.03 (1)(d) states that: "A communication is "confidential" if not intended to be disclosed to 3rd persons..."

The memo on its face shows that it is made for the purpose of facilitating legal services—it is an investigatory memo about the case by one of the attorneys assisting the case—and it obviously not intended to be read by anyone but its recipient. It does not matter that it was turned over inadvertently because the Protective Order in this case preserves plaintiff's objection, Paragraph 33, and because Supreme Court case law mandates that result:

... We conclude that a lawyer, without the consent or knowledge of a client, cannot waive the attorney-client privilege by voluntarily producing privileged documents (which the attorney does not recognize as privileged) to an opposing attorney in response to a discovery request. We hold that only the client can waive the attorney-client privilege under Wis. Stat. § 905.11 regarding attorney-client privileged documents.

679 N.W.2d 794 at 795.

In sum, the defendants should be required to turn back to the state its privileged document.

B. The Document is Inadmissible.

The document is inadmissible because it is hearsay, lacks any foundation, and contains an inadmissible legal conclusion. The document consists of Mr. Gebhart apparently relating a conversation he had with a couple of unidentified state employees. It is clearly hearsay since it is an out of court statement designed to prove the truth of the matter asserted. Wis. Stat. § 908.01(3). And there is no exception to the hearsay rule available which would permit the defendants to admit the document in evidence.

Defendants apparently contend that it is an admission; but it is hardly that. It falls within none of the statutory definitions of an admission. All the admission categories at the very least require that the admission be a statement by the party making it. For example, Wis. Stat. 908.01(4)(b)(3) requires a “statement by a person authorized by the party to make a statement concerning the subject,” and subsection (4) requires a “statement by a party’s agent or servant concerning a matter within the scope of the agent’s....employment.” This memo contains no such statement. Instead, it is a characterization of someone else’s statements, the precise contents of which are unknown. This hardly qualifies as an exception to the hearsay rule.

The memo is wholly devoid of the required foundation; it does not come close to being admissible as a report of a conversation. It lacks all the basic requirements: where the conversation took place, who was present, when it was held, and who said what to whom. And it lacks any patina of reliability. For all we know, the unknown persons who made these comments had no personal knowledge of the subject, or were seeking to blame others for Wisconsin's overpayments. We just cannot tell.

The memo is about, and contains, an inadmissible and hugely uninformed legal opinion. In characterizing this law suit as baseless (assuming that they did so) simply because some employees knew of discounting in the market place, the persons so concluding show that they probably were unaware of defendants deliberately unlawful conduct and their attempts to cover it up, were unaware of Wisconsin's legal rights when confronted by such fraud, and did not know of the statutory obligation of the defendants not to advertise a wholesale price when retailers were paying less. (That the employees were apparently in the dark on all these matters may explain why Wisconsin did not sue sooner.) In any event, no citation is needed for the proposition that lay legal opinions are entitled to no weight whatsoever. If opinions like this are admissible, Wisconsin can produce a number of employees who believe that the defendants have violated the law over and over again.

C. The Document is Irrelevant.

For all the reasons set forth in section I of this brief, the Gebhart memo is irrelevant and cannot lead to relevant evidence. Indeed, it is a perfect example of why defendants are not entitled to pursue this line of inquiry. Defendants want to argue to the jury that the knowledge of discounting in the market place described in the Gebhart

memo charged Wisconsin with the duty to lower reimbursement rates more aggressively, and that having not done so Wisconsin cannot recover because its employees were negligent, or embraced the fraud, or for any other reason defendants can drum up. This kind of argument is exactly what is precluded by the uniform case law.

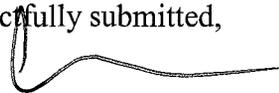
The Gebhart memo should be returned to Wisconsin.

CONCLUSION

For all the forgoing reasons Wisconsin respectfully requests that the Court issue a protective order holding that Wisconsin need not search the files of its individual employees for documents that relate solely to defendants' contention that Wisconsin employees had knowledge that some drugs were being sold at prices below their published average wholesale prices or their contention that Wisconsin employees knew of, and approved of, defendants' unlawful conduct.

Dated this 9th day of October, 2007.

Respectfully submitted,



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EXHIBIT A

Westlaw

Page 1

Code of Federal Regulations Currentness

Title 42. Public Health

Chapter IV. Centers for Medicare & Medicaid
Services, Department of Health and Human
Services (Refs & Annos)

Subchapter C. Medical Assistance Programs

Part 447. Payments for Services (Refs
& Annos)→ Subpart F. Payment Methods for
Other Institutional and Noninstitutional
Services (Refs & Annos)**§ 447.300 Basis and purpose.**

<Text of section effective until Oct. 1, 2007.>

In this subpart, §§ 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

§ 447.301 Definitions.<Section reserved effective Oct. 1, 2007; see 72 FR
39239.>

For the purposes of this subpart--

Brand name means any registered trade name commonly used to identify a drug.

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.

Multiple source drug means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and

without such a name.

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

§ 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is not available for a State's expenditures for services that are in excess of the amounts allowable under this subpart.

Outpatient Hospital and Clinic Services**§ 447.321 Outpatient hospital and clinic services:
Application of upper payment limits.**

(a) Scope. This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) General rules.

(1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) Exceptions--

(1) Indian Health Services and tribal facilities. The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub.L. 93-638).

(2) Disproportionate share hospitals. The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) Compliance dates. Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals-- Medicaid State plan rate year 2008.

(2) For State government operated and non-State government operated clinics-- Medicaid State plan rate year 2009.

(3) For all other facilities--March 13, 2001.

(e) Transition periods--

(1) Definitions. For purposes of this paragraph, the following definitions apply:

(i) Transition period refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) UPL stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

(iii) X stands for the payments to a specific group of providers described in paragraph (a) of this section in State FY 2000 that exceeded

the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) General rules.

(i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraph (a) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following--

(1) For State FY 2003: State FY 2003 UPL + .75X.

(2) For State FY 2004: State FY 2004 UPL + .50X.

(3) For State FY 2005: State FY 2005 UPL + .25X.

(4) For State FY 2006; State FY 2006 UPL.

(C) For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:

(1) For State FY 2004: State FY 2004 UPL + .85X.

(2) For State FY 2005: State FY 2005 UPL + .70X.

(3) For State FY 2006: State FY 2006 UPL + .55X.

(4) For State FY 2007: State FY 2007 UPL + .40X.

(5) For State FY 2008: State FY 2008 UPL + .25X.

(6) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(7) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(1) through (e)(2)(ii)(C)(7) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan

amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) Reporting requirements for payments during the transition periods. States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

Other Inpatient and Outpatient Facilities

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

Drugs

§ 447.331 Drugs: Aggregate upper limits of payment.

<Section reserved effective Oct. 1, 2007; see 72 FR 39239.>

(a) Multiple source drugs. Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, the amount that would result from the application of the specific limits established in accordance with § 447.332. If a specific limit has not been established under § 447.332, then the rule for "other drugs" set

forth in paragraph (b) applies.

(b) Other drugs. The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the--

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) Certification of brand name drugs.

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.332 does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.332 Upper limits for multiple source drugs.

<Section reserved effective Oct. 1, 2007; see 72 FR 39239.>

(a) Establishment and issuance of a listing.

(1) CMS will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA)

have been evaluated as therapeutically equivalent in the most current edition of their publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations, including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) CMS will identify the sources used in compiling these lists.

(b) Specific upper limits. The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by CMS that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

§ 447.333 State plan requirements, findings and assurances.

<Section reserved effective Oct. 1, 2007; see 72 FR 39239.>

(a) State plan. The State plan must describe comprehensively the agency's payment

methodology for prescription drugs.

(b) Findings and assurances. Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) Findings. The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.332(a) of this subpart, are in accordance with the upper limits specified in § 447.332(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart.

(2) Assurances. The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.331 and 447.332 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) Recordkeeping. The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.334 Upper limits for drugs furnished as part of services.

<Section reserved effective Oct. 1, 2007; see 72 FR 39239.>

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

Clinical Laboratory Services--[Reserved]

§ 447.342 [Reserved]**Prepaid Capitation Plans****§ 447.361 [Reserved]****§ 447.362 Upper limits of payment: Nonrisk contract.**

Under a nonrisk contract, Medicaid payments to the contractor may not exceed--

(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus

(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

Rural Health Clinic Services**§ 447.371 Services furnished by rural health clinics.**

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in Part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per

visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c)(1) or (2) of this section.

(d) For purposes of paragraph (c)(1) and (3) of this section, "visit" means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

Current through September 20, 2007; 72 FR 53906
END OF DOCUMENT

EXHIBIT B



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Governor

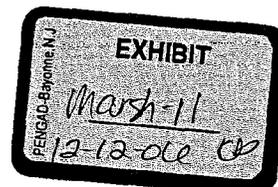
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Joe Leean
Secretary

Department of Health and Family Services

**PHARMACY
TERMS OF REIMBURSEMENT**



The Department will establish maximum allowable fees for all covered pharmaceutical items and disposable medical supplies provided to Wisconsin Medicaid recipients eligible on the date of service. Maximum allowable fees may be adjusted to reflect reimbursement limits or limits on the availability of federal funding as specified in federal law (42 CFR 447.331).

All covered legend and over-the-counter drugs will be reimbursed at the lower of the Estimated Acquisition Cost (EAC) of the drug, plus a dispensing fee, or the provider's usual and customary charge.

EAC of legend and over-the-counter drugs will be determined based on the following:

The Department of Health and Family Services' best estimate of prices currently and generally paid for pharmaceuticals. Individual drug cost estimates will be based on either Maximum Allowed Costs (MAC); or discounted published average wholesale prices.

Drug costs will be calculated based on the package size from which the prescription was dispensed, as indicated by the NDC. The only exceptions are for those drugs for which quantity minimums are specified by federal regulations and for drugs listed on the Wisconsin MAC list.

The maximum allowable dispensing fee shall be based on allowed pharmacy overhead costs and determined by various factors, including data from previous cost of dispensing surveys, the Wisconsin State Legislature's Medicaid budgetary constraints, and other relevant economic limitations.

The maximum allowable fees for disposable medical supplies shall be established upon a review of various factors. These factors include a review of usual and customary charges submitted to Wisconsin Medicaid; cost, payment, and charge information from companies that provide disposable medical supplies; Medicaid payment rates from other states; and the current Medicare fee schedule. Other factors taken into consideration include the Wisconsin State Legislature's Medicaid budget constraints, limits on the availability of federal funding as specified in federal law, and other relevant economic and reimbursement limitations. Maximum allowable fees may be adjusted periodically.

Providers are required to bill their usual and customary charges for disposable medical supplies. Covered supplies shall be reimbursed at the lower of the provider's usual and customary charge or the maximum allowable fee established by the Department. Medicaid

reimbursement, less appropriate copayments and payments by other insurers, will be considered to be payment in full.

Providers are required to bill their usual and customary charges for services provided. The usual and customary charge is the amount charged by the provider for the same service when provided to non-Medicaid patients. For providers using a sliding fee scale for specific services, the usual and customary charge is the median of the individual provider's charge for the service when provided to non-Medicaid patients.

Wisconsin Medicaid reimbursement, less appropriate copayments and payments by other insurers, will be considered to be payment in full.

The Department will adjust payments made to providers to reflect the amounts of any allowable copayments which the providers are required to collect pursuant to Chapter 49, Wisconsin Statutes.

Payments for deductible and coinsurance payable on an assigned Medicare claim shall be made in accordance with Section 49.46(2)(c), Wisconsin Statutes..

In accordance with Federal regulations contained in 42 CFR 447.205, the Department will provide public notice in advance of the effective date of any significant proposed change in its methods and standards for setting maximum allowable fees for services.

Applicable Provider Type(s): 26

Effective Date: February 2000

EXHIBIT C

drugs required by Medicaid eligible participants at a price no greater than the estimated price these providers paid for these drugs (the estimated acquisition cost or “EAC”) plus a dispensing fee. Because almost all drug manufacturers have chosen to participate in the Medicaid program (doing so is purely voluntary) the number of different drugs that may be prescribed by providers to Medicaid participants numbers well over 50,000. To keep track of the current prices of these drugs for purposes of estimating their acquisition cost for reimbursement purposes, Wisconsin has relied on pricing compendiums which have undertaken to publish what they term are accurate average wholesale prices paid by providers.

J&J has interfered with Wisconsin’s ability to estimate accurately the acquisition cost of the drugs used by its citizens by providing the pricing compendiums, drug wholesalers and directly to Wisconsin, wholesale prices that J&J knows are inflated and unconnected with any real price paid by providers. These phony prices have been incorporated into the pricing compendiums reported prices, which Wisconsin has used in its reimbursement formula.

J&J’s conduct in publishing phony and inflated wholesale prices violates Wisconsin Stat. Sec. 100.18(1) which prohibits any representation with the intent to sell that contains any assertion that is untrue, deceptive or misleading, Sec. 100.18(10)(b) which declares it to be a deceptive act to represent a price as a wholesale price when retailers are paying less, Sec. 133.05(1) which prohibits the “secret payment or allowance of rebates, refunds, commissions or unearned discounts whether in the form of money or otherwise....”, and the Medicaid Fraud Act which prohibits the making of “any false statement or representation of a material fact for use in determining rights to a benefit or payment,” Wis. Stat. Sec. 49.49(4m)(a)(2). Indeed, for over 40 years it has been the law everywhere and in every context that it is unlawful to publish a price of any kind, no matter what it is called—manufacturer’s list,

suggested list, regular or wholesale—where that price does not truly represent a price at which significant sales are made.

As the Court will see, J&J has freely admitted circulating false wholesale prices. J&J seeks to excuse this facially unlawful conduct by arguing that Wisconsin is estopped from enforcing its laws because Wisconsin employees knew that discounts were being given to providers beyond the published wholesale prices in the compendiums and that, as a result, Wisconsin had a duty to change its Medicaid program to account for this fact. As plaintiff will show, this defense is unavailable to J&J as a matter of law for two reasons. First, under the statutes relied upon here, liability attaches upon the publication of a false price, nothing more is required, and a state employee cannot change this result even if he or she wanted to. Second, as a matter of law, the state may not be estopped from enforcing its laws whatever its employees knew or did not know.

II. THE STATUTORY BASIS FOR WISCONSIN'S CLAIMS.

All of Wisconsin's claims at issue here are purely creatures of statute, the language of each of which outlines the elements which plaintiff must prove.

A. Wis. Stat. 100.18(1)—Count I.

This statute provides:

No person, firm, corporation or association, or agent or employee thereof, with intent to sell, distribute, increase the consumption of or in any wise dispose of any real estate, merchandise, securities, employment, service, or anything offered by such person, firm, corporation or association, or agent or employee thereof, directly or indirectly, to the public for sale, hire, use or other distribution, or with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase, sale, hire, use or lease of any real estate, merchandise, securities, employment or service, shall make, publish, disseminate, circulate, or place before the public, or cause, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state, in a newspaper, magazine or other publication, or in the form of a book, notice, handbill, poster, bill, circular, pamphlet, letter, sign, placard, card, label, or over any radio or

television station, or in any other way similar or dissimilar to the foregoing, an advertisement, announcement, statement or representation of any kind to the public relating to such purchase, sale, hire, use or lease of such real estate, merchandise, securities, service or employment or to the terms or conditions thereof, which advertisement, announcement, statement or representation contains any assertion, representation or statement of fact which is untrue, deceptive or misleading.

B. Wis. Stat. 100.18(10) (b)—Count II.

This statute states: “It is deceptive to represent the price of any merchandise as a manufacturers or wholesalers price, or price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise.”

C. Wis. Stat. 133.05—Count III.

This statute provides in pertinent part: “The secret payment or allowance of rebates, refunds, commissions or unearned discounts, whether in the form of money otherwise,...such payment allowance or extension injuring or tending to injure a competitor or destroying or tending to destroy competition, is an unfair trade practice and is prohibited.”

D. Wis. Stat. 49.49(4m)(a)(2)—Count IV.

This provision states: “No person, in connection with medical assistance, may: 2. Knowingly make or cause to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment.”

III. THE INDISPUTABLE FACTS SUPPORTING WISCONSIN’S MOTION.

1. Defendant Johnson & Johnson (J&J) is a holding company which operates through a number of different subsidiaries including the additional defendants Janssen Pharmaceutical Products, LP, Ortho Biotech Products, LP, Ortho-McNeil Pharmaceutical, Inc.

and McNeil-PPC, Inc. All of these subsidiaries manufacture drugs which are purchased by Wisconsin's Medicaid program. (Parks at 12-17)¹

2. The purpose of Wisconsin's Medicaid program is to provide medical assistance to the state's neediest citizens. (Parks at 17-19)

3. Wisconsin, through its Medicaid Program, purchases hundreds of millions of dollars of drugs for its citizens annually. (See http://dhfs.wisconsin.gov/medicaid4/pharmacy/data_tables/manufacturer.asp) For a general description of the program's coverage see Pharmacy Handbook - Claims Submission Section, July 2001 (Exhibit 1 at 3 et. seq.) and see Wisconsin Medicaid Program, 2006 (Exhibit 2 at 2, 6)

4. Participation in Wisconsin's Medicaid Program is purely voluntary for drug manufacturers. J&J has chosen to participate. (Parks at 20)

5. In its simplest form, the Wisconsin Medicaid program works in the following manner. Persons eligible for Medicaid (for eligibility requirements see Ex. 2 at 3) obtain a prescription from a prescriber. They then take this prescription to any Medicaid participating pharmacy and have it filled. The state via the fiscal agent, is then billed for the drug dispensed by the provider.

6. By Federal Regulation Wisconsin is limited in how much it may reimburse pharmacies for drugs prescribed for Wisconsin Medicaid participants. According to 42 C.F.R. sec. 447.331, Wisconsin is required to reimburse pharmacies "the lower of the 1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or 2) Providers' usual and customary charges to the general public." 42 C.F.R. sec. 447.331.² The "estimated

¹ Plaintiff has filed all relevant depositions and exhibits with the Court and has also prepared an Appendix which contains the excerpted portions of the depositions and exhibits for ease of reference.

² In the case of certain multi-source generic drugs, where the federal government has set a ceiling, a Federal Upper Limit ("FUL"), Wisconsin is to pay the lower of the estimated acquisition cost, the providers' charge or the FUL.

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.” 42 C.F.R. sec. 447.301.

7. Most of the large drug manufacturers have chosen to participate in Wisconsin’s Medicaid program by signing a federal drug rebate agreement. If a company chooses to participate in the state’s Medicaid Program Wisconsin will reimburse pharmacies for any drug covered by the program. (Pharmacy Handbook – Covered Services and Reimbursement, July 2001, Exhibit 3 at 9) As a consequence, Wisconsin must be able to keep track of the prices of many thousands of drugs on a daily basis. (See Exhibit 4, Manufacturer Table, which lists the participating drug manufacturers.)

8. To enable it to keep track of this huge volume of drugs Wisconsin uses EDS as a fiscal intermediary who, in turn uses First Data Bank to supply it electronically with up-to-date average wholesale prices (“AWPs”) from which Wisconsin estimates the acquisition cost of the drugs purchased by providers by means of the formula described below. (Ex. 2, at 4, 40)

9. From time to time First Data Bank has informed its subscribers that its published AWPs are averages of actual prices paid by retailers. (See Exhibits 5 and 6, excerpted pages of First DataBank’s publications.)

10. Wisconsin uses First DataBank’s AWPs in the following manner. At the time a prescription is presented to a pharmacy, the pharmacy submits a real-time claim to EDS electronically through what is called a Point-of-Sale (POS) claims processing system. Upon receipt, the POS system monitors the reimbursement claim for eligibility, covered drugs, Medicaid cost containment policies, and pricing. EDS then sends a real time response which includes the authorized payment and any patient liability, for example a co-pay. Thereafter EDS

sends Remittance and Status Reports (R&S) to Medicaid certified providers for paid claims. (Ex. 1 at 5-7) First DataBank sends its current average wholesale prices (AWPs) for the thousands of NDC codes listed in its data base to EDS on a weekly basis and this information is entered into the system. These prices become the basis for Wisconsin's reimbursements to providers. (Ex. 3 at 17, and "At-A-Glance" Summary of Most of 2007 Financial Eligibility/Rates in Long Term Support, Ex. 7 at 7.)

11. For the years 1990 to the present Wisconsin estimated the acquisition cost of J&J's drugs using various formulas based on the published AWP ranging from AWP minus 10% to the present AWP minus 13%. (See, e.g. Exhibits 8 and 9 showing the reimbursement formula in different years)

12. Historically through the year 2000, J&J and its subsidiaries, sent to pricing compendiums including First DataBank and Red Book, wholesalers reselling their drugs, and the State of Wisconsin, documents stating average wholesale prices for their drugs. (See Parks at 54-61; Webb at 65-67) (Various letters sent to Wisconsin by J&J, Exhibits 10, 11) Through 2000 the pricing compendiums published these prices as their average wholesale prices for J&J's drugs and J&J so knew. (Parks at 32-33; Webb at 65-67) (See paragraph 15 below)

13. During this period of time J&J knew that the average wholesale prices that it was sending to these various entities were not true average wholesale prices for its drugs. (See paragraphs 14 and 15 below)

14. J&J sells its drugs to wholesalers who, in turn, sell them to retail pharmacies including retail pharmacies who participate in Wisconsin's Medicaid program. During this period of time it was common knowledge among pharmaceutical manufacturers—and J&J so knew—that wholesalers did not mark up the drugs they purchased from J&J and other

manufacturers for resale to providers by more than 2% to 3%, of what the industry terms “WAC”—Wholesale Acquisition Cost—(and often less than this). (Parks at 37-47, 51-55, 76-77)

15. J&J created the prices it represented to be its average wholesale prices by marking up the WAC by 20%. (Webb at 59-60, 65; Ortiz II, Ex. 8) Thus, J&J knew that the average wholesale price it reported for its drugs was generally 17% to 18% higher than the retailers were actually paying for its drugs during this period (since the actual markup was no more than 3%). (Parks at 46-49, 53-55, 75-78) J&J is not able to provide any business reason for marking up the average wholesale price it circulated by such a large amount. (Parks at 38; Webb at 59-60)

16. J&J has filed briefs in this case admitting that it establishes its AWP by marking up its selling price to wholesalers by 20%, that it knows that wholesalers have very thin margins—not in excess of 2% or 3%—and that “it is reasonable to believe (and the J&J Defendants do believe) that the prices paid by retail pharmacies are close to the prices at which the J&J Defendants sell to wholesalers.” (J&J’s Reply Memorandum in Support of Their Motion for a Protective Order, Exhibit 12)

17. In 2001, after Congress’ began its investigation into the drug companies pricing practices in connection with the Medicare program, (See Joint Hearing Before the Subcommittee On Health and the Subcommittee on Oversight and Investigations, Sept. 21, 2001, Serial No. 107-65,³) J&J modified the pricing materials it sent to the pricing compendiums, wholesalers and the state of Wisconsin by adding the phrase “suggested” to their average wholesale price quotations. (Parks at 59-62) (See Exhibit 9) Thus, in 2001 and thereafter, J&J’s pricing documents reported a “suggested average wholesale price”, not simply an average wholesale price. Different subsidiaries phased this phrase in at different times. (Parks at 187-89) J&J

³ The transcript of this hearing with exhibits is hundreds of page long and since plaintiff’s only point in citing to it is to show that a public investigation of industry pricing practices had begun plaintiff has not submitted the transcript. If the Court wishes the plaintiff to supplement the record in this regard plaintiff would be happy to do so.

knew at the time that it made this linguistic change that the price it called a “suggested average wholesale price” was, in reality, generally 17% to 18% higher than wholesalers were actually charging retailers. The change in language was requested by the legal group. (Parks at 61-62, 188)

18. In 2001 First DataBank raised the mark up on J&J’s brand drugs from 20% above the WAC to 25% above the WAC. Prior to this time First DataBank had published the exact AWP’s sent it by J&J. (Parks at 81-83, Ex. 80; Barry at 129; Pearson at 180; Webb at 66-67)

19. J&J was concerned about this change in First DataBank’s conduct (speculating that this change resulted from a Department of Justice investigation) and discussed this change extensively in house. (Ortiz II, Ex. 3)⁴ Initially it was viewed as “a very bad thing. It was a higher price that our payers would have to absorb.” (Ortiz II at 42) Diane Ortiz, a J&J employee, was asked to do a report about this. After research and conversation with managers inside J&J (Ortiz II at 42-49) she concluded, among other things:

With the price action of 1Q 2002, it was discovered that First Data Bank (FDB) published AWP’s higher than what was recommended by the J&J operating companies, moving most products from a 20% spread to a 25% spread (vs. list). Examining AWP prices in Dec 2001 and June 2002 indicate a much greater price increase than the manufacturer intended (a 5% increase in list price would translate into 9.3% increase at the AWP level, including the increase in spread).

For example:

Timeframe:	Dec 2001	June 2002	Result
Spread:	20%	25%	
Price Action:		+5% LP (Q1)	
List Price:	\$100	\$105	+\$5 (+5%)
AWP:	\$120	\$131.25	+\$11.25 (+9.3%)

Since AWP is the basis for reimbursement in many segments, this action will increase the strain on multiple payers. The inflated AWP’s would benefit pharmacies under Medicaid payment procedures and since AWP is the primary

⁴ Ms. Ortiz has been deposed twice, once in this case and once in the MDL. Ortiz II is the deposition taken in this case.

basis of Medicaid reimbursement, the impact to states could be significant. From a Medicare perspective, Congress is actively considering moving away from AWP for payment purposes; J&J has offered assistance in this effort.

Status:

A white paper is being developed by an outside consultant that J&J will provide to key stakeholders (potentially CMS, state Medicaid directors, key managed care organizations, etc.) to alert them to these discrepancies and the lack of control the manufacturer has over the published AWP. The J&J team working on the paper includes: Kathy Schroeder, Kathy Buto, Jerry Holleman, Pat Molino, Bruce Colligen, and Diane Ortiz with input from OC finance and trade relations contacts. The draft paper is currently under review by legal.

Background:

AWPs are not defined in law or regulation and are considered vague, artificial prices established and manipulated at the discretion of the manufacturer but are the cornerstone of a larger pricing infrastructure. AWP is intended to represent the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers. It is considered a flawed pricing mechanism that, although not widely understood, plays a pivotal role in the overall prescription drug pricing and reimbursement systems. (NHPF Issue Brief, June 7, 2002)

(Ortiz II, Ex. 13)

20. Subsequent to Ms. Ortiz' memo and the creation of the white paper group, a J&J employee raised the issue of whether FDB's action was actually a net benefit to J&J and asked that someone find this out. (Ortiz II, Ex. 5)

21. A subsequent e-mail concludes that on balance the rise in J&J's spread is probably "positive" for J&J. (Ortiz II, Ex. 5) Another later e-mail asks whether it was possible for one of J&J's non-branded drugs, Procrit, which, because it was a generic equivalent had not had its spread raised from 20 to 25%, to also have its spread raised. (Ortiz II, Ex. 5)

22. Ultimately no white paper was ever sent to any state authority or to CMS. Indeed, the primary investigator was never informed about what happened to it. (Ortiz II at 179-81) Nor did J&J ever alert Wisconsin to the fact that First Data Bank had raised the AWP of its drugs

from 20% above the wholesale purchase price to 25%. (Parks at 143) Wisconsin continued to use J&J's average wholesale prices as reported by First DataBank in its reimbursement formula thereafter.

23. In 2003, The House Committee on Energy and Commerce expanded Congress' Medicare investigation into pricing practices in the state Medicaid program. On June 26, 2003, Chairman Billy Tauzin (R.-La.) and Oversight and Investigations Subcommittee Chairman James Greenwood (R.-Pa.) wrote as follows:

The Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. This inquiry builds upon the earlier work by this Committee on the relationship between the drug pricing practices of certain pharmaceutical companies and reimbursements rates under the Medicare program. In that investigation, the Committee uncovered significant discrepancies between what some pharmaceutical companies charged providers for certain drugs and what Medicare then reimbursed those providers for dispensing those drugs. This price difference resulted in profit incentives for providers to use the drugs of specific companies as well as higher costs to the Medicare system and the patients it serves. For example, we learned that one manufacturer sold a chemotherapy drug to a health care provider for \$7.50, when the reported price for Medicare was \$740. The taxpayer therefore reimbursed the doctor almost \$600 for dispensing the drug and the cancer patient had a \$148 co-payment. Such practices are unacceptable in the view of the Committee, which is why we are in the process of moving legislation to address these abuses.

The Committee has similar concerns regarding drug prices in Medicaid, which has a substantially larger pharmaceutical benefit than Medicare.

House Committee on Energy and Commerce Press Release, Tauzin, Greenwood Expand Medicaid Fraud Investigation (June 26, 2003), available at http://energycommerce.house.gov/108/News/06262003_1003.htm.

24. Notwithstanding this investigation J&J continues to publish, or participate in the publication of, inflated wholesale prices.

ARGUMENT

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

The Medicaid program was well intentioned and well designed. It was intended to help the very neediest citizens obtain basic health care, and it was designed to do so at the lowest cost to the taxpayers by paying providers of drugs no more than their acquisition cost plus a dispensing fee. (PUF 2, 6) The Achilles heel of the program was the fact that the State Medicaid program relied on others to supply the program with the information its employees needed to estimate accurately the acquisition cost of the drugs their citizens needed. (PUF 8-11) Johnson & Johnson (and the other defendants as well) subverted this system by flooding the pricing compendiums Wisconsin used to estimate drug costs with false and inflated prices. (PUF 14 et. seq.) Tautologically, had Johnson & Johnson published its true price in the pricing compendiums it would have been easier to estimate J&J's true wholesale prices. This is an enforcement action brought by the Attorney General of the State of Wisconsin to enjoin defendant J&J's participation in this illicit scheme.

A. Background To Motion.

Medicaid is a voluntary program. Drug manufacturers may elect to participate or not. (PUF 4) As a participant a manufacturer must follow certain rules. The first of these is the general rule applicable to all businesses benefiting from public expenditures:

Justice Holmes wrote: 'Men must turn square corners when they deal with the government.' *Rock Island, A. & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). This observation has its greatest force when a private party seeks to spend the Government's money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.

Heckler v. Community Health Servs., 467 U.S. 51, 63 (1984).

One of the most important Medicaid rules is the rule limiting the amount of money states may pay as reimbursement to providers. The rule says: “The agency payments for brand name drugs...must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the—(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or (2) Providers’ usual and customary charges to the general public.” 42 C.F.R. sec. 447.331(b). (Or in the case of multi-source drugs with upper limits, the lower of the estimated acquisition cost, the usual and customary charge or the FUL.) This rule is designed to maximize the benefits of the program to society’s neediest people while holding down the cost to the taxpayers. There is no exception to this rule and defendant J&J was required to be aware of it. *Heckler v. Community Health Servs.*, 467 U.S. 51, 63 (1984).

Because of the huge volume of drugs eligible for reimbursement, Wisconsin, as most other states, utilizes the services of First DataBank, a pricing service, to provide it with up to date pricing information in electronic form which it can utilize within its payment system. (PUF 8) First DataBank purports to provide Wisconsin with an accurate statement of the average wholesale prices of the drugs it lists. As First DataBank stated to its customers in 1999: “As you know, AWP represents the average wholesale price; the average price a wholesaler would charge a customer for a particular product. The operative word is average. AWP was developed to provide a price which all parties could agree upon for electronic processing to be possible.” (PUF 9) Wisconsin uses these prices on a daily basis. Wisconsin, however, has added a discount to First DataBank’s published prices through the years. For the years 1990 to the present Wisconsin estimated the acquisition cost of J&J’s drugs using various formulas based on the published AWP ranging from AWP minus 10% to the present AWP minus 13%. (PUF 11)

All during the period covered by Wisconsin's complaint J&J has lied about what its average wholesale prices are. J&J reports an average wholesale price, more recently a "suggested average wholesale price," that is far higher than the actual price pharmacies are generally paying for its drugs. J&J calculates the average wholesale price it sends to Wisconsin, the price reporting services, and wholesalers by multiplying J&J's WAC to wholesalers by 20%. J&J does this even though it knows, and it is common knowledge in the pharmaceutical industry, that wholesalers are marking up these drugs by 2% at most as one of J&J's corporate designees admitted.

Q. Prior to 2002 and backwards, how did Janssen determine what the average wholesale price of its drugs was?

A. Just a mechanical calculation. We multiplied it by 120 percent, and that's what was put onto the form.

(Deposition of Parks, 09/15/06, 37:8-13)

Q. Why did Johnson & Johnson or Janssen determine the average wholesale price or suggest an average wholesale price by marking up the WAC 20 percent?

MR. MANGI: Object to the form.

THE WITNESS: I don't know that either. It had been done before me. I just continued it.

Q. Now were all of Janssen and Ortho-McNeil's drugs marked up 20 percent?

A. To the best of my knowledge, yes.

(Parks, 39:1-11)

Q. My question to you is were you aware when you were forwarding these average wholesale prices to First Databank on behalf of Janssen that wholesalers were actually selling Janssen's products at prices significantly lower than the average wholesale price you were sending to First Databank?

MR. MANGI: Objection to the form.

THE WITNESS: Yes, yes, they were selling at below that suggested AWP price to retailers, yes.

(Parks, 47:7-17)

Q. In fact, it was your understanding at the time that you were sending these average wholesale prices to First Databank that wholesalers often charged their customers less than they paid Janssen for these drugs, is that correct?

MR. MANGI: Object to the form, lack of foundation.

THE WITNESS: There are certain customers that the wholesalers sold the Janssen products for for less than the acquisition cost.

(Parks, 48:6-16) (PUF 14-16)

This testimony has been confirmed by J&J's lawyers who admit that "[t]he MDL record establishes, beyond question, that the J&J Defendants sell their medicines to wholesalers at or about the WAC price (not AWP), that the AWP figures submitted by the J&J Defendants to First Data Bank and the Red Book were 120% of the WAC price, and that AWP, as used by the J&J Defendants and other manufacturers, does not represent, or purport to represent, an actual selling price. (Ex. 12 at 4, 5; PUF 16)

Thus, J&J sent to all state Medicaid programs, pricing services and wholesalers, average wholesale prices which it knew were false by some 17-18%. J&J has never disclosed this to Wisconsin. These false prices were plugged into First DataBank's data base which Wisconsin used to estimate the actual acquisition cost of the drugs purchased by providers leading to massive overpayments by Wisconsin. (PUF 8)

J&J's corporate designee could not articulate a business reason for marking up the true wholesale price of J&J's drugs by 20% and publishing this marked up figure as an average wholesale price. (PUF 15)

In 2001, J&J, during the pendency of the first Congressional hearings into pricing abuses in the Medicare system, began to send to all the recipients of its pricing information "suggested average wholesale prices." These were determined in the same manner as the average wholesale

prices had been determined, and were just as unrelated to any real wholesale price of J&J's drugs. (PUF 16) This change was requested by the legal group. (PUF 16)

Then, at some point during 2001, First DataBank increased the spread on J&J's brand drugs from 20% to 25% without informing J&J. This was the first time First DataBank had not reported the AWP's sent to it by J&J. Consternation ensued inside J&J. Indeed, the initial reaction within J&J was that this was "a very bad thing. It was a higher price that our payers would obviously have to absorb." (PUF 18) And an employee named Diane Ortiz was requested to look into the matter and report up the chain of command. Here is what she wrote in part:

Status:

A white paper is being developed by an outside consultant that J&J will provide to key stakeholders (potentially CMS, state Medicaid directors, key managed care organizations, etc.) to alert them to these discrepancies and the lack of control the manufacturer has over the published AWP's. The J&J team working on the paper includes: Kathy Schroeder, Kathy Buto, Jerry Holleman, Pat Molino, Bruce Colligen, and Diane Ortiz with input from OC finance and trade relations contacts. The draft paper is currently under review by legal.

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Thus, at least for a brief moment, J&J looked like it would do the right thing and explain to the state Medicaid programs that they were now paying more for J&J drugs and the reason for it. These good intentions slowly eroded. First, after Ms. Ortiz' report one J&J employee questioned whether this price rise might be in J&J's interest. Another suggested that maybe J&J could get First DataBank to raise the spread on J&J's generic drug, Procrit. And a later one

concluded that, on balance, the price rise was favorable to J&J. The white paper to let state Medicaid directors know what was happening to J&J drugs just mysteriously disappeared. And no further word was heard about it by anyone, including Ms. Ortiz who was a pivotal figure in its creation. (PUF 18-22)⁵

B. Defendant's Conduct Violates Wisconsin Statutory Law

J&J's practice of distributing prices it knows have no basis in fact is unlawful under several Wisconsin laws.

1. J&J's Conduct Violates Wis. Stat. sec. 100.18(1).

a. J&J's Publication of False and Inflated Prices is Unlawful.

Wis. Stat. sec. 100.18(1) prohibits any representation with the intent to sell, distribute, or increase the consumption of merchandise when the representation contains any assertion, representation, or statement of fact that is untrue, deceptive or misleading. Defendant J&J's made up prices are all of these things.

There is no question what the term average wholesale price means. Judge Saris, in the MDL, turned to her dictionary and determined that it meant exactly what it says: the average price paid for goods for resale. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277, 287-88 (D. Mass. 2006). Where a statute does not define a term Wisconsin courts also turn to the dictionary. *Jauquet Lumber Co. v. Kolbe & Kolbe Millwork Co.*, 164 Wis.2d 689, 698, 476 N.W.2d 305, 308 (Ct. App. 1991). Any dictionary the Court chooses confirms Judge Saris' reading of the meaning of average wholesale price.⁶

⁵ J&J has asserted a privilege in connection with the white paper. Shortly plaintiff will move to compel this document.

⁶ *See Federated Nationwide Wholesalers Service v. FTC*, 398 F.2d 253, 257 n.3 (2nd Cir. 1968) where the Court says "[t]he term 'wholesale price' is generally defined as the price which a retailer pays to its source of supply when purchasing goods for resale. . . ."

Defendant's conduct in publishing average wholesale prices that are admittedly not average wholesale prices violates 100.18(1)'s prohibition against untrue statements. "[A] statement is untrue which does not express things exactly as they are." See *Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis.2d 56, 65 n.3, 416 N.W.2d 670, 673 n.3 (Ct. App. 1987). See Wis. J.I. – Civil Sec. 2418 (1998). A statement is untrue "if it is false, erroneous, or does not state or represent things as they are."

Adding the term "suggested" to its reported average wholesale prices after Congress began its investigation of the drug industry does not get J&J off the hook. Whatever a "suggested average wholesale price" is—the prices J&J sends out are not that. J&J knows that no one is selling its product to retailers at those prices, far from it, and J&J is not seriously suggesting anyone should. Thus, the term "suggested" average wholesale prices do not "express things exactly as they are." Moreover, it has been the law for a couple of generations that it is improper to publish a price—suggested or otherwise—unless substantial sales are made at that price.

Pricing information is material as a matter of law. "The materiality of such information cannot be denied. Information concerning prices or charges for goods or services is material..." *FTC v. Crescent Publ'g Group, Inc.*, 129 F.Supp.2d 311, 321 (S.D.N.Y 2001).⁷ As a consequence, it has been the law for over 40 years that it is unlawful to publish a price of any kind, no matter what it is called—manufacturers list, suggested list, regular or wholesale—where that price does not truly represent a price at which significant sales are made. See *Giant Food, Inc. v. FTC*, 322 F.2d 977, 981-82 (D.C.Cir. 1963):

The Commission here has determined that the use of the term 'manufacturer's list price' represents to the public that that was the price at which the product was

⁷ Wisconsin looks to FTC case law in interpreting its consumer protection statutes. See *Tim Torres, Inc.* supra at 142 Wis.2d 66-67.

usually and customarily sold by other stores in the area. This determination was within its power, unless it was 'arbitrary or clearly wrong.' * * * If a manufacturer can be prevented from placing a deceptive price on its product, we see no reason to permit a retailer to make reference to a deceptive *suggested price*.

Giant Food, Inc. v. FTC, 322 F.2d 977, 982 (D.C. Cir. 1963)(emphasis added)(The case also describes why automobile manufacturers can attach suggested retail prices to their cars irrespective of whether substantial sales are made at that price—they are permitted to do so by a specific statute.)

In *Regina I*, 61 F.T.C. Lexis 92, at 34-36, the FTC issued a cease and desist order holding that:

In this case, Regina disseminated its *suggested list prices* to resellers rather than directly to the purchasing public. Regina was fully aware that these *suggested list prices* were not the usual and customary retail prices at which Regina products were sold in the trading areas involved. In so furnishing fictitious retail prices to resellers, Regina placed in hands of retailers and others the means and instrumentalities by which they could mislead and deceive the purchasing public. Such practice is a violation of the Federal Trade Commission Act. (Emphasis supplied)

Regina I, 1962 F.T.C. Lexis 92, at *34-35 (citations omitted). See *Regina Corp. v. FTC*, 322 F.2d 765 (3rd Cir. 1963); *In re Matter of George's Radio and Television Company, Inc.* 62 F.T.C. 179, 1962 WL 75744 (F.T.C.)

Subsequent to this decision the FTC revised its pricing guidelines to provide that use of the term list prices is impermissible unless "substantial (that is, not isolated or insignificant) sales are made in the advertiser's trade area (the area in which he does business)." FTC Guides Against Deceptive Pricing, 16 C.F.R. sec. 233.3(d). In *Helbros Watch Co. v. FTC.*, 319 F.2d 868, 870 n.4 (D.C. Cir. 1962), the FTC took the position, and the D.C. Circuit agreed, that where 40% of all sales were made at prices substantially less than the preticketed price sales at the announced price were not substantial.

In sum, defendant J&J's publication of false and inflated average wholesale prices is a violation of Wis. Stat. 100.18(1).

- b. J&J cannot escape liability by blaming the pricing compendiums who publish inflated prices for J&J's drugs.

J&J cannot escape liability by blaming the pricing compendiums who publish J&J's phony prices. J&J substantially participates in the publication of false pricing information of its drugs by supplying false prices to every link in the purchasing chain from the wholesalers to the pricing compendiums to the actual purchaser, the State of Wisconsin. Indeed, J&J's conduct is nothing more than an inflated pre-ticketing scheme, something that has long been banned.

It is, and has been for a couple of generations, unlawful for a manufacturer to publish inflated suggested retail prices which it knows will be used in the market place by others in connection with the sale of its products. The case of *Baltimore Luggage Company v. FTC*, 296 F.2d 608 (4th Cir. 1961) illustrates this principal. There the Baltimore Luggage Company preticketed its luggage pieces with prices which the retailers could either leave on the luggage or remove which were some \$2.00 higher than the luggage was actually being sold at. As the court explained what happened:

Although Baltimore's pretickets were sometimes removed by the retailers who sold the luggage at less than the preticketed price when the luggage was put on sale, generally the retailers left Baltimore's tickets on the luggage. Some stores also exhibited cards furnished by Baltimore showing the same price as that printed on Baltimore's tickets. The hearing examiner found, and the Commissioner adopted his findings, that by preticketing its luggage, and in some instances also by furnishing customers with display cards showing retail prices, Baltimore represented that the prices on the tickets and cards were the usual and regular retail prices, for its luggage, and that this representation was false in those trade areas where the luggage was usually and regularly sold at retail at approximately \$2.00 less.

Id. at 609.

The court had no difficulty agreeing with the Federal Trade Commission that this conduct was unlawful. Indeed, the defendant agreed that manufacturers who preticket their products with fictitious prices “are guilty of engaging in an unfair trade practice in violation of the Act.” *Baltimore Luggage Company*, supra, 296 F.2d at 610. Instead, the defendant argued that the market from which the FTC secured evidence that its goods were being sold below the advertised price was too narrow.

The *Baltimore Luggage* case is just one in a long line of decisions holding that it is unlawful for a manufacturer to publish a fictitious price which it knows will be used in the market place in connection with the sale of its product. See, e.g., *Clinton Watch Co. v. FTC*, 291 F.2d 838, 840 (7th Cir. 1961) where the court described the vice of preticketing: “Petitioners’ practice places a means of misleading the public into the hands of those who ultimately deal with the consumer. Notwithstanding the prevalence of these practices and the familiarity therewith among members of the trade, these activities are proscribed to protect the interest of the public.”

J&J’s conduct in putting false wholesale prices in the hands of the compendiums, the industry’s voice to the public, (as well as wholesalers and purchasers) is no different in kind than the preticketing schemes described in the preceding cases.

The holding of those preticketing cases are just one application of the broader rule that consumer protection law prohibits participation in any manner in connection with commercial schemes which bilk the public. As the court stated in *FTC v. Windward Marketing, Ltd.*, 1997 WL 33642380 at 13 (N.D. Ga. 1997), “direct participation in the fraudulent practices is not a requirement for liability. Awareness of fraudulent practices and failure to act within one’s authority to control such practices is sufficient to establish liability.” In that case a check factoring business was held liable because it neither “ceased doing business with the selling

Defendants, or even questioned their practices.” *Id.* See also, Section 876(b) of the Restatement of Torts. The *Windward* case is consistent with a long line of FTC precedent.

In *Regina Corporation v. FTC*, 322 F.2d 765 (3rd Cir. 1963) the defendant supplied its retailers and distributors with “list prices” or “suggested list prices” which were higher than the usual and customary price charged by other retailers. The defendant argued that it was not liable because, in some instances, while it supplied the inflated list prices, it had not paid for the advertising which contained its misleading pricing reports, only the retailers had. The court rejected defendant’s argument holding: “With respect to those instances where petitioner did not contribute to the cost of misleading advertising, it is settled that ‘One who places in the hands of another a means of consummating a fraud or competing unfairly in violation of the Federal Trade Commission Act is himself guilty of a violation of the Act. [citations omitted] Proof of petitioner’s intention to deceive is not a prerequisite to a finding of a violation [citation omitted]; it is sufficient that deception is possible.” 322 F.2d at 768.

“That a person is a wrongdoer who so furnishes another with the means of consummating a fraud has long been a part of the law of unfair competition.” *FTC v. Winsted Hosiery Co.*, 258 U.S. 483, 494 (1922).

“It is settled law that ‘one who places in the hands of another a means of consummating a fraud or competing unfairly in violation of the Federal Trade Commission Act is himself guilty of a violation of the Act. . .’ *C. Howard Hunt Pen Co. v. FTC*, 197 F.2d 273, 281 (3d Cir. 1952).” *In the Matter of Coro, Inc.*, 63 F.T.C. 1164 (1963). See, *Coca Cola Co. v. Gay-Ola Co.*, 200 F. 720 (1912); *Von Mumm v. Frash*, 56 F. 830 (2nd Cir. 1893); *Idaho v. Master Distributors, Inc.*, 101 Idaho 447, 458 (1980).

The principles set forth in this case law have special resonance here. As Justice Holmes long ago made clear, J&J, in its multi-million dollar dealings with Wisconsin's taxpayers, accepted a greater standard of care than if it were operating in the private market place. "Men must turn square corners when they deal with the Government." *Rock Island, A & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). No matter how J&J's conduct is spun, supplying pricing data to a business that J&J knew was publishing false prices for its drugs is not turning square corners.

J&J's unlawful conduct is compounded by its failure to come clean when J&J officials saw that First DataBank was further abusing the opacity of the drug market by extending J&J's own misrepresentations by another five percent. For a couple of months it looked like J&J officials were going to tell the States that First DataBank had increased J&J's already exaggerated 20% markup to 25%. A number of employees and an outside consultant began work on a white paper which was to be publicly released and sent to the states telling them that this increase in the spread was not J&J's doing.

Then on September 22, 2002, Joseph Scodari, World Wide Chairman of the Pharmaceutical Business wrote: "...we need to understand if this is potentially a net benefit to J&J (i.e, Procrit would benefit from this situation if determined to be real) or a net loss, so that we can then take appropriate actions."

In response, on September 27, 2002, Bill Pearson concluded that "net impact on J&J brands is "probably" positive under existing payment mechanisms for Medicare, Medicaid and private party." Following this the White Paper just disappeared with the chief catalyst for the paper, Diane Ortiz, never even being informed of what happened to it. Although it is hard to believe, to this day she says she has no idea of what the final decision was in connection with the

white paper. (PUF 19-23) Thus, J&J simply continued its pattern of publishing false prices knowing that they were even more separated from reality as a result of First DataBank's conduct.

J&J's conduct in dealing with Wisconsin's Medicaid program has been a refutation of its obligations to behave with scrupulous honesty toward Wisconsin and its taxpayers.

2. J&J's Conduct Violates Wis. Stat. 100.18(10)(b).

Defendant's false prices even more clearly violate 100.18(10)(b). That statute specifically declares it to be a deceptive act to represent a price as a wholesale price when retailers are paying less. Here defendant concedes that the average wholesale prices it sent to Wisconsin, the pricing publications and wholesalers, were substantially greater—17% to 18%—than the prices retailers were actually paying for J&J's product. (PUF 14- 16) Wisconsin need prove nothing more.

Wisconsin's section 100.18(10)(b) is consistent with FTC law. In *Federated Nationwide Wholesalers Service v. FTC*, 398 F.2d 253 (2nd Cir. 1968) the court defined wholesale price as follows: "The term 'wholesale price' is generally defined as the price which a retailer pays to its source of supply when purchasing goods for resale to the ultimate consumer." *Id.* at 256, n.3. The opinion then held that it was unlawful to call a price a wholesale price when retailers are paying less for it: "The evidence clearly shows that the prices charged by the petitioners for items in the Spalding 'regular' line are uniformly higher, although by modest amounts, than the prices paid by retailers to Spalding. Their representations of 'wholesale prices,' therefore, are deceptive..." *Id.* at 257.

The *Federated* case was not new law. In *L. & C. Mayers Co. v. FTC*, 97 F.2d 365 (2d Cir. 1938) the court held that it was deceptive for a jeweler to call itself a wholesaler and identify

its prices as wholesale when they were selling retail at prices in excess of normal wholesale prices. As the opinion states:

The groups to whom the petitioner is directed not to sell representing itself as a 'wholesaler' are consumers. There is evidence to justify the finding that the prices at which the petitioner sold were higher than normal wholesale prices.

* * *

Petitioner contends that there is no public interest involved and therefore the order should not be approved. It is in the interest of the public to prevent the sale of commodities by the use of false and misleading statements and representations. *Federal Trade Comm. v. Winsted Hosiery Co.*, 258 U.S. 483, 494, 42 S.Ct. 384, 385, 66 L.Ed. 729; *Federal Trade Comm. v. Balme Co.*, 2 Cir., 23 F.2d 615, 620. Indeed, a representation may be unlawful under section 5 although the trader makes it innocently. *Federal Trade Comm. v. Algoma Lumber Co.*, 291 U.S. 67, 81, 54 S.Ct. 315, 321, 78 L.Ed. 655. It is not necessary that the product so misrepresented be inferior or harmful to the public; it is sufficient that the sale of the product be other than as represented. *Federal Trade Comm. v. Royal Milling Co.*, *supra*.

Id. at 367.

Defendants' practice of publishing or circulating wholesale prices which are greater than retailers are actually paying clearly violates Wis. Stat. 100.18(10)(b) and FTC case law to which Wisconsin looks for guidance.

3. J&J Has Participated In A Scheme to Provide Pharmacies With Secret Rebates.

Section 133.05(1) prohibits the "secret payment or allowance of rebates, refunds, commission or unearned discounts whether in the form of money or otherwise...." Defendant's scheme violates this provision.

In *Obstetrical & Gynecological Associates of Neenah, S.C. v. Landig*, 129 Wis.2d 362, 384 N.W.2d 719 (Ct. App. 1986), the interior decorator for the plaintiff Obstetrical & Gynecological Associates, obtained discounts from the published price of her suppliers, which she did not report to the plaintiff. Instead, she collected her fee based on the undiscounted price.

The court held that the plaintiff stated a cause of action, rejecting the defense that because the decorator was not a competitor of the plaintiff, the plaintiff could not show the type of direct injury contemplated by the statute:

There is no need to make the direct-indirect distinction under our statute. Section 133.18(1), Stats., explicitly allows any person injured directly *or indirectly* to sue upon this statute. Similar language is not found in the federal law. *See* 15 U.S.C.A. § 15 (1973). This, coupled with the legislature's instruction that we give the most liberal construction to achieve the aim of competition, compels us to the conclusion that an ultimate consumer who pays a higher price for goods and services indirectly due to a secret rebate comes within the ambit of the statute. In addition to the clear wording of the statute, we perceive a valid policy reason for our holding. By encouraging ultimate consumers (tertiary level) to bring lawsuits for violation of this section, the perpetrators will evaluate risk differently. They may decide that it is not worth the risk because of the chance of having to pay treble damages under sec. 133.18(1). *OB-GYN*, we conclude, has standing.

129 Wis.2d 362, 371-72, 384 N.W.2d 719, 723-24 (Ct.App.1986).

The only difference between this case and the *Landig* case is that here plaintiff is suing the party responsible for the hidden discounts, not the party tendering the bill. For that reason this case is stronger than *Landig*. *Landig* permitted the person reaping the benefit of the secret discount to be sued, but the Act is even more specifically directed at the party providing the secret discounts. The statute says: "The secret payment or allowance of rebates, refunds, commissions or unearned discounts, whether in the form of money or otherwise....is an unfair trade practice and is prohibited." Defendant's conduct in providing phony, inflated published prices for its drugs while at the same time either selling these drugs directly to pharmacies, or to wholesalers and through them to pharmacies, at prices which are secretly and substantially discounted from the published prices is exactly what the Act precludes.⁸

This result is consistent with the application of FTC law over multiple decades:

⁸ The Act requires an injury to competition. As this case makes clear secret discounts are the kind of injury the Act prohibits.

Preticketing at fictitious and excessive prices must be deemed to have the tendency of deceiving the public as to the savings afforded by the purchase of a product thus tagged as well as to the value of the product acquired. Petitioners' practice places a means of misleading the public into the hands of those who ultimately deal with the consumer. Notwithstanding the prevalence of these practices and the familiarity therewith among members of the trade, these activities are proscribed to protect the interest of the public.

Misrepresentation as to the retail value of merchandise by means of an attached, fictitious price and deception as to savings afforded by the purchase of the product at a substantially lower price than that indicated thereon constitute unfair methods of competition.

Clinton Watch Co. v. Federal Trade Com., 291 F.2d 838, 840 (7th Cir. 1961)

The practice of a drug manufacturer printing false prices for use by the retail pharmacy is especially noxious in the context of the Medicaid program. It robs taxpayers of their tax money, reduces the funds available to help treat society's neediest citizens, and creates an incentive to prefer the drug with the biggest spread instead of the most efficient or inexpensive drug.

4. J&J's Conduct Violates the Medicaid Fraud Act.

The Medicaid Fraud Act is a statutory creation which sets forth the only elements necessary to prove a violation. It states simply: "No person, in connection with medical assistance, may: 2. Knowingly make or cause to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment." Wis. Stat. 49.49(4m)(a)(2).

As we have already seen, price is a material fact as a matter of law. And it is beyond dispute that the prices J&J has been purveying are false. J&J knows that Medicaid uses these false prices in connection with its Medicaid program—it is a matter of public record. Nothing more is required by statute.

C. J&J Has No Defense As A Matter Of Law To Plaintiff's Motion.

J&J's defense to this clear case of unlawful conduct is to argue that certain Wisconsin employees connected with the Medicaid program believed that First DataBank's published

wholesale prices for at least some drugs were being discounted to pharmacies and doctors. Notwithstanding their belief, J&J argues, these employees failed adequately to revise the Medicaid program to account fully for such discounting thereby permitting, through negligence, inadvertence or design, pharmacies to be reimbursed at rates higher than the federally authorized estimated acquisition cost. (Plaintiff does not believe that J&J will argue that Wisconsin knew that J&J was deliberately creating and sending false prices to the pricing compendiums. Even if J&J took that position, however, it would not make its argument against a liability judgment any stronger.)

What makes this case ripe for summary judgment on liability is that for two reasons this defense is no defense at all. First, the statutes upon which Wisconsin relies leave no room for such a defense. As these statutes make clear, for liability purposes the only conduct that is important is defendants' unlawful conduct, nothing else. And, second, even assuming that state employees either negligently or purposely looked the other way as defendant violated the law, case law is clear that such conduct cannot estop Wisconsin from seeking a judgment in favor of the taxpayers against defendant for its wrongful acts.

First, in connection with three of the statutes which defendant is accused of violating, liability is established by virtue of defendant's admissions that it published average wholesale prices that were false. No more needs to be proven—and nothing else is relevant for a liability determination. Thus, Wis. Stat. Sec. 100.18(1) makes it unlawful to publish an untrue representation—period. Similarly, 100.18(10)(b) simply says that as a matter of law “it is deceptive” to publish wholesale prices where retailers are actually paying less. These provisions require proof of no other elements, and they do not contain any language which would excuse defendant's conduct. (Thus, there is no requirement that the false statements be knowingly made

or that anyone rely on them. Contrast these provisions with 100.18(12)(b) where the legislature shielded real estate brokers from liability unless they had “knowledge that the assertion. . . is untrue, deceptive or misleading.”)

Wisconsin case law does require what is termed a “causal connection” between the untrue statements and a plaintiff’s loss—but only in connection with Section 100.18(11)(b)2, the statutory provision authorizing pecuniary damages. *See Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis.2d 56, 70, 416 N.W.2d 670, 675 (Ct. App. 1987).

The same analysis applies to Count IV, the Medicaid Fraud count. Section 49.49 under the heading “(1) Fraud. (a) Prohibited conduct”, says: “No person, in connection with a medical assistance program, may...2. Knowingly and willfully make or cause to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment.” Defendant admits to making false statements about the prices of its drugs—price representations are material as a matter of law—and J&J knew that these prices were being used in determining reimbursement for the state’s pharmacies and providers.

This provision further holds that the making of such statements is, without more, a felony for which penalties may be assessed: “Penalties. Violators of this subsection may be punished as follows:

1. In the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing by that person of items or services for which medical assistance is or may be made, a person violating this subsection is guilty of a Class H felony, except that, notwithstanding the maximum fine specified in s. 939.50(3)(h), the person may be fined not more than \$25,000.

2. In the case of such a statement, representation, concealment, failure, or conversion by any other person, a person convicted of violating this subsection may be fined not more than \$10,000 or imprisoned for not more than one year in the county jail or both.

Section 49.49(1)(b). Thus, the very making of a false statement at odds with this provision renders defendant not only liable for the judgment plaintiff requests now, but liable for penalties as well. [Section 49.49, as 100.18, has a separate section governing damages, 49.49(1)(c).]

A different analysis is required, but the result is the same, in connection with plaintiff's secret discount claim under Wis. Stat. 133.05. That section bars the "allowance of rebates or unearned discounts whether in the form of money or otherwise tending to destroy competition." Unlike the statutes cited above this statute obviously requires a showing beyond the conduct of the defendant—an injury to competition—for Wisconsin to prevail on liability. But this latter element is present as a matter of law according to *Obstetrical & Gynecological Associates of Neenah, S.C. v. Landig*, 129 Wis.2d 362, 384 N.W.2d 719 (Ct.App. 1986). There the court held that concealed discounts, such as those present here, constituted an injury to competition which the Act was intended to cover.

In sum, each of these statutes (with the *Landig* twist) base liability solely on whether the defendant did or did not make a false statement—nothing more needs to be proved. Thus, such things as defendant's belief about its conduct, whether anyone relied on defendant's lies, or whether the conduct of state employees was appropriate are irrelevant to a finding on liability.

Second, defendant's claim that Wisconsin is estopped from enforcing its laws because state employees permitted the state to pay more than the federally mandated cap on drug payments is defeated by a line of cases that date back to the Supreme Court's earliest days holding that a defendant who breaks the law cannot excuse its conduct by pointing to negligent, misleading or intentional misconduct on the part of state employees.⁹

⁹ The determination of whether estoppel is available as a defense against a governmental entity is a question of law to be decided by the Court. *Mowers v. St. Francis*, 108 Wis.2d 630, 633, 323 N.W.2d 157, 158 (Ct. App. 1982).

As the Court stated this principle in *Heckler v. Community Health Services*, 467 U.S. 51, 63 (1984):

Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.”

The *Heckler* opinion is consistent with an unbroken line of authority holding that a defendant may not excuse its unlawful conduct by blaming a government employee when a public right is involved: “As a general rule laches or neglect of duty on the part of officers of the Government is no defense to a suit by it to enforce a public right or protect a public interest.”

FTC v. Crescent Publ’g Group, Inc., 129 F.Supp.2d 311, 324 (S.D.N.Y. 2001). See *United States v. Kirkpatrick*, 22 U.S. 720 (1824). See *Nevada v. US*, 463 U.S. 110 (1983), relying on *Utah Power & Light Co. v. US*, 243 U.S. 389, 409 (1917) where the Court rejected the argument that certain officials of the United States had granted a power company the unfettered right to utilize federal lands holding:

As presenting another ground of estoppel it is said that the agents in the forestry service and other officers and employees of the Government, with knowledge of what the defendants were doing, not only did not object thereto but impliedly acquiesced therein until after the works were completed and put in operation. This ground also must fail. As a general rule laches or neglect of duty on the part of officers of the government is no defense to a suit by it to enforce a public right or protect a public interest.

Or as the Court said in *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384 (1947):

Whatever the form in which the Government functions, anyone entering into an arrangement with the Government takes the risk of having accurately ascertained that he who purports to act for the Government stays within the bounds of his authority. The scope of this authority may be explicitly defined by Congress or be limited by delegated legislation, properly exercised through the rule-making power. And this is so even though, as here, the agent himself may have been unaware of the limitations upon his authority.

See US v. Socony-Vacuum Oil Co., 310 US 150, 226 (1940): “Though employees of the government may have known of those (unlawful) programs and winked at them or tacitly approved them, no immunity would have thereby been obtained.”

This doctrine dates back to the infancy of the Supreme Court. *See US v. Kirkpatrick*, 22 U.S. 720, 735 (1824). *See US v. Insley*, 130 U.S. 263, 266 (1889): “The principle that the United States are not bound by any statute of limitations nor barred by any laches of their officers, however gross, in a suit brought by them as a sovereign government to enforce a public right or to assert a public interest, is established past all controversy or doubt.”

Wisconsin adopted these principles in the seminal case of *State v. City of Green Bay*, 96 Wis.2d 195, 291 N.W.2d 508 (1980). There the Court held:

We have not allowed estoppel to be invoked against the government when the application of the doctrine interferes with the police power for the protection of the public health, safety or general welfare. *State of Chippewa Cable Co.*, 21 Wis.2d 598, 608, 609, 124 N.W.2d 616 (1963); *Park Bldg. Corp. v. Ind. Comm.*, 9 Wis.2d 78, 87, 88, 100 N.W.2d 571 (1960); *Town of Richmond v. Murdock*, 70 Wis.2d 642, 653, 654, 235 N.W.2d 497 (1975); *McKenna v. State Highway Comm.*, 28 Wis.2d 179, 186, 135 N.W.2d 827 (1965); *Milwaukee v. Milwaukee Amusement, Inc.*, 22 Wis.2d 240, 252-53, 125 N.W.2d 625 (1964).

City of Green Bay, 96 Wis.2d at 201-202, 291 N.W.2d at 511. In this case Wisconsin’s Attorney General is acting for the “public health, safety (and) general welfare,” hence, estoppel is unavailable to the defendant. *And see Westgate Hotel, Inc. v. E.R. Krumbiegel*, 39 Wis.2d 108, 113, 158 N.W.2d 362, 364 (1968) where the Court rejected the argument that because the City had not enforced an ordinance for nine years the defendant had been lulled into thinking that it was in full compliance with the ordinance.

V. RELIEF SOUGHT

Wisconsin requests the Court grant its Motion for Summary Judgment on liability against these Defendants on each of the four counts for which such relief is sought.

Dated this 23rd day of May, 2007.

One of Plaintiff's Attorneys

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STATE OF WISCONSIN

CIRCUIT COURT
Branch 9

DANE COUNTY

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

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of **WISCONSIN’S MOTION FOR PARTIAL SUMMARY JUDGMENT ON LIABILITY AGAINST JOHNSON & JOHNSON AND ITS SUBSIDIARIES WITH RESPECT TO COUNTS I THROUGH IV OF WISCONSIN’S COMPLAINT, AND SUPPORTING MEMORANDUM, and the DECLARATION OF CHARLES BARNHILL AND APPENDIX** to be served on counsel of record by transmission to LNFS pursuant to Order of the Circuit Court of Dane County, Branch 7, Case Number 04-CV-1709, dated December 20th, 2005.

Dated this 23rd day of May, 2007.

Charles Barnhill

EXHIBIT D

STATE OF WISCONSIN

CIRCUIT COURT
Branch 6

DANE COUNTY

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

**THE JOHNSON & JOHNSON DEFENDANTS' SUPPLEMENTAL RESPONSES AND
OBJECTIONS TO PLAINTIFF'S THIRD SET OF INTERROGATORIES AND
FOURTH REQUEST FOR PRODUCTION OF DOCUMENTS TO ALL DEFENDANTS**

Pursuant to Wisconsin Rule of Civil Procedure 804.08, Johnson & Johnson, Janssen, L.P., McNeil-PPC, Inc., Ortho Biotech Products., L.P., and Ortho-McNeil Pharmaceutical, Inc. (the "J&J Defendants"), by their attorneys, hereby supplement their objections and responses to Plaintiff's Third Set of Interrogatories and Fourth Request for Production ("Plaintiff's Requests") as follows:

PRELIMINARY STATEMENT

The J&J Defendants repeat and incorporate their previous responses and objections as if fully set forth herein. In addition, as a general basis for denying all of Plaintiff's allegations, the J&J Defendants rely on the fact that their pricing practices, including their conduct respecting AWP, were consistent with long-standing and well-known industry practices, were lawful and not deceptive, and were found to be lawful and not deceptive by the only court that has considered the issue. (See In re Pharmaceutical Industry Average Wholesale Price Litig., 491 F.Supp.2d 20 (D. Mass. 2007) ("In re AWP"), and the discovery and trial record related thereto). Notwithstanding their objections, the J&J Defendants supplement their previous

Allegation 25. Allegation 25 states a conclusion of law, not fact.

Allegation 26. The J&J Defendants object to identifying “each fact” that supports their denial of the Plaintiff’s characterization of the “essential structure” of the pharmaceutical market. Notwithstanding their objection, the J&J Defendants state that a more accurate description of the pharmaceutical market is set forth in the Tutorial given by Gregory Bell and Fiona Scott Morton in In re AWP.

Allegation 27. The J&J Defendants object to identifying “each fact” that supports their denial based on lack of knowledge and information sufficient to form a belief as to the Plaintiff’s claim that the market for prescription drugs is “differs in two crucial respects from most markets.” See Response to Allegation 26.

Allegation 28. The J&J Defendants object to identifying “each fact” that supports their denial of Plaintiff’s characterization of the first alleged “crucial” difference between the market for prescription drugs and “most markets.” See Response to Allegation 26.

Allegation 29. The J&J Defendants object to identifying “each fact” that supports their denial of Plaintiff’s characterization of the second alleged “crucial” difference between the market for prescription drugs and “most markets.” See Response to Allegation 26.

Allegation 30. The J&J Defendants object to identifying “each fact” that supports their denial of Plaintiff’s claim that the J&J Defendants engaged in an “unlawful scheme.” Notwithstanding their objection, the J&J Defendants state that they did not “cause” Wisconsin Medicaid or other payors to pay Wisconsin’s providers more than acquisition cost for prescription drugs. Rather, it appears from the evidence that Wisconsin Medicaid knowingly and intentionally elected, based on public policy and/or political considerations, to pay Wisconsin’s Medicaid providers more than acquisition cost. (See, e.g., Depositions of James Vavra and

Christopher Decker). Plaintiff apparently intends its Medicaid reimbursement formula to provide Medicaid providers a profit over acquisition cost. (See, e.g., Vavra Deposition, Ex. 4). For example, Wisconsin elected in 1975 not to pay acquisition cost after it was encouraged to do so by Lieutenant Governor Martin J. Schrieber. (See, e.g., Vavra Deposition, Exs. 4 and 12). Plaintiff elected in 1976 not to pay acquisition cost after the Medicaid Pharmacy Task Force appointed by Governor Patrick J. Lacey encouraged it to do so. (See, e.g., Jan. 16, 1976 Memo. from Robert Durkin to Medicaid Pharmacy Task Force). Plaintiff elected in 1989 not to pay acquisition cost after considering that it had the option to do so. (See, e.g., WI-Prod-AWP-097939). Plaintiff elected not to pay acquisition cost after being advised by HCFA in 1989 that EAC should not be based on undiscounted AWP. (See, e.g., WI-Prod-AWP-097949). Plaintiff elected not to pay acquisition cost after it was proposed as part of the Governor's 1995-1997 Biennial Budget Bill. (See, e.g., Office of Policy and Budget, Elizabeth Barron, Budget Section, July 5, 1995). Plaintiff elected not to reduce pharmaceutical reimbursement from AWP-10% to AWP-18% after such reduction was proposed by as part of the Governor's 1999-2001 Biennial Budget Bill. (See, e.g., WI-Prod-AWP-108297; WI-Prod-AWP-44639; WI-Prod-AWP-108022; WI-Prod-AWP-097609; WI-Prod-AWP-097695; see also Oct. 15, 1998 Letter from State Representative David A. Brandemuehl to Secretary Joe Leraan, Oct. 8, 1998 Note from State Senator Brian D. Rude to Kevin _____, Oct. 16, 1998 Letter from Governor Tommy G. Thompson to Chris Decker, Oct. 26, 1998 Letter from Joe Leraan to State Senator Brian Rude, Oct. 26, 1998 Letter from Joe Leraan to State Representative David A. Brandemuehl). Plaintiff elected not to implement a planned reduction in pharmaceutical reimbursement from AWP-10% to AWP-15% in 1998. (See, e.g., WI-Prod-AWP-044636). Plaintiff elected not to implement a proposed reduction in pharmaceutical reimbursement from AWP-10% to AWP-15% after such

reduction was proposed by as part of the Governor's 2001-2003 Biennial Budget Bill. (See, e.g., WI-Prod-AWP-117906; see also Nov. 6, 2000 Letter from Morton Pharmacy to Governor Tommy Thompson; WI-Prod-AWP-117936; WI-Prod-AWP-117910; WI-Prod-AWP-118056; WI-Prod-AWP-117931). Plaintiff did not reduce pharmaceutical reimbursement after being told by the OIG in 2002 that retail pharmacies in Wisconsin were purchasing brand name pharmaceuticals at or about the published WAC price. (See, e.g., WI-Prod-AWP-104215). Plaintiff elected not to reduce pharmaceutical reimbursement from AWP-11.25% to AWP-15%. (See, e.g., WI-Prod-AWP-109462; WI-Prod-AWP-121428; WI-Prod-AWP-108880; WI-Prod-AWP-110606; WI-Prod-AWP-061664). Plaintiff elected not to reduce pharmaceutical reimbursement from AWP-13% to AWP-16% after Governor Doyle proposed such reduction in 2004. (See, e.g., WI-Prod-AWP-111935; WI-Prod-AWP-105387; WI-Prod-AWP-110628; WI-Prod-AWP-105387; WI-Prod-AWP-111642; WI-Prod-AWP-110754; WI-Prod-AWP-11038; WI-Prod-AWP-11609; WI-Prod-AWP-111831). The J&J Defendants further state that they typically preferred lower AWP's to higher AWP's, because lower AWP's made their drugs less costly to payers in comparison to drugs with higher AWP's. (See, e.g., Deposition of William Parks; see also Deposition of Patricia Kay Morgan). In 2002, representatives of the J&J Defendants notified the Centers for Medicare and Medicaid Services (CMS) that First DataBank (FDB) unilaterally increased certain of their AWP's, and was told by CMS that CMS was aware of FDB's action. (See Deposition of Larry Reed; WI-JJ00018998-99; WI-JJ00020645).

Allegation 31. The J&J Defendants object to identifying "each fact" that supports their denial based on lack of knowledge and information sufficient to form a belief as to the purpose of Wisconsin's Medicaid program.

EXHIBIT E

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL No. 1456
_____)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti Saris
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	Magistrate Judge Marianne B. Bowler
<i>the Florida Keys, Inc., v. Abbott Laboratories,</i>)	
<i>Inc.,</i>)	
CIVIL ACTION NO. 06-11337-PBS)	

**UNITED STATES' OPPOSITION TO DEFENDANT ABBOTT LABORATORIES,
INC.'S RENEWED MOTION TO COMPEL EVIDENCE WITHHELD UNDER
THE DELIBERATIVE PROCESS PRIVILEGE**

In its Motion to Compel, defendant Abbott Laboratories Inc. (Abbott) contends that the United States should be prohibited from asserting the deliberative process privilege in this case since its claims against Abbott "put [the Government's] knowledge and deliberations at issue." In the alternative, Abbott claims that its particularized need for the privileged documents in the context of this case outweighs the public interest in protecting the Government's deliberative processes from disclosure. Abbott further argues that the United States has not asserted the privilege in a procedurally and substantively appropriate manner.

All three of Abbott's contentions are baseless and should be rejected by this Court. The documents listed on the United States' privilege logs are collateral to the critical issues in this case. This fact fatally undermines (1) Abbott's assertions that the Government "waived" its deliberative process privilege by bringing this case, or (2) that Abbott's need for the documents outweighs the Government's interest in preserving the confidentiality of its deliberative

processes. Furthermore, the United States has complied with all substantive and procedural requirements in asserting the deliberative process privilege with respect to the documents on its privilege logs, and Abbott's contention to the contrary contravenes well established case law in this and other Circuits. Abbott's Motion should be denied in its entirety.

BACKGROUND

I. PROCEDURAL HISTORY

In late 2003, the United States received several subpoenas from the defendants in this and another multi-district litigation pending in this district: MDL Nos. 1456 and 1430. The subpoenas were directed to both the Department of Health and Human Services (HHS) and the several regional Medicare carriers that HHS uses to administer the Medicare program ("Carriers"). In response to these subpoenas, in 2004, the United States produced approximately 95,000 pages of documents from the Carriers, and approximately 22,000 pages of documents from HHS itself. After discussions between the United States and the defendant manufacturers, the United States later produced privilege logs, both from the Carriers and from the Centers for Medicare and Medicaid Services (CMS), and asserted a claim of privilege over 600 documents from this production, many of which were withheld on the basis of the deliberative process privilege. These privilege assertions were never challenged in Court by any of the parties in the two MDL proceedings.

After the United States intervened as to Abbott, Abbott propounded a Request for Production (RFP) seeking all of the documents the government withheld from its response to the 2003 subpoenas on the grounds of the deliberative process privilege. *See Ex. 1, Abbott's First Set of Requests for Production*, p. 27, RFP No. 126. In response to Abbott's request, the United

States undertook an additional review of the documents withheld from its earlier production. After completing this review, the United States agreed to release all or part of approximately 200 documents from the 2004 Carrier and CMS privilege logs. The updated CMS and Carrier privilege logs contain entries for 451 documents, a substantial majority of which have been withheld on the basis of the deliberative process privilege.¹ Abbott has now moved to compel production of all of the documents on these logs that have been withheld solely on this basis.

In addition, Abbott has propounded a number of RFPs seeking documents maintained by the HHS Office of Inspector General (OIG). Specifically, Abbott has sought the underlying work papers and files associated with a set of Inspection Reports and Audits that various OIG offices have published over the last 25 years. *See Ex. 1, Abbott's First Set of Requests for Production*, pp. 13-14, RFP Nos. 20-21, Schedule A. The United States has produced a substantial number of responsive documents in response to Abbott's requests, but has asserted the deliberative process privilege over approximately 240 responsive documents. Abbott's Motion to Compel seeks documents from this log as well.

II. GOVERNING PRINCIPLES OF THE DELIBERATIVE PROCESS PRIVILEGE

The deliberative process privilege is an "ancient privilege [that] is predicated on the recognition that the quality of administrative decision making would be undermined if agencies were forced to operate in a fishbowl." *Dow Jones & Co., Inc. v. Department of Justice*, 917 F.2d 571, 573 (D.C. Cir. 1990) (internal quotation marks and citation omitted). The privilege is

¹ The attached privilege logs include documents withheld pursuant to the attorney-client privilege and the work product doctrine. Abbott's Motion to Compel does not challenge the United States' withholding of documents on these bases; the Motion to Compel is limited to documents withheld solely on the basis of the deliberative process privilege.

designed to protect inter-agency and intra-agency deliberations and advice, the disclosure of which would be injurious to the federal government's decision-making functions. *Petroleum Info. Corp. v. United States Dep't of Interior*, 976 F.2d 1429, 1433 (D.C. Cir. 1992). The Supreme Court has held that exposing such materials to outside review would tend to inhibit the candid discussion necessary to effective government. See *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150-51 (1975); *EPA v. Mink*, 410 U.S. 73, 87 (1973).

The central theme of the well developed body of case law interpreting and applying the deliberative process privilege has been the need to safeguard the integrity of the internal debates and discussions necessary to responsible governmental decision making. As the D.C. Circuit explained in *Coastal States Gas Corp. v. United States Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980), the deliberative process privilege protects the "give and take" process of effective government by:

- 1) Ensuring that subordinates in an agency can be candid with decision makers and can provide "uninhibited opinions and recommendations without fear of later being subject to public ridicule or criticism";
- 2) Protecting "against premature disclosure of proposed policies before they have been finally formulated or adopted"; and
- 3) Guarding "against confusing the issues and misleading the public by dissemination of documents suggesting reasons and rationales for a course of action which were not in fact the ultimate reasons for the agency's action."

(citing *Jordan v. United States Dep't of Justice*, 591 F.2d 753, 772-74 (D.C. Cir. 1978)); accord *United States Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (The privilege "rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news.").

The deliberative process privilege protects evidence from disclosure if it is both pre-decisional and deliberative in nature, containing opinions, recommendations, or advice about agency decisions. *See Renegotiation Bd. v. Grumman Aircraft Eng'g Corp.*, 421 U.S. 168, 184 (1975). Generally, pre-decisional documents will be created prior to the agency decisions to which they contributed; however, it is important to recognize that agency decision making is a continuous process, and documents containing protected recommendations or advice may not ripen into a specific agency decision – and indeed, may be subsequent to related agency decisions. *See Sears, Roebuck & Co.*, 421 U.S. at 151 (“Agencies are, and properly should be, engaged in a continuing process of examining their policies; this process will generate memoranda containing recommendations which do not ripen into agency decisions, and the lower courts should be wary of interfering in this process.”). Internal agency documents are “deliberative” when they reflect the “give-and-take” of the consultive/deliberative process. *Coastal States*, 617 F.2d at 866; *American Fed’n of Gov’t Employees, AFL-CIO, v. United States Dep’t of Health and Human Servs.*, 63 F.Supp.2d 104, 107 (D. Mass. 1999).

The deliberative process privilege is not absolute. After concluding that the privilege has been properly invoked, the court must balance the public interest in protection of the deliberative process against the particularized need for the information as evidence in the case before it. *See Comm. for Nuclear Responsibility, Inc. v. Seaborg*, 463 F.2d 788, 791 (D.C. Cir. 1971); *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 327 (D.D.C. 1966), *aff’d*, 384 F.2d 979 (D.C. Cir. 1967); *Scott v. PPG Indus., Inc.*, 142 F.R.D. 291, 294 (N.D. W. Va. 1992). To compel disclosure, the claimant must make “a showing of necessity sufficient to outweigh the adverse effects the production would engender.” *Carl Zeiss*, 40 F.R.D. at 328-29.

One of the most oft cited statements of the factors to be considered in balancing the requisite interests is found in *In re Franklin Nat'l Bank Sec. Litig.*, 478 F.Supp 577, 583 (E.D.N.Y. 1979). When balancing the Government's interest in protecting its deliberative processes against the defendant's need for the evidence, Judge Weinstein articulated the following considerations:

(i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

Id. (internal citations omitted).

ARGUMENT

I. THE DOCUMENTS ABBOTT SEEKS TO COMPEL ARE COLLATERAL TO THE CORE ISSUES IN THIS CASE

Abbott's Motion to Compel rests on a fundamentally flawed premise – namely, that the allegations in the United States' complaint place the Government's deliberative processes at issue in this litigation. Seeking to shift attention from its own conduct, Abbott contends this case turns on why the Government designed or continued to use a drug reimbursement system that relied on AWP. This case, however, is ultimately about Abbott's conduct – specifically, about Abbott's practice of reporting fraudulent prices to third-party compendia, and Abbott's scienter in reporting those fraudulent prices. In other words, this case has nothing to do with whether AWP-based drug reimbursement systems are flawed; it is about how Abbott knowingly abused the reimbursement systems that were in place during the period covered by the United States' complaint. The Government's deliberative processes, as reflected in the documents that Abbott

has moved to compel, are irrelevant to the specifics of Abbott's conduct, and thus irrelevant to the core issues of the complaint.

Abbott's ability to prevail on its first two arguments – namely, that (1) the United States has waived its deliberative process privilege by bringing this case, and/or (2) that Abbott's particularized need for these documents outweighs the governmental interest in preserving the privilege – rests wholly on its ability to articulate a credible need for these documents in developing its defenses to the specific allegations in this case. As discussed in Section II, *infra*, however, wholesale waiver of the deliberative process privilege is dependent on the governmental entities' subjective motivation being *the* issue in a given piece of litigation, such as in a Title VII context. Such is not the case here. Abbott fares no better when the balancing test is applied to its demands. The balancing test weighs the proponents' need for documents in the context of the issues in the case against the governmental and public interest in retaining the documents. Abbott's inability to demonstrate a need for these documents thus also fatally undermines this argument. As detailed below, an assessment of the United States' core contentions in the instant case, brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (FCA), and common law fraud, reveals the fundamental irrelevance of the documents sought to Abbott's defenses in this case.

A. The Documents Are Irrelevant to the FCA Causes of Action

The First and Second Causes of Action of the United States' complaint seek relief under several provisions of the FCA. *See* Ex. 2, United States' Complaint, pp. 26-27, ¶¶ 102-107. Abbott contends that the government's deliberative processes, as reflected in the documents that it has moved to compel, may shed light on what HHS employees "knew, understood, or agreed to

in the area of drug reimbursement,” and that a resolution of these issues is relevant to the disposition of the Government’s allegations in this case.

The flaw in Abbott’s position is that what particular government officials knew, understood, or agreed to in the area of drug reimbursement is not relevant to a defense of an FCA claim unless that knowledge, understanding, or agreement was communicated to Abbott. The fact that a particular CMS, carrier, or OIG official knew or understood certain facts about drug reimbursement is not, in and of itself, relevant, because “government knowledge” is not a defense under the FCA. *See United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (“that the relevant government officials knew of the falsity is not in and of itself a defense.”).

In certain circumstances, evidence of government knowledge *may* be relevant to the question of whether the defendant possessed the requisite scienter under the FCA. Under the FCA, to negate scienter, Abbott must show (1) that the Government was fully informed by Abbott of the conduct at issue and (2) that the Government *approved* of the conduct at issue. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 861178, at *7 (D. Mass. March 22, 2007) (denying motion to dismiss California False Claims Act claim, noting that government approval of the particulars is necessary to negate scienter). Mere acquiescence is not enough to constitute approval negating FCA scienter. *See United States ex rel. Tyson v. Amerigroup*, 2007 WL 781729, at *20 (N.D. Ill. March 13, 2007) (denying defendant’s motion for new trial, noting that the proper test is whether the government knew and approved the particulars of defendant’s conduct, and that mere acquiescence, rather than approval, by government employees is not sufficient to avoid FCA liability).

For a defendant to an FCA action to establish that government knowledge and approval negates scienter, the defendant must demonstrate that it reasonably believed that it (1) fully disclosed the conduct at issue and (2) was complying with its contractual or regulatory obligations based upon representations of approval made to it by appropriate government officials. Abbott has not come close to establishing the threshold element of a government knowledge-based defense, *i.e.*, that it fully disclosed and informed the government of the conduct alleged in the complaint. The United States has issued several discovery requests for evidence of such disclosures and has not received any such evidence to date. *See Ex. 3, United States' First Set of Requests for Production*, pp. 8-9, RFP Nos. 3-8.

Even if Abbott argues that the government obtained the information from other sources, what government officials knew, understood, or agreed to with respect to drug reimbursement can only be relevant to Abbott's defense under the FCA if that knowledge, understanding, or agreement was shared with Abbott. The documents listed on the attached privilege logs have never been shared with anyone outside of the Government and its agents, and thus have obviously never been shared with Abbott. Indeed, none of the documents on any of the logs refer to any communications between the government and Abbott concerning drug reimbursement, a fact that (1) is apparent from the logs themselves (describing the documents) and the attached declarations, and (2) could be confirmed through an *in camera* review of the documents.

Given these facts, Abbott cannot make a credible argument that the deliberative processes contained in the documents on the attached privilege logs could possibly be construed to undermine *Abbott's* scienter under the FCA.

B. The Documents Are Irrelevant to the Common Law Fraud Cause of Action

The Fourth Cause of Action in the United States' complaint concerns common law fraud. The United States alleges that it was justified in relying on Abbott's reported AWP's, as such reliance is an element of the cause of action for common law fraud. *See Ex. 2, United States' Complaint*, p. 28, ¶¶ 113-115. Abbott's Motion never squarely addresses the issue of justifiable reliance as an element of common law fraud, but is replete with assertions that appear to implicate justifiable reliance, such as the notion that "the Government's knowledge of spreads and its deliberations about using published AWP's despite knowing of large spreads is obviously relevant to a fraud case." *See Def's Memorandum (Memo.)* at 6.

Abbott's arguments fail because of a fundamental misapprehension of the nature of the justifiable reliance element in the United States' common law fraud cause of action. It is well established that "men must turn square corners when dealing with the government." *Heckler v. Community Health Servs.*, 467 U.S. 51, 63 (1984) (internal citation omitted). Thus, it follows, that the relevant inquiry is *not* whether the government was justified in using AWP as a benchmark for reimbursement in general. The relevant question is whether the United States, given the statutory and regulatory system in place, justifiably relied upon *Abbott's* reported AWP's for the drugs at issue in this case in reimbursing claims for those *Abbott* products. As detailed below, the answer to that question is yes.

During the relevant time period, Congress and the Secretary of HHS have limited Medicare payments to the lower of the estimated acquisition cost or the national average wholesale price of a drug. 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991) (final rule). This regulation governed Part B drug payments until 1997, when Congress amended the Medicare Act

and set Part B drug payments at 95 percent of the average wholesale price. *See* Pub. L. 105-33, 111 Stat. 462-463 (1997). The Secretary amended the Medicare regulations in 1998 to conform with the Balanced Budget Act amendment and, effective January 1, 1999, Medicare paid the lesser of the supplier's actual charge or 95 percent of the national average wholesale price. 63 Fed. Reg. 58814, 58905 (Nov. 2, 1998). This payment system remained in place until 2003, when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA). Pub L. 108-173, 117 Stat. 2066 (2003).

During the same time frame, a majority of State Medicaid agencies have likewise incorporated published AWP's or Wholesale Acquisition Cost (WAC) into their reimbursement formulae. *See* Ex. 2, *United States' Complaint*, p. 14, ¶¶ 42-44.

This Court has held that the term "average wholesale price," as a statutory and regulatory term, *had a plain meaning* during this time frame. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 287 (D. Mass. 2006) (emphasis added) (holding that "the term 'average wholesale price' in the Medicare statute is not a term of art for any price the pharmaceutical industry places in the industry publication and will be construed under the plain language doctrine of statutory construction"). Under the systems that were in place for the reimbursement of generic drugs during the period covered by the United States' complaint, Abbott was obligated to report prices for its drugs that would ensure that published AWP's were consistent with the plain meaning of the regulatory term. Reliance under these circumstances was established by statute and regulation, not by a specific agency decision that Abbott's customers deserved to be reimbursed based on whatever AWP Abbott chose to report, regardless of its truth or falsity.

The government's complaint focuses on very specific pricing and marketing conduct related to drugs comprising 45 NDCs and is based on facts uncovered during a fraud investigation. Government documents containing macro-level discussions about the Medicare and Medicaid reimbursement systems for generic drugs between 1991 and 2003 are not relevant to Abbott's defense of the United States' common law fraud claim. The privileged documents Abbott seeks are relevant only if they relate to the issue of whether the United States justifiably relied on Abbott's price representations (1) for the drugs at issue or (2) Abbott drugs generally. Abbott, however, has not shown how particular documents on the United States' privilege logs involved Governmental decisions about whether to reimburse the *Abbott* drugs at issue in the case at some amount other than an amount based on *Abbott's* reported prices. Abbott points to nothing on the United States' privilege logs that it believes contain Abbott-specific deliberations or determinations about whether to reimburse Abbott's subject drugs at any particular amount. The documents on the OIG log relate to pre-decisional deliberations concerning the findings of specific Inspections and Audits, and in no way involve decisions about the bases upon which to reimburse specific claims. The great bulk of documents on the CMS and Carrier logs similarly focus on macro-level policy issues. There are no documents on any of the three logs that could afford Abbott a reasonable defense to its common law fraud claim.

**II. THE COLLATERAL NATURE OF THE DOCUMENTS AT ISSUE
ELIMINATES ANY ARGUMENT OF BLANKET WAIVER, AND THE
BALANCING TEST IS DECIDEDLY IN THE UNITED STATES' FAVOR**

**A. There is no Blanket Waiver of the Deliberative Process Privilege Based on
the United States' Allegations in this Case**

In light of Section I above, Abbott's contention that the United States has comprehensively waived its deliberative process privilege by intervening in the instant against

Abbott is completely unsupportable in the law. The United States' allegations in the instant case do not place at issue the subject matter of any of the deliberations contained on its privilege logs, and a wholesale waiver in such circumstances would be unprecedented.

Courts have consistently rejected the argument that the deliberative process privilege is waived simply because the government is a plaintiff in an enforcement action. *See Landry v. FDIC*, 204 F.3d 1125, 1136 (D.C. Cir. 2000); *United States v. Hooker Chemicals and Plastics*, 114 F.R.D. 100, 103 (W.D.N.Y. 1987). The only circumstances in which any courts have effected a blanket waiver of the privilege have been in circumstances where the governmental entity's subjective motivations were *the* issue in the litigation, such as in a Title VII context. *See In re Subpoena Duces Tecum Served on the Comptroller of the Treasury*, 145 F.3d 1422, 1425 (D.C. Cir. 1998) (privilege must give way when issues in case make deliberative processes the issue, as in Title VII discrimination cases). As described in Section I, *supra*, the allegations in the United States' complaint involve no such issue; this case is about Abbott's conduct, not about the United States' subjective motivations.

Even assuming, *arguendo*, that the "knowledge and deliberations" of the United States were at issue in this litigation, it would not follow that a blanket waiver of the United States' deliberative process privilege would be appropriate. Courts have routinely applied the "balancing test," described above, after concluding that the Government's knowledge or deliberations are *an* issue in the underlying litigation. *See Alexander v. FBI*, 186 F.R.D. 200, 206 (D.D.C. 1999) (finding government conduct and intent at issue before engaging in balancing analysis); *Department of Econ. Devel. v. Arthur Anderson & Co.*, 139 F.R.D. 295, 298-99 (S.D.N.Y. 1991) (same).

Further undercutting its own argument, Abbott's Motion cites cases that apply the fact-specific balancing test (rather than wholesale waiver) to the Government's invocations of the privilege. *See Def's Memo.* at 5. Nonetheless, Abbott persists in its claim that the United States should be barred from asserting the privilege with respect to future documents or testimony in this case, and its proposed order does not provide any alternative to such a sweeping ruling. *See Def's Memo* at 5-7; *Def's Proposed Order* at ¶ 2 (barring the United States from asserting the privilege in the future absent a Court order). Abbott is therefore asking this Court to apply the balancing test *now* to documents and testimony described in hypothetical future privilege logs and agency declarations the Court has never reviewed.

This suggestion runs completely contrary to case law. The balancing test clearly envisions a well-defined, individualized review of each assertion of the deliberative process privilege. *See In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997) ("each time the deliberative process privilege is asserted the district court must undertake a fresh balancing of the competing interests.") (internal quotation marks and citations omitted). It would be speculative in the extreme to apply an individualized balancing test to hypothetical documents or testimony over which over which the privilege may be asserted. The United States has not identified any case where courts undertook such an speculative exercise. This Court should assess the merits of the United States' privilege assertions on a document-by-document basis, and should reject Abbott's legally insupportable attempt to convert a factor-specific balancing inquiry into a black-letter rule.

B. The Balancing Test Favors the United States' Position

The appropriate manner in which the Court should assess the United States' privilege assertions is to balance the United States' interest in preserving the privilege against Abbott's need for the documents, in light of the specific issues involved in this case. Given the fundamentally collateral nature of the privileged documents to any of Abbott's defenses, Abbott's purported need for the documents should give way to the United States' interests in protecting its deliberative processes. An analysis of the various prongs of the balancing test bears this conclusion out.

The first two elements of Judge Weinstein's articulation of the balancing test are: (1) the relevance of the documents, and (2) the availability of other evidence enabling the opposing party to prove its claim or construct its defense. *See Franklin Nat'l Bank*, 478 F. Supp at 583. As was discussed *supra*, the documents contained on the United States' privilege logs themselves are simply not relevant to any defenses Abbott could raise to the allegations in the United States' complaint. A requesting party cannot, as a matter of law, demonstrate "need" in the absence of relevance, and the relevance of the privileged documents here are dubious at best. *See United States v. Farley*, 11 F.3d 1385, 1390 (7th Cir. 1993). Abbott cannot and does not argue that these non-public documents are somehow relevant to its scienter, and Abbott cannot show that any of these documents are pertinent to issues concerning the United States' reliance on Abbott's reported prices in reimbursing Abbott's subject drugs.

As to the second element of the test, i.e., the "availability of other evidence," the key point is the following – this case is about *Abbott's* conduct, not about the United States' system for the reimbursement of prescription drugs. Evidence relevant to Abbott's knowledge,

understanding, and conduct is much more likely to be found in Abbott's files than in the Government's. With the exception of the United States' claims data, it is unlikely the United States could produce any documents relevant to the core issues in the case that are not already in Abbott's possession.

The fifth element of the balancing test concerns the possibility of future timidity by government employees if the documents are disclosed.² *See Franklin Nat'l Bank*, 478 F. Supp at 583. This prong is directed to assessing the possibility of a chilling effect on candid and frank agency discussion if the deliberative processes at issue are disclosed to the public and used as fodder for litigation. Given the nature of the documents and processes at issue in Abbott's Motion to Compel, future timidity is a serious concern in this case.

The attached Government declarations clarify the specifics of this concern. The OIG log consists largely of documents generated pursuant to formal internal processes at the Office of Evaluation and Inspections (OEI), such as minutes of entrance and exit conferences and drafts of the OEI's publicly issued inspection reports. *See Ex. 4, Declaration of Robert Vito* (attached privilege log). Robert Vito, the Regional Inspector General, notes the critical role that the candid advice of staff plays in the formulation of work plans and the ultimate drafting of OEI reports. *See Id.* at p. 13. Documents directly analogous to those on the OIG log have been found to fall within the scope of the privilege in the past. In *Moye, O'Brien, O'Rourke, Hogan, & Pickert v.*

² The third and fourth prongs of the balancing test, less relevant to the instant case, concern the (3) seriousness of the litigation and (4) role of the government in that litigation. *See Franklin Nat'l Bank*, 478 F. Supp at 583. The Government is the plaintiff in this litigation, and the issues are undoubtedly serious. The Government's status as a plaintiff does not affect the United States' ability to assert the privilege – especially where, as here, the privileged documents are of dubious relevance to the defendant's case. *See, e.g., Landry*, 204 F.3d at 1136.

Nat'l R.R. Passenger Corp., the court found that the body of internal work papers generated by Amtrak's OIG in connection with financial and performance audits were covered by the privilege. 376 F.3d 1270, 1279 (11th Cir. 2004). In its decision, the court held that the privilege covered "the entire body of collaborative work performed by the auditors," including "the initial work plan for the audit describing its purpose and objectives as well as the methodologies and sampling techniques that will be used to gather and analyze audit data." *Id*; see also *Hamilton Sec. Group v. Department of Housing and Urban Dev.*, 106 F.Supp 2d. 23, 29-32 (holding that OIG draft audit materials were protected by deliberative process privilege). Release of the documents from the OIG privilege log would, as Mr. Vito's declaration states, chill the vigorous internal debate and discussion that characterizes the work of his and other OIG offices.

The documents contained on the CMS and carrier privilege logs come from a broader set of offices and sections within the agency than do the documents on the OIG log. However, the declaration from Leslie Norwalk, the acting Administrator of CMS, spells out quite clearly the concern within that agency about the possibility of a chilling effect upon agency deliberations if these documents are to be released. Ms. Norwalk's declaration articulates the key role that candid internal discussion plays in CMS's efforts to set policy consistent with the agency's controlling statutes, regulations, and objectives, and notes that her belief that CMS employees would feel constrained in offering candid advice if they lacked confidence that their views would be treated as confidential. *See Ex. 5, Declaration of Leslie Norwalk*, at 17-21.

In sum, the documents contained on the United States' privilege logs bear little if any relevance to Abbott's defenses to the allegations in the United States' complaint. However, as the attached declarations state, the release of these materials would likely have a chilling effect

on the internal deliberations necessary for effective agency action. The balance of these considerations tips heavily towards preserving the United States' privilege assertions.

III. THE UNITED STATES HAS COMPLIED WITH ALL PROCEDURAL AND SUBSTANTIVE REQUIREMENTS IN ASSERTING THE PRIVILEGE

Abbott complains that the United States has failed to support its privilege assertions in the procedural and substantive manner required. Abbott's complaints have no basis in the law of this or any other Circuit, and should be summarily rejected this Court.

A. The Attached Declarations are Timely as a Matter of Law

Abbott's initial complaint is that the United States was obligated to submit agency declarations supporting the United States' assertion of the deliberative process privilege at the time that the United States placed the documents on its privilege logs in response to Abbott's discovery requests. This contention runs contrary to the great weight of authority, which confirms the principle that declarations of agency personnel are only necessary when asserting a governmental privilege in court, in response to a motion to compel or in support of a motion for a protective order. *See In re Sealed Case*, 121 F.3d at 741 (White House was not obliged to "formally invoke its [executive] privileges in advance of the motion to compel;" it was sufficient that it said, in response to a subpoena, that it "believed the withheld documents were privileged."); *Huntleigh USA Corp. v. United States*, 71 Fed. Cl. 726, 727 (2006) (procedural requirements for privilege assertion are satisfied through the production of a declaration or affidavit by the agency head in response to a motion to compel); *Tri-State Hosp. Supply Corp. v. United States*, 226 F.R.D. 118, 134 n.13 (D.D.C. 2005); *In re Consol. Litig. Concerning Int'l Harvester's Disposition of Wis. Steel*, Nos. 81 C 7076, 82 C 6895 & 85 C 3521, 1987 WL 20408, at *7 (N.D. Ill. Nov. 20, 1987) (rejecting assertion that agency head's affidavit must be submitted

when privilege is first invoked); *Abramson v. United States*, 39 Fed. Cl. 290, 294 n.3 (1997) (“procedural requirements generally are satisfied through the production of a declaration or affidavit . . . in response to a motion to compel”); *Securities & Exch. Comm’n v. Downe*, 1994 WL 23141, at *5 (S.D.N.Y. Jan. 27, 1994) (unpublished opinion) (government meets its obligation regarding affidavit by filing it with its papers opposing motion to compel). Abbott does not point to a single First Circuit case holding that an agency declaration in support of an assertion of the deliberative process privilege is necessary at all, let alone that such a declaration must be submitted in response to a discovery request as opposed to in response to a motion to compel.

It should be noted that the above-cited holdings concerning the appropriate timing of an agency declaration make eminent practical sense. In the course of complex litigation, litigants routinely place documents on privilege logs and withhold such documents from production. Many such privilege notations are unchallenged by the opposing party. Until a litigant has actually sought judicial intervention to compel the production of documents withheld on the basis of the deliberative process privilege from a privilege log, it makes little sense to require senior agency officials to personally review the logged documents in order to formally invoke the privilege. Such a review would be exceptionally burdensome to the agency and quite possibly entirely academic to the litigation. In *Scott*, 142 F.R.D. 291, 293-94 (N.D. W. Va. 1992), the court noted that “it is ludicrous to suggest that the agency head rather than the EEOC’s litigation attorney should be required to invoke the deliberative process privilege in a deposition.” It is similarly inappropriate to require senior federal officials to be burdened with submitting

declarations formally invoking the deliberative process privilege over documents that may never be the subject of litigation.

The bulk of the cases Abbott cites in support of its argument that an agency declaration is required at the time that documents are placed on a privilege log do not stand for the propositions for which they are cited. *Mobil Oil*, a case cited heavily by Abbott, concerned a situation where the agency apparently did not submit an agency affidavit or declaration at all in response to a motion to compel. *See Mobil Oil Corp. v. Dep't of Energy*, 102 F.R.D. 1, 6 (N.D.N.Y. 1983). The court held that such a declaration was required, but did not address the issue of the appropriate timing for submitting such an affidavit. The *Grossman* case similarly did not squarely address the appropriate timing of an appropriate declaration, but noted that the purpose of such a declaration was to enable “the *court* to make an intelligent and informed judgment as to each requested piece of information” – thus suggesting that such declarations only need be produced in response to a motion to compel. *Grossman v. Schwartz*, 125 F.R.D. 376, 381 (S.D.N.Y. 1989). The portion of the Federal Claims Court’s decision in *Pacific Gas* case, cited by Abbott for the proposition that the Government’s failure to submit an affidavit at the time the documents were logged waived the privilege, was modified in a corrected opinion. *See Pacific Gas & Elec. Co. v. United States*, 71 Fed. Cl. 205, 208-09 (2006) (stating that there was no waiver of right to assert deliberative process privilege by waiting to produce agency affidavit in response to motion to compel, rather than earlier in the process, but that such affidavits would be subjected to “heightened scrutiny”). The same Court of Federal Claims, within two months of publication of the corrected *Pacific Gas & Electric* opinion, held that “the procedural requirements for asserting the privilege “are satisfied through the production of a declaration or

affidavit by the agency head, and produced in response to a motion to compel.” *Huntleigh*, 71 Fed. Cl. at 727.

In sum, the great bulk of authority addressing the issue holds that production of agency declarations in response to motions to compel is procedurally proper. Abbott’s contention to the contrary is both impractical and unsupported by the law, and should be rejected for both reasons.

B. The Documents on the United States’ Privilege Logs Satisfy the Substantive Requirements for Assertion of the Deliberative Process Privilege

Abbott also attacks the United States’ privilege assertions on substantive grounds, contending that the United States has failed to identify the decision to which certain documents relate and that it has improperly withheld certain draft documents. Abbott’s argument is vague and unfocused – other than citing several examples, it fails to note precisely which documents on the United States’ privilege logs it views as falling outside the scope of the privilege and for which reasons. Nevertheless, the United States will address this point.

Citing *Providence Journal Co. v. United States Dep’t of the Army*, 981 F.2d 552, 557, Abbott argues that the United States must identify, with respect to each document on its logs, the “specific agency decision to which the document correlates.” It is a misreading of both *Providence Journal* and the broader state of the case law to suggest that such an identification is required for the privilege to be asserted properly. Agency decision making is a complex process, and agencies often generate documents that may be prior to one agency decision, while being subsequent to other agency decisions. The Supreme Court has held as much:

Our emphasis on the need to protect pre-decisional documents does not mean that the existence of the privilege turns on the ability of an agency to identify a specific decision in connection with which a memorandum is prepared. Agencies are, and properly should be, engaged in a continuing process of examining their policies; this

process will generate memoranda containing recommendations which do not ripen into agency decisions; and the lower courts should be wary of interfering with this process.

Sears, Roebuck and Co., 421 U.S. at 151-52; *see also Moye*, 376 F.3d at 1280 (“contrary to the district court’s finding and the firm’s assertion, Amtrak need not cite to a specific policy decision in connection with which the audit work papers and internal memoranda were prepared in order for these documents to be protected from disclosure by the deliberative process privilege.”); *Access Reports v. United States Dep’t of Justice*, 926 F.2d 1192, 1196 (D.C. Cir. 1991) (internal memorandum prepared was protected by deliberative process privilege despite claim that it did not relate to any particular decision). *Providence Journal* itself notes that an agency “may” meet its burden of demonstrating that a document is pre-decisional by identifying the specific agency decision to which it relates; the case does not state that such identification is mandatory. *Providence Journal*, 981 F.2d at 559.

Indeed, the *Providence Journal* court later framed the following as “the appropriate judicial inquiry” when assessing claims of deliberative process privilege: “whether the agency document was prepared to facilitate and inform a final decision *or deliberative function* entrusted to the agency.” *Id.* at 560 (emphasis added). Certain of the documents on the United States’ privilege logs do not necessarily relate to final policy decisions, yet absolutely were prepared to inform “deliberative functions entrusted to the agency.” The OIG privilege log contains numerous documents relating to that organization’s deliberative functions, such as preliminary drafts of the reports and notes of entrance and exit conferences associated with the reports. Such documents may or may not have led to specific agency policy decisions – their

status as privileged does not depend on identifying any such decision. *See Moye*, 376 U.S. at 1280.

Many of the documents on the United States' privilege logs are drafts of agency statements, reports, or deliberations on a variety of issues. Drafts are inherently deliberative, and rarely relevant, as they do not constitute a final agency position or statement on any disputed issue. *See Grossman*, 125 F.R.D. at 385. Stated differently, drafts represent the personal opinion of the author, not yet adopted as the position of the agency. *See Judicial Watch, Inc. v. Clinton*, 880 F. Supp. 1, 13 (D.D.C. 1995), *aff'd*, 76 F.3d 1232 (D.C. Cir. 1996).

This Court has embraced the reasoning of the above-cited authorities in a relatively recent decision involving draft documents. *See AFL-CIO*, 63 F.Supp.2d at 108. Noting that "draft documents have frequently been held to be deliberative material," this Court went on to state that releasing the draft at issue in that case "would enable a careful reader to determine the substance of HHS's proposed changes," because the draft consisted of "the suggestions of individual agency employees as to what the final [document] should look like." *Id.* The Court concluded that release of the draft "would discourage candid discussion within the agency and thereby undermine HHS' ability to perform effectively its assigned function," and upheld the United States' privilege assertion over the document. *Id.* The rationale that this Court used in the *AFL-CIO* case is equally applicable to the drafts contained on the United States' privilege logs, and that rationale should be used to deny Abbott's Motion to compel production of these documents.

CONCLUSION

For the foregoing reasons, Abbott's Renewed Motion to Compel Production of Evidence Withheld Under the Deliberative Process Privilege should be denied.

Respectfully submitted,

For the United States of America,

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Dated: April 20, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "MEMORANDUM IN OPPOSITION TO ABBOTT'S MOTION TO COMPEL EVIDENCE WITHHELD UNDER THE DELIBERATIVE PROCESS PRIVILEGE" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: April 20, 2007

/s/ John K. Neal
John K. Neal

EXHIBIT 4

EXHIBIT F

MAY 14 2005

RECEIVED
TO BE A

MAY 09 2005

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE
ON OPINIONS

CLERK OF THE SUPERIOR COURT
CLERK OF THE SUPERIOR COURT
STEPHEN C. McCARTHY
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LAW DIVISION
CAPE MAY COUNTY**

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**CASE: Bernard Walker v TAP Pharmaceutical Products, Inc., et al
DOCKET NO: CPM L 682-01**

**NATURE OF APPLICATION: Plaintiff's Motions to Preclude Government and Insurer
Knowledge - Motion # 28 and 29**

**MEMORANDUM OF DECISION ON MOTION
PURSUANT TO RULE 1:6-2(f)**

I have carefully reviewed the moving papers and any response filed, and after oral argument rule on the above motions as follows:

Before the court are Plaintiff's Motions *In Limine* to Preclude Defendants from Presenting Evidence or Testimony at Trial Respecting alleged Insurer Knowledge and Government Knowledge about the AWP.

At trial, defendants will proffer evidence regarding insurer and government knowledge pertaining to the AWP of Lupron® in an attempt to defeat plaintiff's claims founded on Common Law Fraud and the Consumer Fraud Act. In opposition to plaintiff's motion, defendants contend that such evidence is relevant to a number of issues including, (1) fraudulent intent; (2) misrepresentation; (3) reliance; (4) unconscionable commercial practice; and (5) intervening cause. Further, defendants contend that evidence regarding insurer and government knowledge can be imputed to plaintiff, thereby totally defeating plaintiff's claim of fraud. These arguments are without merit and rejected.

Defendants have failed to identify and articulate how "general knowledge" held by various insurance companies and the government that relates to their awareness of the inflated Lupron® AWP is relevant to plaintiff's Complaint. The basic fact that

certain insurance companies and government agencies were aware that Lupron® could have been purchased at a price lower than the AWP does not at all address the fact of whether the AWP was in fact artificially inflated, the means by which the AWP may have been artificially inflated and the use of the inflated AWP in sales of Lupron®.

Defendants offer a variety of reasons for admissibility of various records. I will assume for purposes of these two motions that Defendants are correct, that is, that each of the documents for one reason or another are admissible. The question is, What have Defendants established by such evidence? As Defendants have said repeatedly, the following would be proven:

- 1) The insurance companies and the government knew the AWP was higher than the acquisition costs.
- 2) AWP was the basis for reimbursement.
- 3) Physicians were billing and being reimbursed at AWP or some formula based on AWP.
- 4) That the insurance companies and the government knew that the AWP was fictional.
- 5) Physicians were making a profit because of the difference between acquisition cost and AWP.

Defendants claim that this evidence negates certain elements of Plaintiff's claim, namely, Unconscionable Commercial Practices, Intent, Reliance and support certain defenses such as Justification, Customary Business Practices, Statute of Limitations, Intervening Cause and Concealment. Further, all of these issues raised as affirmative defenses, may in fact go to a systemic problem in the Medicare reimbursement policy.

The argument urges an inference, that since the difference between AWP and acquisition costs were known, readily apparent and were allowed to continue, that the "Return to Practice" was accepted and authorized by the government and the insurers.

Notably, I have not seen any record, and Defendants have not cited any, that acknowledge and/or approve the alleged "Return to Practice" used in the sale of this drug. If there are any, Defendants are free to point that out in the course of the trial.

Plaintiff's motions are granted.

May 9, 2005

Joseph C. Visalli, J.S.C.

MAY 14 2005

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WITNESSED
 TO BE A
 TRUE COPY

MAY 09 2005
 FILED
 Office of the Superior Court Clerk
 by Deputy Clerk of the Superior Court
 CHARLES L. McCARTHY
 Superior Court

BERNARD WALKER, individually,
 and on behalf of those similarly situated,

 Plaintiff,

v.

TAP PHARMACEUTICAL PRODUCTS, INC.,
 ABBOTT LABORATORIES AND
 TAKEDA CHEMICAL INDUSTRIES, LTD.

 Defendants.

SUPERIOR COURT OF NEW JERSEY
 LAW DIVISION
 CAPE MAY COUNTY

CIVIL ACTION NO.: CPM-L-682-01

JURY TRIAL DEMANDED

ORDER on 4/20/05
 28 + 29

AND NOW, THIS 9th DAY OF May, 2005, upon consideration
 of Plaintiff's Motion ⁵ *in Limine* to Preclude Defendants from Presenting Evidence Or Testimony At
 Trial Respecting Alleged Insurer Knowledge ^{AND GOVERNMENT KNOWLEDGE} and Defendants' responses thereto, and having heard
 argument thereon, the Court hereby ORDERS that Defendants are precluded from introducing any
 such evidence or testimony at trial.

IT IS FURTHER ORDERED that a copy of this Order be served on all parties within
7 days from the date hereof.

1 Plaintiff's Motion ^{WAE} was opposed.

 Plaintiff's Motion was unopposed.

Joseph C. Visalli

 HON. JOSEPH C. VISALLI, J.S.C.

EXHIBIT G

lower income individuals. Each state administers its own Medicaid program, but the states' programs are governed by federal statutes, regulations and guidelines. Medicaid is funded jointly by the federal and state governments. 42 U.S.C. §1396 (2003).

1.2 As a part of its participation in the Medicaid program, Texas provides drug reimbursement coverage to program participants. TEX. HUM. RES. CODE ch. 51. The Texas Medicaid Vendor Drug Program ("VDP") was established to provide statewide access for its Medicaid recipients to prescription drugs. Only drugs contained within Texas' formulary of covered drugs are eligible for reimbursement under the program. In order to be listed, the manufacturer must submit an application to the VDP for each product to be included in the formulary. 25 TEX. ADMIN. CODE § 35.801(Vernon 2003). On the application, the drug manufacturer must supply numerous types of price information about the drug, including the "average of the suggested wholesale price to the pharmacy" (the "AWP") and the "price to the wholesaler and/or distributor." A representative of the drug manufacturer must also attest to the fact, when signing the application, that all information contained within the application is accurate. Furthermore, drug manufacturers must notify the VDP within 15 days of any price change. The VDP uses the manufacturer's reported price, along with other information, to establish the reimbursement amount to be paid to the pharmacist. The information reported by the drug's manufacturer is an integral component of the established reimbursement amount. *See* 1 TEX. ADMIN. CODE § 355.8541(2) (Vernon 2003) *and* 25 TEX. ADMIN. CODE § 35.801(b) (Vernon 2003).

1.3 When a manufacturer reports a falsely high price to VDP, the amount VDP reimburses the pharmacist is greatly inflated. A pharmacist who chooses the brand with the most inflated price report receives from VDP a reimbursement amount far in excess of a reasonable

estimate of his acquisition costs. By making these inflated price reports to VDP, the Defendants have manipulated the pharmacy reimbursement system to generate overpayments to the pharmacists. The Defendants engage in this manipulation in order to gain market share for their products and to compete with each other.

1.4 The State brought this suit in conjunction with Relator for violations of the Texas Medicaid Fraud Prevention Act (“Act”) to recover these overpayments, interest on the overpayments, double damages and civil penalties as provided in § 36.052 of the Act. TEX. HUM. RES. CODE ch. 36. In its Sixth Amended Petition, the State alleges the Defendants have engaged in common law fraud and have violated §§ 36.002(1), 36.002(2), 36.002(4) and 36.002(9) of the Act, which prohibit:

- (1) knowingly or intentionally making, or causing to be made, false statements or misrepresentations (A) on an application for a contract, benefit, or payment under the Medicaid program; or (B) that is intended to be used to determine a person’s eligibility for a benefit or payment under the program. (§§ 36.002(1) (A) and (B));
- (2) knowingly or intentionally concealing or failing to disclose an event that permits “a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized.” (§ 36.002(2));
- (3) knowingly or intentionally making, causing to be made, inducing or seeking to induce the making of a false statement or misrepresentation of material fact concerning (B) “information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.” (§ 36.002(4)); and
- (4) knowingly or intentionally entering into “an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent.” (§36.002(9)).

1.5 Extensive discovery has been conducted in this case, including the completion of

over ninety oral depositions. Pursuant to the Scheduling Order in effect, the deadline for additional discovery has passed.

1.6 Defendants Roxane, Warrick, Schering and Schering-Plough filed answers to the State's Sixth Amended Petition that plead, in addition to a general denial, numerous "Additional Defenses." See Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, pp. 5-15 and Defendant Warrick Pharmaceuticals Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, pp. 2-12. Among these are the affirmative defenses of limitations, estoppel, laches, express waiver, implied waiver, unclean hands, failure to mitigate damages, ratification, mutual mistake, unilateral mistake, unjust enrichment, TDH regulations, and the filed rate doctrine; all defenses which are not applicable to the State, or for which no evidentiary support exists at the conclusion of the period for discovery in this case. Because these defenses are untenable in this lawsuit, the State has brought this motion for partial summary judgment to dispose of all of these defenses against the Defendants prior to trial.

2. Summary Judgment Standard and Function.

2.1 To obtain a summary judgment, the movant must establish that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. TEX. R. CIV. P. 166a(c); *Randall's Food Mkts., Inc. v. Johnson*, 891 S.W.2d 640, 644 (Tex. 1995); *Nixon v. Mr. Property Management Co.*, 690 S.W.2d 546, 548-49 (Tex. 1985). In deciding whether there is a disputed material fact issue precluding summary judgment, "evidence favorable to the non-movant will be taken as true." *Randall's*, 891 S.W.2d at 644; *Nixon*, 690 S.W.2d at 548-49. In addition, "[e]very reasonable inference must be indulged in favor of the non-movant and any doubts resolved in its

favor.” *Nixon*, 690 S.W.3d at 549. *Accord Randall’s*, 891 S.W.2d at 644. An appropriate function of summary judgment is the elimination of untenable defenses. *Swilley v. Hughes*, 488 S.W.2d 64, 68 (Tex. 1972).

2.2 To obtain a no-evidence motion for summary judgment, each element of the affirmative defense being challenged must be stated with specificity. *Ebner v. First State Bank of Smithville*, 27 S.W.3d 287, 305 (Tex. App.-Austin 2000, pet. ref’d). No supporting evidence is required to obtain a no-evidence motion for summary judgment. *McClure v. Attebury*, 20 S.W.3d 727, 727 (Tex. App.-Amarillo 1999, no pet.). A no-evidence motion places the burden on the non-movant to present summary judgment evidence raising a genuine issue of material fact as to the challenged elements and if the non-movant is unable to do so, the court must grant the motion. *Harrill v. A.J.’s Wrecker Serv., Inc.*, 27 S.W.3d 191, 193 (Tex. App.-Dallas 2000, pet. dismiss’d). There must be adequate time for discovery before a no-evidence motion for summary judgment is ripe, but it is not required that discovery be completed. *Specialty Retailers, Inc. v. Fuqua*, 29 S.W.3d 140, 145 (Tex. App.-Houston [14th Dist.] 2000, pet. denied).

3. The equitable defense of limitations does not apply to the State.

3.1 Although Defendants contend that limitations bar this action, they do not cite a particular statute of limitations. *See* Defendant Roxane Laboratories, Inc.’s Special Exceptions and Original Answer to Sixth Amended Petition, p. 9 *and* Defendant Warrick Pharmaceuticals Corporation’s, Schering Corporation’s and Schering-Plough Corporation’s Special Exceptions and Original Answer to Sixth Amended Petition, p. 6. Regardless of the statute they contend bars this action, it does not apply to the State. The State in its sovereign capacity is not like ordinary litigants and equitable defenses such as limitations do not apply to the State. *State v. Durham*, 860 S.W.2d

63, 67 (Tex. 1993); *Shields v. State*, 27 S.W.3d 267, 275 (Tex. App.- Austin 2000, no pet.).

4. The equitable doctrines of estoppel and laches do not apply to the State.

4.1 Defendants contend that the State's action is barred by the equitable doctrines of estoppel, quasi-estoppel and laches. *See* Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, p. 9 *and* Warrick Pharmaceuticals Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, p. 6. Like the equitable defense of limitations, the State in its sovereign capacity is not subject to the equitable defenses of estoppel and laches. *Durham*, 860 S.W.2d at 67; *Leeco Gas & Oil Co. v. County of Nueces*, 736 S.W.2d 629, 630 (Tex. 1987); *City of Hutchins v. Prasifka*, 450 S.W.2d 829, 835 (Tex. 1970). The State is acting in its sovereign capacity in this case by administering the State Medicaid pharmacy program for indigent Texans and in enforcing the Texas Medicaid Fraud Prevention Act. Thus, Defendants' claim that estoppel, quasi-estoppel and laches bars the State's claims must fail as a matter of law.

5. The doctrine of waiver does not apply to the State when enforcing its laws.

5.1 Defendants claim the State has waived its right to seek remedies for their violations of the Act. *See* Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, p. 8 *and* Warrick Pharmaceuticals Corporation's, Schering Corporation's, and Schering-Plough Corporation's Original Answer to Sixth Amended Petition, p. 6. However, the Defendants do not explain how this waiver came about or who executed this waiver on behalf of the State. *Id.* Waiver consists of the knowing relinquishment of a known right and can occur through an express renunciation of the right or through silence or inaction for so long a period as to show an intention to yield the known right. *Motor Vehicle Bd. of the Tex. Dep't of Transp. v. El Paso Indep.*

Auto. Dealers Ass'n, Inc., 1 S.W.3d 108, 111 (Tex. 1999); *Tenneco, Inc. v. Enterprise Prods. Co.*, 925 S.W.2d 640, 643 (Tex. 1996). However, mere inaction or silence is not sufficient to establish waiver against the State. *State v. Crawford*, 771 S.W.2d 624, 629-30 (Tex. App.- Dallas 1989, writ denied) (explaining the State's failure to send a bill for services rendered for over 7 years did not constitute a waiver of the State's right to payment). *See also Durham*, 860 S.W.2d at 64-65 (permitting the State to proceed with a cause of action initiated in the late 1980s for violations of the Relinquishment Act which occurred in the 1930s, even though a former Attorney General issued a letter stating the alleged conduct was not a violation of the law in the 1960s). To hold otherwise would allow a backdoor application of the doctrine of limitations, which clearly does not apply to the State. *Id.* at 67.

5.2 In their pleadings, the Defendants do not disclose who they believe executed the waiver on behalf of the State. As noted above, the waiver would have to be an express waiver and not merely a policy statement or inaction. Of course, when dealing with the State, the person executing the waiver must be authorized to do so. *Crawford*, 771 S.W.2d at 630 (citing *Rolison v. Puckett*, 145 Tex. 366, 198 S.W.2d 74, 78 (1946)). The State cannot be bound by the unauthorized acts of its officers. *Id.* At the conclusion of discovery in this case, there is no evidence that any official, much less an authorized official, executed an express waiver of the State's right to pursue this action for violations of the Act. Express relinquishment of a known right is an essential element of the defense of waiver asserted against the State. Defendants have no evidence of this essential element. Further, it is not possible under the circumstances alleged in the State's petition for an official of the State to be authorized to waive the State's right to reimbursement for overpayments made from the Medicaid program because that would constitute a gift of state funds, which is

expressly prohibited by the Texas Constitution. TEX. CONST. art. III, § 51 and art. XVI, § 6; *State v. City of Austin*, 160 Tex. 348, 331 S.W.2d 737, 742 (Tex.1960) (explaining that “The purpose of article III, § 51 and article XVI, § 6 of the Constitution is to prevent the application of public funds for private purposes; in other words, to prevent gratuitous grants of such funds to any individual or corporation whatsoever.”).

6. The State is not required to mitigate its damages under the Act.

6.1 Defendants claim the State has failed to mitigate its damages in this case. *See* Defendant Roxane Laboratories, Inc.’s Special Exceptions and Original Answer to Sixth Amended Petition, p. 9 *and* Defendant Warrick Pharmaceuticals Corporation’s, Schering Corporation’s and Schering-Plough Corporation’s Special Exceptions and Original Answer to Sixth Amended Petition, p. 6. Again, Defendants have failed to provide any information as to the amount of the alleged mitigation offset or state what actions the State should have taken to mitigate its damages. *Id.* Nothing in the Act requires the State to mitigate its damages. TEX. HUM. RES. CODE § 36.002 sets out the acts declared to be unlawful. Section 36.052 sets out the civil remedies to be imposed upon persons who commit one or more of the unlawful acts described in § 36.002. Nowhere is there a provision for a reduction in the amount of civil remedies based on a lack of mitigation by the State. To recognize the principle of mitigation in this context would be to write into the statute a provision not enacted by the Legislature in contravention of long established rules of statutory construction. *Fitzgerald v. Advanced Spine Fixation Sys, Inc.*, 996 S.W.2d 864, 867 (Tex. 1999) (explaining that “We may add words into a statutory provision only when necessary to give effect to clear legislative intent. Only truly extraordinary circumstances showing unmistakable legislative intent should divert us from enforcing the statute as written.”); *Public Util. Comm’n of Tex. v. Cofer*, 754 S.W.2d 121,

124 (Tex. 1988) (orig. proceeding) (stating “ A Court may not write special exceptions into a statute so as to make it inapplicable under certain circumstance not mentioned in the statute.”). Further, mitigation is an equitable doctrine and as such, does not apply to the State in its sovereign capacity. *See Durham*, 860 S.W.2d at 67 (explaining that equitable principles of limitations, estoppel and laches do not apply to the State).

7. The equitable doctrine of ratification does not apply to the State.

7.1 Defendants contend the State’s claims are barred by the doctrine of ratification. *See* Defendant Roxane Laboratories, Inc.’s Special Exceptions and Original Answer to Sixth Amended Petition, p. 9 *and* Defendant Warrick Pharmaceuticals Corporation’s, Schering Corporation’s, and Schering-Plough Corporation’s Special Exceptions and Original Answer to Sixth Amended Petition, p. 6. Yet again, the Defendants have failed to provide any explanation as to how the equitable doctrine of ratification applies to this case. *Id.* Ratification is “the adoption or confirmation by a person, with knowledge of all material facts, of a prior act that did not then legally bind that person and which that person had the right to repudiate.” *Lesikar v. Rappeport*, 33 S.W.3d 282, 300 (Tex. App.-Texarkana 2000, pet. denied). Again, this is an equitable doctrine and as such, does not apply to the State acting in its sovereign capacity. *Durham*, 860 S.W.2d at 68 (stating this argument is ratification by estoppel and does not apply to the State). Further, mere silence or inaction by the State cannot constitute ratification. *See Durham*, 860 S.W.2d at 68 (explaining acceptance of lease benefits by the State is insufficient to ratify the defendants’ actions). *See also Crawford*, 771 S.W.2d at 629-30.

7.2 Defendants’ pleadings do not allege who ratified their actions on behalf of the State or what specific actions that person took to ratify the Defendants’ actions. Again, when dealing with

the State, the person making the ratification must be authorized to do so. *Bache Halsey Stuart Shields, Inc. v. Univ. of Houston*, 638 S.W.2d 920, 931 (Tex. App.- Houston [1st Dist.] 1982, writ ref'd n.r.e.). *See also Crawford*, 771 S.W.2d at 630 (citing *Rolison*, 198 S.W.2d at 78). The State cannot be bound by the unauthorized acts of its officers. *Id.* At the conclusion of discovery in this case, there is no evidence identifying any official, much less an authorized official, who committed an express ratification of the Defendants' unlawful conduct as set forth in the State's petition. It is not possible under the circumstances alleged in the State's petition for an official of the State to be authorized to ratify the Defendants' unlawful conduct because it results in overpayments of state funds made from the Medicaid program. Such overpayments would constitute a gift of state funds, which is expressly prohibited by the Texas Constitution. TEX. CONST. art. III, § 51 and art. XVI, § 6; *State v. City of Austin*, 160 Tex. 348, 331 S.W.2d 737, 742 (Tex. 1960) (explaining that "The purpose of article III § 51 and article XVI, § 6 of the Constitution is to prevent the application of public funds for private purposes; in other words, to prevent gratuitous grants of such funds to any individual or corporation whatsoever."). An essential element of the defense of ratification is an express adoption or confirmation by a person with knowledge of all the material facts. There is no evidence that such an adoption or confirmation was ever made by any such person, and therefore, the defense of ratification is not applicable against the State in this case.

**8. The equitable doctrine of unclean hands presents
no defense to a statutory or common law action**

8.1 Defendants' assert the Plaintiffs' claims are barred, in whole or in part, by the equitable doctrine of unclean hands. *See* Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, p. 8 *and* Defendant Warrick Pharmaceuticals

Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, p. 6. The doctrine of unclean hands cannot be raised as a defense in a common law or statutory action, unless it is being raised in response to a claim of equitable estoppel. *Steubner Realty 19, Ltd. v. Cravens Road 88, Ltd.*, 817 S.W.2d 160, 165 (Tex. App.-Houston [14th Dist.] 1991, no writ); *Furr v. Hall*, 553 S.W.2d 666, 672 (Tex. Civ. App.-Amarillo 1977, writ ref'd n.r.e.); *Ligon v. E.F. Hutton & Co.*, 428 S.W.2d 434, 437 (Tex. Civ. App.-Dallas 1968, writ ref'd n.r.e.). Defendants assert the defense of unclean hands in response to the Plaintiffs' statutory claims under the Texas Medicaid Fraud Prevention Act and its allegations the Defendants engaged in various acts of common law fraud, not in response to any claim of equitable estoppel. Clearly, the equitable doctrine of unclean hands is not available to the Defendants in this case.

9. Plaintiffs' claims are not barred by the doctrine of mistake.

9.1 Defendants assert Plaintiffs' claims are barred by the doctrines of unilateral and mutual mistake. *See* Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, p. 8 *and* Defendant Warrick Pharmaceuticals Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, p. 6. The doctrines of unilateral and mutual mistake are grounds for rescission of a contract as an equitable remedy. *Newell v. Mosely*, 469 S.W.2d 481, 483 (Tex. Civ. App.-Tyler 1971, writ ref'd n.r.e). Contract rescission is not an issue raised by any pleading in this case, and it is unclear from the Defendants' pleadings on what basis they believe the doctrines of unilateral or mutual mistake provide a defense to the Texas Medicaid Fraud Prevention Act or common law fraud.

9.2 A party seeking to rescind a contract by asserting the doctrine of mutual mistake must show (1) a mistake of fact, (2) held mutually by the parties, and (3) which materially affects the agreed upon exchange. *Wallerstein v. Spirt*, 8 S.W.3d 774, 780 (Tex. App.-Austin 1999, no pet.). At the conclusion of discovery in this case, there is no evidence that there was a mistake of fact mutually held by the parties. While several defense witnesses claim their misrepresentations of prices to the State of Texas were the result of a mistaken understanding of the type of information Texas was requesting, there is no evidence that representatives of the State of Texas had the same mistaken understanding of the information being sought from the Defendants. Since the Defendants can offer no evidence of one or more of the elements of the defense of mutual mistake, the defense is not available to them in this case.

9.3 A party seeking to assert the doctrine of unilateral mistake must show (1) the mistake is of so great a consequence that enforcement of the contract would be unconscionable, (2) the mistake relates to a material feature of the contract, (3) the mistake was made regardless of the exercise of ordinary care, and (4) the parties can be placed in status quo in the equity sense. *Boland v. Mundaca Inv. Corp.*, 978 S.W.2d 146, 149 (Tex. App.-Austin 1998, no pet.). At the conclusion of discovery in this case, there is no evidence that the Defendants made the alleged mistake despite the exercise of ordinary care. There is no evidence that the Defendants ever sought to confirm that their understanding of the pricing information Texas was requesting was a correct understanding. There is no evidence that the Defendants read the Texas laws from which the duty to report pricing information to Texas arises. Further, there is no evidence that the Defendants ever sought instruction or direction from the State of Texas as to how to report pricing information. Any mistake of fact on

the Defendants' part was the result of their indifference to their responsibility to comply with the laws of the State of Texas. The defense of unilateral mistake is not available to those whose mistake is the result of carelessness, inattention or indifference. *Boland*, 978 S.W.2d at 149. Since the Defendants can offer no evidence of one of the elements of the doctrine of unilateral mistake, i.e. that the mistake was made regardless of the exercise of ordinary care, the doctrine is not available to the Defendants as a defense in this case.

10. Plaintiffs' claims are not barred by the doctrine of unjust enrichment.

10.1 The Defendants assert that the doctrine of unjust enrichment bars the Plaintiffs' claims. *See* Defendant Roxane Laboratories, Inc.'s Special exceptions and Original Answer to Sixth Amended Petition, p. 9 *and* Defendants Warrick Pharmaceuticals Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, p. 11. The doctrine of unjust enrichment is an equitable *theory of recovery*. *Mowbry v. Avery*, 76 S.W.3d 663, 679 (Tex. App.-Corpus Christi 2002, pet. denied); *Amoco Prod. Co. v. Smith*, 946 S.W.2d 162,164 (Tex. App.-El Paso 1997, pet. denied). This *theory of recovery* provides no defense that bars the Plaintiffs' claims under the Texas Medicaid Fraud Prevention Act or common law fraud.

10.2 The theory of unjust enrichment is applicable to situations in which 1) money, property, or a benefit is obtained or retained by a party, 2) at the expense of another, and 3) under circumstances contrary to the principles of justice, equity, or good conscience. *Heldenfels Brothers, Inc. v. City of Corpus Christi*, 832 S.W.2d 39, 40 (Tex. 1992); *Fun Times Ctrs., Inc. v. Continental Nat'l Bank of Fort Worth*, 517 S.W. 2d 877, 884 (Tex. Civ. App.-Tyler 1974, writ ref'd n.r.e.). At the conclusion of discovery in this case, there is no evidence that Plaintiffs' obtained or retained

anything at the expense of another and there is no evidence of any circumstances created by the Plaintiffs' that would violate the principles of justice, equity or good conscience.. Quite the contrary, the evidence shows that it is the Defendants who profited at the expense of the taxpayers, under a scheme which offends the notions of fair play and justice. Again, the Defendants lack the evidence to prove one or more essential elements of an affirmative defense they assert, and therefore, the theory of unjust enrichment is not available as a defense to any cause of action in this case. There is no evidence that Plaintiffs engaged in any conduct that caused them to be unjustly enriched.

11. The Plaintiffs' claims are not barred by the filed rate doctrine.

11.1 The Defendants assert that the "filed rate doctrine" bars the Plaintiffs' claims in this case. *See* Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, p. 4 *and* Defendants Warrick Pharmaceuticals Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, p. 11. The file rate doctrine prohibits regulated utilities from charging rates for their services other than those properly filed with the appropriate regulatory authority. *Entex v. R.R. Comm'n of Tex.*, 18 S.W.3d 858, 862, (Tex. App.-Austin 2000, pet. denied). The filed rate doctrine has never been applied by a Texas court in any context other than utility and transportation rates. The United States Supreme Court established the filed rate doctrine to address the unique situation of utility rates and the Texas Legislature codified the filed rate doctrine in the Texas Utilities Code. TEX. UTIL. CODE ANN. § 104.005 (a) (Vernon 2003); *Entex*, 18 S.W.3d at 862. The one Texas case that has applied the filed rate doctrine in any context other than utility rates, did so in reliance upon 49 U.S.C.A. § 1076(a) (1982), in a case about transportation rates that are subject the jurisdiction of the United States Commerce Commission. *Roberts Exp., Inc. v. Expert Transp., Inc.*,

842 S.W.2d 766, 770 (Tex. App.-Dallas 1992, writ refused.) Clearly, the filed rate doctrine does not apply to this case. There are no state or federal codifications of the filed rate doctrine that govern the subject matter of this case, and no Texas case has ever applied the doctrine in a context that is in any way similar to the Texas Vendor Drug reimbursement system. As a matter of law, the filed rate doctrine provides no defense to the Plaintiffs claims in this case.

12. The Plaintiffs' claims are not barred by the Texas Department of Health regulations.

12.1 Defendants have alleged that Plaintiff's claims are barred by TDH regulations; specifically, 25 T.A.C. § 35.804. *See* Defendant Roxane Laboratories, Inc.'s Special Exceptions and Original Answer to Sixth Amended Petition, p. 11 *and* Defendants Warrick Pharmaceuticals Corporation's, Schering Corporation's and Schering-Plough Corporation's Special Exceptions and Original Answer to Sixth Amended Petition, p. 9. There is nothing contained in 25 T.A.C. § 35.804 or any other TDH regulation that bars Plaintiff's claims.

13. Common law defenses do not apply to the Texas Medicaid Fraud Prevention Act

13.1 In addition to the foregoing, the Plaintiffs submit to the Court that no common law defenses are applicable to the Texas Medicaid Fraud Prevention Act. In 1980, the Texas Supreme Court noted that the Texas Deceptive Trade Practices Act does not represent a codification of the common law and that the primary purpose of the statute is to provide consumers a cause of action without the numerous defenses encountered in a common law fraud or breach of warranty case. *Smith v. Baldwin*, 611 S.W.2d 611, 616 (Tex.1980). Similarly, the Texas Medicaid Fraud

Prevention Act is not a codification of the common law, but is a statutory prohibition of fraudulent and wrongful conduct. Thus, the Defendants are limited to any defenses specifically included in the Act and they cannot avail themselves of common law defenses such as waiver, estoppel and laches to justify their violations of the Act.

14. Summary Judgment Record.

14.1 Because all aspects of this motion are questions of law or no-evidence challenges to the Defendants' asserted affirmative defenses and do not involve factual disputes, the State relies upon the pleadings on file in this cause and the statutes, regulations and cases cited herein, all of which are not "evidence," but form the basis of the State's right to relief.

15. Request for Relief.

15.1 For the above and foregoing reasons, the Plaintiffs respectfully request that the court grant its motion for partial summary judgment and order that the following defenses are not available to Defendants as a matter of law:

- (1) limitations;
- (2) estoppel;
- (3) laches;
- (4) waiver;
- (5) lack of mitigation;
- (6) ratification;
- (7) unclean hands;
- (8) mutual or unilateral mistake;

- (9) unjust enrichment;
- (10) the filed rate doctrine; and
- (11) TDH regulations.

The Plaintiffs further request that the Court dismiss with prejudice to the refiling of the same the aforementioned defenses. The Plaintiffs seek such other and further relief, both general and special, to which it may be justly entitled.

Respectfully submitted,

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NOTICE OF HEARING

Please take notice that the above motion and any summary judgment motions filed by the Defendants are set for hearing before Judge Covington beginning at 2 p.m. on July 15, 2003 and the hearings will continue the following day, beginning at 9 a.m. on July 16, 2003. Confirmation of precise time the motions will be heard will be forwarded once it is received from the Court.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing PLAINTIFFS' FIRST AMENDED MOTION FOR PARTIAL SUMMARY JUDGMENT was sent via certified mail, return receipt requested on this the ____ day of _____, 2003, to the following:

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CYNTHIA O'KEEFFE

CAUSE NO. GV0-02327

THE STATE OF TEXAS

ex rel.,

VEN-A-CARE OF THE
FLORIDA KEYS, INC.

Plaintiffs

V.

DEY, INC., ROXANE
LABORATORIES, INC., and
WARRIK PHARMACEUTICALS
CORPORATION,

Defendants

§ IN THE DISTRICT COURT OF

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TRAVIS COUNTY, TEXAS

§ 53RD JUDICIAL DISTRICT

**ORDER ON PLAINTIFFS' FIRST AMENDED MOTION
FOR PARTIAL SUMMARY JUDGMENT**

On this 29th day of July 2003, came on to be heard Plaintiffs' First Amended Motion for Partial Summary Judgment. The Court has considered the motion, the response, the summary judgment evidence, the pleadings and the arguments of counsel. Plaintiffs' First Amended Motion for Partial Summary Judgment is GRANTED.

SIGNED this 15th day of August 2003.

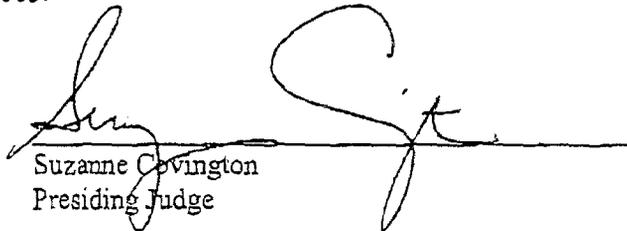

Suzanne Covington
Presiding Judge

EXHIBIT H

C

People ex rel. Spitzer v. Pharmacia Corp.
 N.Y.A.D. 3 Dept., 2007.

Supreme Court, Appellate Division, Third
 Department, New York.

In the Matter of the PEOPLE of the State of New
 York, by Eliot SPITZER, as Attorney General of the
 State of New York, Respondent,

v.

PHARMACIA CORPORATION, Appellant.
 (Proceeding No. 1.)

In the Matter of the People of the State of New York,
 by Eliot Spitzer, as Attorney General of the State of
 New York, Respondent,

v.

Aventis Pharmaceuticals, Inc., Appellant.
 (Proceeding No. 2.)
 April 26, 2007.

Background: State commenced proceedings to recover overpayments of reimbursements made by state health care programs to participating pharmacies for the cost of certain drugs. The Supreme Court, Albany County, McCarthy, J., denied pharmacies' cross-motions to compel discovery, and pharmacies appealed.

Holding: The Supreme Court, Appellate Division, Rose, J., held that information and documents from various state agencies and elected officials which purportedly showed that state was aware of pharmacies' failure to provide prices actually paid to reporting services was neither necessary nor material to pharmacies' defense, and, thus, disclosure of such material was not required.

Affirmed.
 West Headnotes

[1] Pretrial Procedure 307A 380

307A Pretrial Procedure
307AII Depositions and Discovery
307AII(E) Production of Documents and
 Things and Entry on Land
307AII(E)3 Particular Documents or Things
307Ak380 k. Government Records and
 Papers. Most Cited Cases

Information and documents from various state agencies and elected officials which purportedly showed that state was aware of pharmacies' failure to provide prices actually paid to reporting services was neither necessary nor material to pharmacies' defense in state's proceeding to recover overpayments of reimbursements made by state health care programs to participating pharmacies for the cost of certain drugs, and, thus, disclosure of such material was not required, where state's claims did not depend upon an allegation that agencies or officials were deceived, but rather that pharmacies intentionally inflated reported prices in order to manipulate and deceive the mandated statutory reimbursement formulae. McKinney's CPLR 3101(a).

[2] Appeal and Error 30 961

30 Appeal and Error
30XVI Review
30XVI(H) Discretion of Lower Court
30k961 k. Depositions, Affidavits, or
 Discovery. Most Cited Cases

Pretrial Procedure 307A 19

307A Pretrial Procedure
307AII Depositions and Discovery
307AII(A) Discovery in General
307Ak19 k. Discretion of Court. Most Cited
 Cases

The trial court is vested with broad discretion to control disclosure and an appellate court will not disturb its determination unless a clear abuse is shown.

[3] Pretrial Procedure 307A 31

307A Pretrial Procedure
307AII Depositions and Discovery
307AII(A) Discovery in General
307Ak31 k. Relevancy and Materiality.
Most Cited Cases

While statute governing scope of disclosure mandates full disclosure of all matter material and necessary in the prosecution or defense of an action, the party seeking disclosure must demonstrate how the requested materials are relevant to issues in the matter. McKinney's CPLR 3101(a).

****486** Morgan, Lewis & Bockius, L.L.P., Philadelphia, Pennsylvania and Nixon Peabody, L.L.P., Albany (Andrew C. Rose of counsel), for Pharmacia Corporation, appellant.

Greenberg Traurig, L.L.P., New York City (Stephen L. Saxi of counsel) and Shook, Hardy & Bacon, L.L.P., Kansas City, Missouri, for Aventis Pharmaceuticals, Inc., appellant.

****487** Andrew M. Cuomo, Attorney General, New York City (Patrick E. Lupinetti of counsel), for respondent.

Before: PETERS, J.P., MUGGLIN, ROSE and LAHTINEN, JJ.
ROSE, J.

***1117** Appeals from an order of the Supreme Court (McCarthy, ***1118** J.), entered July 24, 2006 in Albany County, which, in two proceedings pursuant to Executive Law § 63(12), inter alia, denied respondents' cross motions to compel discovery.

[1] Petitioner commenced these proceedings to recover overpayments of reimbursements made by the New York State Medicaid and EPIC programs to participating pharmacies for the cost of certain drugs. Drug reimbursements under these programs were calculated from the "average wholesale price" listed in reports published by prescription drug price reporting services and based upon information provided by drug manufacturers (see Social Services Law former § 367-a [9][b]; Executive Law former § 547-j [1][b]). Alleging that respondents intentionally provided inflated prices to the reporting services, petitioner asserts violations of General Business Law § 349, which prohibits deceptive commercial practices, and Executive Law § 63(12), which prohibits repeated fraudulent acts in carrying on a business. To aid their defense against these claims, respondents demanded production of information and documents from various state agencies and elected officials which purportedly will show that the state was aware that the reported prices do not reflect the actual prices paid by the pharmacies. When respondents sought to compel compliance with their discovery demand, Supreme Court denied their motion because it found that the requested materials were irrelevant to what the Legislature had meant by the term "average wholesale price" in the reimbursement statutes. Respondents appeal.

[2][3] Supreme Court is vested with broad discretion to control disclosure and we will not disturb its determination unless a clear abuse is shown (see Czarnecki v. Welch, 23 A.D.3d 914, 915, 803

N.Y.S.2d 817 [2005]; Fox v. Fox, 309 A.D.2d 1056, 1057-1058, 765 N.Y.S.2d 906 [2003]). While CPLR article 31 mandates "full disclosure of all matter material and necessary in the prosecution or defense of an action" (CPLR 3101[a]), the party seeking disclosure must demonstrate how the requested materials are relevant to issues in the matter (see e.g. Allen v. Crowell-Collier Publ. Co., 21 N.Y.2d 403, 406-407, 288 N.Y.S.2d 449, 235 N.E.2d 430 [1968]; Vyas v. Campbell, 4 A.D.3d 417, 418, 771 N.Y.S.2d 375 [2004]). We are not persuaded that respondents have done so here.

Respondents concede that the prices they provided to the reporting services were not average prices actually paid by the pharmacies, but rather they were list wholesale prices before discounts. They maintain, however, that they did not represent the reported prices to be the prices actually paid, and the affected state agencies and officials knew this. However, regardless of what officials may have known, the causes of action against respondents ultimately depend upon petitioner's ability *1119 to prove that the Legislature intended the "average wholesale price" to be based upon prices actually paid and that respondents were required to provide those prices rather than list prices to the reporting services. Because petitioner's claims do not depend upon an allegation that agencies or officials were deceived, but rather that respondents intentionally inflated the reported prices in order to manipulate and deceive the mandated statutory488 reimbursement formulae, any evidence that agencies or officials were aware of respondents' failure to provide prices actually paid would be neither necessary nor material to their defense. It is, among other things, the statutory mandate that reimbursements be calculated based upon reported prices, regardless of what agencies or officials may have known about those prices, that makes the holding in State of New York v. Rachmani Corp., 71 N.Y.2d 718, 530 N.Y.S.2d 58, 525 N.E.2d 704 [1988] inapplicable here.**

ORDERED that the order is affirmed, without costs.

PETERS, J.P., MUGGLIN and LAHTINEN, JJ., concur.

N.Y.A.D. 3 Dept., 2007.

People ex rel. Spitzer v. Pharmacia Corp.

39 A.D.3d 1117, 835 N.Y.S.2d 486, 2007 N.Y. Slip Op. 03620

EXHIBIT I

Lopez, Ibis [OB]
From: Klein, Maren [OB]
Sent: Wednesday, January 07, 1998 4:38 PM
To: Keele, Bruce [OB]; Lopez, Ibis [OB]
Subject: FW: MEDICARE REIMBURSEMENT

From: Doolley, Cathleen [OB]
Sent: Wednesday, January 07, 1998 2:33 PM
To: Klein, Maren [OB]; Pearson, Bill [OB]
Subject: FW: MEDICARE REIMBURSEMENT

EXHIBIT 4A
Doolley
Jan. 17, 2006

FYI - I meant to copy you both on this . .
Cathy

From: Doolley, Cathleen [OB]
Sent: Wednesday, January 07, 1998 2:31 PM
To: Galant, Richard [JCUS]
Cc: Maren, Richard [OB]
Subject: RE: MEDICARE REIMBURSEMENT

Rich-

They initiated a pricing survey in 1994 that was cancelled mid-way as there was a regulatory glitch that they did not take into effect. This was fortunate for us.

A pricing survey is one of the two ways the Secretary of Health can set a price. If they had done a survey and come up with an average price, this would have changed the reimbursement. This is what is happening with Epogen used in ESRD - they did a survey last year and they are now considering lowering the reimbursement rate to \$9.00/1,000 units from the current \$10.00/1,000 units.

The reason that this is not an easy fix for them is that drugs in the Medicare program are billed based on a HCPCS (HCFA Common Procedure Coding System). Each drug is assigned a code which indicates that dosage amount, not a brand. In the Medicaid system the use of the NDC number makes the information easy to track - in the Medicare system it makes it impossible.

The only way they could correct the current system is to require an invoice be submitted with each Medicare claim that is sent in. This would be very cumbersome and the medical providers and Medicare carriers have rejected this. (With 39 million recipients, the number of claims is significant.) Right now they do not know what the cost is for different providers.

If they were smart, they would expand the current demonstration project they have to expand the depots and only allow drugs to be purchased through identified depots where pricing could be controlled.

Please let me know if you need any additional information.

Regards,
Cathy

From: Galant, Richard [JCUS]
Sent: Wednesday, January 07, 1998 11:33 AM
To: Doolley, Cathleen [OB]

Highly Confidential

MDL-OB100058842

Plaintiffs' Exhibit
259
01-12257-PBS

Subject: FW: MEDICARE REIMBURSEMENT

Cathleen, I sent this to Dick but probably should have sent my question directly to you. It seems like they can solve their own problem by using this EAC. Why don't they use EAC to calculate their reimbursement? RG

From: Galens, Richard [LJCUS]
Sent: Wednesday, January 07, 1998 10:30 AM
To: Moran, Richard [ORH]
Subject: RE: MEDICARE REIMBURSEMENT

Dick, as I read the Inspector General report it would seem to me the easy thing for them to do is not use AWP, but use the EAC (which is a survey of ACTUAL prices paid for the drug) to calculate the reimbursement. Do we know why they don't use this EAC approach? RG

From: Moran, Richard [ORH]
Sent: Wednesday, January 07, 1998 9:48 AM
To: Galens, Richard [LJCUS]
Subject: FW: MEDICARE REIMBURSEMENT

From: Dooley, Cathleen [ORH]
Sent: Tuesday, January 06, 1998 6:07 PM
To: Moran, Richard [ORH]
Cc: Klein, Myron [ORH]; Pearson, Bill [ORH]
Subject: RE: MEDICARE REIMBURSEMENT

Dick -

In response to Ed's question, the following information might help clarify this issue:

- The Office of Investigator General (OIG) report refers to the price the physician pays AAC (Average Acquisition Cost) and what Medicare reimburses off of which is AWP (Average Wholesale Price). AWP, as you know, is defined by the Red Book, the official pricing source for Medicare, as list plus 20%. (Some manufacturers request it be list plus 25%.)
- Medicare has historically paid 80% of AWP; effective 1/1/98, they will pay off of AWP minus 5%.
- By law, the physician must bill the patient the remaining 20% co-pay.
- The reason there is no reference to the co-pay in the OIG report is that the government knows that by law, the remaining co-pay of 20% must be billed. They know that a certain percentage of the co-pays will be collected and therefore the physician will "make money" on the administration of certain drugs.
- This will be a sensitive issue because the physician is able to bill Medicare and the patient off of AWP; the patient's 20% co-pay is higher than it would be if it was billed off of acquisition cost (public relations' issue).

As a follow-up to your voice mail, you are correct that this report focuses on the fact that IF the 22 drugs identified in the report had cost under the Medicare program what they cost under Medicaid program, the savings would have been the estimated \$447 million plus. As we discussed yesterday, there is no exposure for Medicaid because Medicaid

gets the calculated "best price" which involves us paying rebates on the lowest possible unit cost on a quarterly basis.

Please let me know if you have any questions.

Thanks

Cathy

From: Moran, Richard [OB]
Sent: Tuesday, January 06, 1998 8:16 AM
To: Dooley, Cathleen [OB]; Klein, Marn [OB]
Subject: FW: MEDICARE REIMBURSEMENT

How should we respond to ed?
Dick

From: Strobino, E. O. (Corp.) [JICUS]
Sent: Monday, January 05, 1998 9:00 PM
To: Gatenc, Richard [JICUS]; Leahy, Kenneth [PH]; Nystrom, Thomas [DMP]; Strobo, John A.
; Moran, Richard [OB]
Cc: Farris, Marlyne [JICUS]
Subject: MEDICARE REIMBURSEMENT

BASED ON THE OFFICE OF INSPECTOR GENERAL REPORT I AM CONFUSED ESPECIALLY IF I USE BIOTECH'S NUMBERS. THE REPORT KEEPS REFERRING TO THE DIFFERENCE BETWEEN THE AWP PRICE THAT MEDICARE PAYS AND WHAT THE PHYSICIAN PAYS. THERE IS NO REFERENCE TO ANY CO-PAY AMOUNT RECEIVED BY THE PHYSICIAN. IF THIS IS THE DIFFERENCE IN THE TWO AMOUNTS, THEN WE DO NOT HAVE A PROBLEM AS IT RELATES TO BIOTECH??? HELP. ED