



STATE OF WISCONSIN

CIRCUIT COURT
BRANCH 9

DANE COUNTY

STATE OF WISCONSIN,)	
)	
Plaintiff,)	Case No. 04-cv-1709
)	
v.)	
)	
ABBOTT LABORATORIES, et al.,)	
)	
Defendants.)	

Aventis Pharmaceuticals Inc.’s Trial Memorandum

This brief is informed by two premises: (1) this Court has expressed a clear and altogether rational desire to avoid re-reading the parties’ issue positions multiple times; and (2) at this point in the litigation there are few surprises left to reveal.

Much has changed since the jury was seated in the Pharmacia case. But the Court’s experience in that trial, together with its recent handling of the Novartis pre-trial motions, suggest that Aventis’ trial brief can accomplish its purpose without further ravaging the forests of North America for paper. Accordingly, Aventis will briefly summarize what it sees as key issues in the case, and provide references to prior submissions where particular issues are more fully treated should the Court desire additional depth of analysis.

The Aventis Products At Issue: Branded, Self-Administered Drugs

As was true for Novartis, the state's trial against Aventis will involve branded, self-administered drugs. The state included two physician-administered drugs among the 116 NDCs it placed at issue, but these will not be part of the trial evidence.

Aventis makes no defense to the state's allegations as to the physician-administered drugs, Anzemet and Taxotere, including the state's calculation of the present value of damages for those drugs, and the number of occurrences upon which the state alleges it can ask the Court to impose forfeitures. Aventis reserves only its legal arguments on the pending dispositive motions, which challenge the competency of the Court to impose penal sanctions for exclusively extra-territorial conduct, and which challenge the state's case based on violations of the dormant Commerce Clause. The legal arguments are not product-specific and require no findings from the jury.

For more detailed information on this issue, the Court is directed to Aventis' Answer to Plaintiff's Third Amended Complaint (filed December 23, 2014) and Aventis' Opposition to Plaintiff's Motion to Strike Aventis' Amended Answer and Proposed Second Amended Answer (filed March 3, 2015).

The State Suffered No Damages

The basic premise of the state's case is that it was damaged because, over the course of 14 years, the amount it paid pharmacists was 6% higher than the bare ingredient cost of the Aventis drugs the pharmacists bought for resale. This premise, in turn, is based on a distortion of the rules governing Medicaid pharmacy

reimbursement. The state claims that it is prohibited from paying pharmacists a fraction of a penny more than their actual acquisition cost by the federal government's Estimated Acquisition Cost (EAC) rules. This position is illogical and unsupported by the law or facts.

The state's argument requires one to pretend the "E" in EAC doesn't exist. What the EAC provisions actually require, however, is that the state *emphasize* the E in EAC, rather than reading it out of existence. Each year the state must submit a plan to the federal government *estimating in advance* what it intends to pay pharmacists serving Medicaid patients. Similarly, under Wisconsin's biennial budget system, the state must *estimate in advance* what it will cost to operate its Medicaid pharmacy benefit. Similarly, ordinary citizens employ advance estimates each day, using them to plan for everything from home repairs to saving for retirement.

The state, however, turns the concept of estimate on its head. It plans to have its liability expert, Dr. Anderson, opine that the only "estimate" that was lawful under federal government regulations governing Medicaid pharmacy reimbursements was the exact cost of the drug purchased. Indeed, if not controlled, Dr. Anderson will tell the jury that Wisconsin was prohibited by law from paying anything more than a "pass-through" reimbursement to pharmacists for each pill dispensed. The Court will instruct the jury on the law. The facts, however, demonstrate the essential fallacy of the state's position.

All states provide their Medicaid beneficiaries a prescription drug benefit. All are subject to the same EAC regulations that govern Wisconsin. Each state, including Wisconsin, must submit its own EACs each year, in advance, for approval by the federal government. If the state's position – as expressed by Dr. Anderson – were valid, there could be only one “estimate” that could be approved; a pass-through reimbursement based on national wholesaler pricing. But the evidence will show that during the relevant period states varied widely in what they told the federal government each year was an appropriate reimbursement level for their retail pharmacists. Some submitted higher EACs than Wisconsin's estimate while others submitted EACs that were lower, but none suggested actual acquisition cost, or a pass-through, would be appropriate. All submitted EACs were higher than that, reflecting common sense and economic reality. And all were approved by the federal government.

Wisconsin Medicaid professionals did an outstanding job of setting the state's EACs during the period while balancing shrinking budgets and growing needs. As a result, the state's ten year-long litigation effort against Aventis was able to muster only a 6% “damage” figure for trial. Even this figure, though, is fiction. The state computes its “damages” by measuring the difference between the bare ingredient cost of the Aventis drugs pharmacists dispensed to Medicaid patients from 1994 to 2008 and the actual reimbursement paid to pharmacists by the state during that time. There are two problems with this approach. First, it is entirely dependent upon the

“pass-through” pharmacy reimbursement model that Dr. Anderson erroneously claims is the law. Second, it includes reimbursement amounts inflated by actual AWP manipulation by McKesson and First DataBank between 2002 and 2008. As is explained in more detail below, the state has sued and settled its claims for those overpayments and they cannot be a part of this case.

Although the ability to convert EACs into ACs is not the test for “damages” here, the evidence will show that the state achieved something very close to 100% accuracy when the McKesson/First DataBank overpayments are excluded. Most of us would be pleased if our estimates of events to occur a year or two into the future were as accurate as the state’s EACs were here. Ultimately, however, the state cannot make Aventis responsible for its failure to be 100% accurate in achieving a goal that is both illusory and illogical.

The Evidence Does Not Support the State’s Price-Manipulation Allegations

The evidence will show that the state’s claims about how Aventis supposedly defrauded the state lack any basis. The state claims Aventis inflated and misrepresented its Wholesale Acquisition Costs (“WACs”) and the Average Wholesale Prices (“AWPs”) published for its drugs. These allegations are not true and, curiously, the state’s own damages expert, Prof. Thomas DiPrete, provides the clearest evidence on these points.

As a branded company, Aventis offered its products for sale to its direct customers – typically wholesalers – at WAC. WACs are published, list prices readily

available to Wisconsin and other participants in the prescription drug distribution system. The state alleges that Aventis inflated these WACs. The evidence is clearly otherwise. Wholesalers and other direct customers were invoiced by Aventis at WAC, subject to a 2% “prompt pay” discount and other minor pricing adjustments during product promotions. These direct customers then resold the Aventis products they purchased at their own mark-ups, which varied by customer. Prof. DiPrete, retained by the state to compute its alleged damages, analyzed Aventis’ WACs and compared them to Wisconsin retail pharmacy acquisition costs. Prof. DiPrete’s analysis confirmed that throughout the 1994 to 2008 period at issue, Wisconsin pharmacists bought their Aventis drugs at WAC. *See* Appendices A1 and A2, Amended Economic Damages Report of Thomas DiPrete, attached as Exhibit A to Aventis’ Second Amended Answer to Plaintiff’s Third Amended Complaint (filed March 3, 2015.)

The state also alleges that Aventis manipulated the AWP’s that third parties published for Aventis drugs. The state obtained these AWP’s through subscription-based price reporting services sold by First DataBank and Red Book. The state concedes that Wisconsin Medicaid did not treat the AWP’s published by these third parties for Aventis drugs as averages of actual wholesale prices. Rather, the state claims that it inaccurately estimated by how much AWP’s overstated pharmacists’ actual acquisition costs. Wisconsin claims Aventis is liable to the state for the state’s unilateral calculation errors.

The problem with this argument is that the facts don't quite match up. From its inception, the AWP was a benchmark used for administrative efficiency at the expense of arithmetical precision. By 1994, when the relevant period in this case begins, Wisconsin and other third party payers were substantially discounting the AWP to reach their reimbursement goals. Other participants in the prescription drug distribution system used AWPs differently to achieve their own, different goals. While these goals differed for public and private payers as well as over time, the mark up between WAC and AWP for branded drugs, like those sold by Aventis, remained stable. The mark-up was set for each branded product at the time of launch and remained unchanged throughout the life of the product. These mark-ups were either 20% or 25% at Aventis, reflecting the fact that the Company was created by the merger of two companies with different AWP mark-up protocols; even after the merger, the product-specific mark-up didn't change. Indeed, chief strength of AWPs for branded drugs was its universally understood stability.

From 1994 through August 2001, Aventis "reported" AWPs for its products to the pricing publishers that were exactly in line with historical precedent. The AWPs for Allegra products, for example, were precisely 20% above the published WACs in January 1994; in August 2001, they were still 20% above the published WACs despite price increases, corporate mergers, and changes in the competitive landscape. In August 2001, Aventis announced it would no longer provide AWPs on any of its products to anyone. Not surprisingly, given their control of the AWP and their

business models, the pricing publishers continued to publish AWP's for Aventis products after August 2001 without any input from the Company.

The bottom line on all of this is that Aventis' WACs have been proven – by the plaintiff – to be real world, market prices that correlate directly to retail pharmacy acquisition cost. The plaintiff has also shown that the AWP's published by the pricing publishers were, to the extent Aventis had anything to do with them, historically accurate and stable, with a fixed, unvarying relationship to product WACs. There was no “manipulation” of these well-known and universally used pricing terms by Aventis.

The Role of Rebates in Medicaid Pharmacy Reimbursement

Throughout the 1994-2008 time period at issue, the state did not pay Aventis a dime for the Aventis drugs dispensed to Wisconsin Medicaid beneficiaries. By contrast, during that period Aventis paid Wisconsin Medicaid drug rebates totaling \$42,915,222.74. *See* Affidavit of Claire Brunken, Attached to Aventis' dispositive motions (filed January 23, 2015).

The evidence will show that Aventis paid rebates equal to 38% of the state's ingredient costs associated with reimbursing pharmacies for dispensing the Aventis drugs at issue. For some of these products, the net discount from AWP the state was enjoying exceeded 50% by 2008. Policymakers were aware of these rebate-driven net prices and factored them into biennial budget projections throughout the relevant time period. As the evidence will show, these mandated rebates directly impacted the

state's net cost of reimbursement and protected the state from the sort of price manipulation alleged here.

The total amount of rebate Aventis paid Wisconsin each calendar quarter was a function of several variables. These rebates were dependent upon the number of prescriptions of the Company's drugs dispensed to Medicaid beneficiaries and the prices charged for them. The state alleges that Aventis created and operated an AWP pricing scheme to increase the Company's Medicaid sales. Obviously, if the number of units prescribed to Medicaid patients increased pursuant to such a scheme, so too would the rebates payable by the Company. More directly linked to alleged pricing manipulation is the "CPI Penalty" rebate. Under this provision of the statute, a drug company increasing prices faster than the rate of growth in the Consumer Price Index (CPI) must refund that "excess" price increase back to the state as an additional rebate.

At branded companies, like Aventis, AWP increases through 2001 were driven by WAC price increases; the AWP increased only if the WAC increased, and only to the same extent of the WAC increase. The state's damages expert, Prof. DiPrete, has shown that the WAC-AWP relationship at Aventis from 1994 through 2001 was constant and unvarying. As a result, a 10% increase in WAC by Aventis during this time would translate to a 10% increase in the AWP – no more and no less. If, however the CPI had registered a 5% increase during this time, Aventis' 10% price increase would trigger an additional 5% rebate on each unit dispensed to Medicaid.

As a result, to the extent that the state alleges that Aventis participated in a price-inflation scheme, the rebates paid by Aventis for its “success” in operating the scheme would increase in direct proportion to the supposed price “inflation.”

The evidence will show that Aventis paid rebates equal to 38% of the state’s pharmacy costs associated with reimbursing pharmacies for dispensing the Aventis drugs at issue here. For some of these products, the net discount from AWP the state was enjoying between its own discounts and Aventis rebates exceeded 50% by 2008. Policymakers were aware of these rebate-driven net prices and factored them into biennial budget projections throughout the relevant time period. As the evidence will show, these mandated rebates directly impacted the state’s net cost of reimbursement and protected the state from the sort of price manipulation alleged here.

The State’s Destruction of Key Evidence

The state claims that: (1) it had neither contemporaneous knowledge of what Wisconsin pharmacies were paying to buy prescription drugs between 1994 and 2008 nor any way to get it; and, (2) had the state plaintiff possessed contemporaneous, electronic pharmacy pricing information the state would not have relied on AWP from the pricing publishers. The evidence will show, however, that neither claim is true.

The state claims that Aventis “hid” its wholesale prices, which forced the state to rely on the pricing publishers for electronically transmitted pricing data. In its Complaint, the state unambiguously alleges that “[t]here [was] no other electronic

source for this information.” Beginning in September 1999, however, the state began requiring pharmacies to electronically disclose their ingredient cost to the state each time they sought Medicaid reimbursement.

The evidence will show that the state mishandled this contemporaneous, electronic data from the beginning. First, the state failed to tell pharmacists how to report the prices, leaving it up to each pharmacist to choose from an unexplained “drop down” menu of options to describe the source of their pricing data, including “other.” The state then completely ignored the data, never using it to either set or evaluate its reimbursement rates. Finally, the state destroyed the data on a 90-day cycle even after filing this lawsuit in 2004.

Had the state been interested in using actual acquisition costs of Wisconsin pharmacists as the basis of reimbursement, its mishandling of these data would be inexplicable. The system collecting the data provided the state with the means to efficiently collect the information needed to run an actual acquisition cost model in real time. The evidence, however, suggests that Wisconsin did not, as it claims, reluctantly accept an AWP-based reimbursement system instead of a point-of-sale system, using Wisconsin-specific, contemporaneous and electronic data on actual pharmacy costs. Rather, the evidence will show that the state operated exactly the system it preferred, which allowed it to easily compare its reimbursement levels and EACs with neighboring states, and to more easily make budget projections and comparisons.

Additional information on this issue can be found in Defendants' Supplemental Response in Support of their Motion for Sanctions for Spoliation, filed September 14, 2014.

The State has Previously Settled and Resolved Its Damage Claim

On November 5, 2013, the Wisconsin Attorney General announced the settlement of an AWP pricing fraud case. That case did not include Aventis as a defendant, although it was premised, in part, on alleged damages the state attributed to reimbursing Wisconsin pharmacists for Aventis products. The settlement announced by the Attorney General that day was with First DataBank, the pricing publisher from whom the state purchased AWP's for Aventis products, and McKesson, a large wholesaler. Under the settlement, Wisconsin received more than \$13,000,000 in damages and attorney fees.

In this case, the state has claimed that it was damaged by Aventis, and particularly by AWP's for Aventis products that were higher than actual wholesale cost. The state has argued that it was unaware of how the prescription drug distribution system worked and was confused by these AWP's. The state has insisted that Aventis had a duty to educate or otherwise inform the state about how the drug distribution system worked. Similarly, the state has refused to acknowledge in this case any reduction in either liability or damages for Aventis after August 2001 when Aventis stopped communicating with anyone about AWP's. Rather, the state claims that

Aventis controlled the AWP publication process and First DataBank acted solely as Aventis' agent in communicating the AWP's to the market.

In its suit against First DataBank and McKesson, however, the state describes the prescription drug distribution system accurately as one in which "when brand manufacturers introduced a drug into the market, they also set and reported a price called an AWP for that drug, calculated by taking the WAC and adding, typically, either 20% or 25%." The state went on to allege that "[p]rior to ... August 2001, the WAC-to-AWP markup or spread of and NDC remained unchanged during the life of the NDC. *See* Complaint and Summons, 12-CV-3948 (filed October 2, 2012).¹ Thus, if the WAC increased, the AWP increased commensurately." The state further alleged in their case against First DataBank and McKesson that these defendants "bumped up" manufacturers' previously stable AWP's for branded pharmaceuticals from early 2001, until around September 2009. The state concludes that it was First Databank's "bump up" that caused Wisconsin Medicaid to overpay pharmacists when it reimbursed them for brand name drugs during this 8-year period. The suit alleged violations of the same statutes at issue in the present case: Wis. Stat. §§ 100.18(1) and (10)(b), and 49.49(4m)(a)(2).

These admissions of a party opponent, along with other evidence, will establish that the pricing publishers, rather than Aventis controlled what would be published as

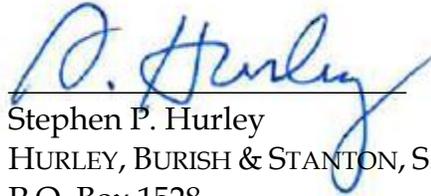
¹ Pursuant to Wis. Stat. § 902.01(2)(a) and (b) and (4) the court is requested to take judicial notice of its own record of proceedings in this case and in case number 12-CV-3948.

AWPs, particularly after Aventis stopped communicating about AWP's in August 2001. Rather than acting as Aventis' agent, the evidence will show that First Databank controlled the publication of Aventis' AWP's, and that it raised Aventis' AWP's without notice to or consultation with Aventis beginning in February 2002. It will also establish that the Plaintiff collected damages from McKesson, First Databank, and Hearst for precisely the same reimbursement differential for which it makes claim against Aventis in this case.

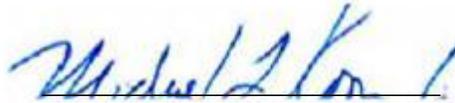
The state's damages expert, Prof. DiPrete, has established that during the time period of the complaint until early 2002 Aventis' self-administered brand name drugs demonstrated an unvarying relationship between published WAC and AWP's. The latter were always a 20% or 25% markup over WAC – just as the state described in its complaint against McKesson, First Databank, and Hearst and just as Aventis has maintained throughout this case. Thereafter, variations in the relationship between the published WAC and the published AWP were the result of First Databank's "bumping up" the AWP. The state is not entitled to duplicative recoveries for the same alleged "losses."

Dated this 9th day of March, 2015

Respectfully submitted,



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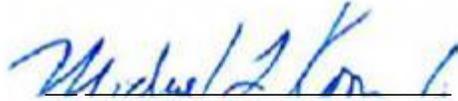


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CERTIFICATE OF SERVICE

I, Michael L. Koon, hereby certify that on this 9th day of March, 2015, I caused a copy of the foregoing Notice of Firm Name Change to be served on all counsel of record via Lexis Nexis File & Serve.



Michael L. Koon