
STATE OF WISCONSIN,)	
)	
Plaintiff,)	Case No. 04-CV-1709
)	
v.)	
)	
AMGEN INC., <i>et al.</i> ,)	
)	
Defendants.)	
)	

**DEFENDANTS SCHERING-PLOUGH CORPORATION¹ AND WARRICK
PHARMACEUTICALS CORPORATION’S MOTION FOR PARTIAL SUMMARY
JUDGMENT IN THEIR FAVOR ON COUNTS I AND II OF THE COMPLAINT AND
SUPPORTING MEMORANDUM OF LAW**

INTRODUCTION AND SUMMARY OF ARGUMENT

Defendants Schering-Plough Corporation (“Schering-Plough”)² and Warrick Pharmaceuticals Corporation (“Warrick”) are entitled to summary judgment in their favor on Counts I and II of the Second Amended Complaint (the “Complaint”) on at least three independent grounds. *First*, the Deceptive Trade Practices Act (the “DTPA” or the “Act”), which forms the basis for the claims alleged in Counts I and II of the Complaint, was never intended to apply, and should not be applied, to the conduct at issue in this case for at least two reasons: (a) the State of Wisconsin cannot demonstrate that it was among the class of people – “the public” – that the Act was intended to protect; and (b) by virtue of the very structure of

¹ Schering-Plough Corporation is a holding company that does not actually manufacture, market, or sell any of the drugs at issue in this case. Although this fact is not relied upon as a basis for this motion, it is a separate ground entitling Schering-Plough Corporation to summary judgment on all counts of the Complaint. Schering-Plough Corporation joins in the present motion without waiving this argument or any rights that might follow from it.

² Schering Corporation (“Schering”), a wholly-owned subsidiary of Schering-Plough, manufactures, markets, and sells the Schering-brand drugs at issue in this case. Plaintiff’s counsel are well-aware of this fact, but have refused to correct their pleadings to name the proper party. Ultimately, as the arguments below make clear, summary judgment should be entered as to all Schering-brand drugs at issue.

Wisconsin's Medicaid Program, Wisconsin could not have been induced to purchase drugs or reimburse providers for dispensing them by any allegedly false or misleading statement.

Second, even if the Act were held to apply, Wisconsin cannot prevail on any of its claims relating to generic or multi-source drugs. Wisconsin Medicaid generally reimbursed multi-source claims on the basis of a Maximum Allowable Cost or MAC that it set **without reference to any price reported by any drug manufacturer or published by any drug pricing compendium** – including average wholesale price (“AWP”) or wholesale acquisition cost (“WAC”). Thus, Wisconsin cannot prove, as to these claims, that Schering or Warrick caused it any harm.

Third, as to the Schering-brand drugs at issue in this case, Plaintiff cannot satisfy its burden of proof as to any of the three elements required to state a DTPA claim. There is no evidence in the record that Schering made any statement about WACs or AWP with an intent to induce a purchase. The AWP that the pricing compendia reported for Schering's brand-name products merely reflected the compendia's addition of a widely-known and expected industry-standard mark-up of 20-25% to Schering's list prices (WACs).³ Schering's list prices or WACs, moreover, were prices at which it made significant sales. Under these circumstances, the State cannot show that the AWP or WAC published for Schering's brand-name drugs were untrue, deceptive, or misleading. To the contrary, the undisputed record evidence shows that, at all relevant times, officials at Wisconsin Medicaid and the Wisconsin Legislature knew and understood that AWP did not represent an actual average of transaction prices. Thus, Schering's AWP and WAC could not, and did not, cause the State any harm.

For these reasons, as discussed in more detail below, summary judgment should enter in

³ Mark-up percentages used by the compendia varied by the compendium and time period.

favor of Schering-Plough and Warrick on Counts I and II of the Complaint.⁴

**STATEMENT OF UNDISPUTED FACTS SUPPORTING SCHERING-PLOUGH AND
WARRICK'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

The Schering and Warrick Drugs at Issue

1. Plaintiff asserts claims against Schering-Plough and Warrick arising out of Wisconsin Medicaid's alleged over-reimbursement of Medicaid providers for claims that they submitted relating to thirty-three different prescription drugs (175 separate NDCs).⁵ See Second Amended Complaint, at ¶ 48 & Ex. E.

2. There are twenty-six Schering drugs at issue: Cedax, Celestone Soluspan, Clarinex, Claritin, Claritin-D, Diprolene, Elocon, Eulexin, Imdur, Intron-A, K-Dur, Lotrimin, Lotrisone, Nasonex, Nitro-Dur, Normodyne, Peg-Intron, Proventil, Rebetol, Rebetron, Solganal, Temodar, Theo-Dur, Trinalin, Vancenase, and Vanceril. See Affidavit of Debra Kane (hereinafter the "Kane Aff."), at ¶ 12.

3. The Schering drugs at issue are all brand-name pharmaceuticals, some of which enjoy patent exclusivity with little or no therapeutically equivalent competition and some of which are multiple-source drugs subject to generic competition. See Kane Aff., at ¶ 12.

4. There are seven Warrick drugs at issue: Albuterol; Clotimazole; Isosorbide MN; Labetalol HCL; Potassium Chloride; Sodium Chloride; and Theophylline. See Second Amended Complaint, at Ex. E (listing seven drugs described only by chemical name with the Warrick labeler code 59930).

⁴ In addition to the arguments set forth in this motion, Schering-Plough and Warrick incorporate by reference and adopt fully all of the facts and arguments advanced in Defendants' Joint Cross-Motion for Summary Judgment and Supporting Memorandum and the cross-motions for summary judgment filed by other defendants to the extent that those motions further entitle them to the entry of summary judgment in their favor.

⁵ An "NDC" or National Drug Code is a unique identifier assigned to each dosage, form, strength, and package size of a particular drug. For example, a single drug such as penicilin might come in many different forms (e.g., liquid or tablets), in many different strengths or concentrations, and in a one-week or ten-day supply. Each dosage, form, strength, and package size of penicilin would be assigned a different NDC.

5. The Warrick drugs at issue are all generic drugs – *i.e.*, drugs that do not have patent exclusivity and for which chemically identical, therapeutically equivalent products are available from two or more manufacturers. *See* Second Amended Complaint, at Ex. E (listing seven drugs described only by chemical name with the Warrick labeler code 59930).

6. Not surprisingly, given the differences in the types of drugs that each company sells, Schering and Warrick have very different business models that must be analyzed separately for summary judgment purposes. *See generally*, Affidavit of Harvey J. Weintraub (hereinafter the “Weintraub Aff.”) (Exhibit 1 to the Declaration of Earl H. Munson Transmitting Documents Relied Upon in the Defendants Schering-Plough Corporation and Warrick Pharmaceuticals Corporation’s Motion for Partial Summary Judgment in their Favor on Counts I and II of the Complaint and Supporting Memorandum of Law (hereinafter the “Munson Decl.”)).

7. Most of the Schering and Warrick drugs at issue do share one common characteristic. The vast majority of the drugs sold by Schering and Warrick are “self-administered” drugs – that is, drugs such as pills and tablets that a patient takes without the assistance of a doctor. *See* U.S. DEP’T OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 27th ED. (2007) (Exhibit 2 to the Munson Decl.).⁶

8. To obtain these self-administered, prescription drugs, a Medicaid beneficiary typically would present a doctor’s prescription to a pharmacist, who would dispense the drug. Some self-administered drugs might be obtained with a doctor’s prescription from a mail order

⁶ *See also* U.S. DEP’T OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 26th ED. (2006) (Exhibit 3 to the Munson Decl.); *see* Medication Guide: Peg-Intron™ Redipen® (Peginterferon alfa-2b) Single-dose Delivery System, <http://www.spfiles.com/pipeg-intron.pdf#page=8> (last visited Jan. 14, 2008) (Exhibit 4 to the Munson Decl.); Solganal® Schering Aurothioglucose Antirheumatic Agent, [http://www.rxmed.com/b.main/b2.pharmaceutical/b2.1.monographs/CPS-%20Monographs/CPS-%20\(General%20Monographs-%20S\)/SOLGANAL.html](http://www.rxmed.com/b.main/b2.pharmaceutical/b2.1.monographs/CPS-%20Monographs/CPS-%20(General%20Monographs-%20S)/SOLGANAL.html) (last visited Jan. 14, 2008) (Exhibit 5 to the Munson Decl.).

pharmacy. *See* 21 U.S.C. § 353(b)(1). The pharmacy that dispensed the drug would then submit a claim for reimbursement to Wisconsin Medicaid. *See* Smithers 8/15/07 Tr. at 58:9-60:14 (Exhibit 23 to the Munson Decl.).

9. Two Schering-brand self-administered drugs at issue in this case – Temodar and Proventil – were the subject of AWP fraud claims in the multi-district AWP litigation (the “MDL” or the “MDL Litigation”) in which the court found no liability for either drug and entered judgment for Schering. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 70-74 (D. Mass. 2007).

10. One Warrick self-administered drug – albuterol – was the subject of AWP fraud claims in the MDL Litigation in which the Court found no liability and entered judgment for Warrick. *See In re Pharm. Indus. Average Wholesale Price Litig.*, C.A. No. 01-12257-PBS, 2007 WL 3235418, at *4 (D. Mass. Nov. 2, 2007).

11. The only “physician-administered” drugs (*e.g.*, intravenous injections requiring the assistance of a physician to administer) sold by Schering at issue in this case are a very few of the high-dosage Schering-brand Intron-A NDCs and the Schering-brand Celestone Soluspan NDC listed in Exhibit E to the Complaint. *See* U.S. DEP’T OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 27th ED. (2007) (Exhibit 2 to the Munson Decl.); *From Diagnosis Through Treatment and Beyond*, at 23, <http://www.introna.com/introna/docs/IN2283.pdf> (last visited Jan. 11, 2008) (Exhibit 6 to the Munson Decl.).

12. With regard to these physician-administered drugs, the doctor would purchase the drug from a wholesaler or other source, administer the drug to the Medicaid beneficiary, and then submit a claim to Wisconsin Medicaid seeking reimbursement for the drug. *See* U.S. GEN.

ACCOUNTING OFFICE, GAO-01-1118, PAYMENTS FOR COVERED OUTPATIENT DRUGS EXCEED PROVIDERS' COST 4 (Sept. 2001) (WI-Prod-AWP-112312-14, WI-Prod-AWP-112318-19) (Exhibit 7 to the Munson Decl.); Smithers 8/15/07 Tr. at 62:9-63:13 (Exhibit 23 to the Munson Decl.).

13. Intron-A was the subject of AWP fraud claims in the MDL Litigation in which the court held that “[g]iven the isolated, minor spreads and little evidence of spread marketing, I find no liability for . . . Intron-A.” See *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 108.

14. The pattern of spreads for Celestone Soluspan does not differ materially from the pattern of spreads for Intron-A for which Judge Saris found no liability. See Affidavit of Sumanth Addanki (hereinafter “Addanki Aff.”), at Ex. 9; see also *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 108.

Schering and Warrick’s Contractual Relationship with the Medicaid Program

15. Schering and Warrick do not, and have never sold their products directly to Wisconsin Medicaid or to any Wisconsin Medicaid beneficiary. See Kane Aff., at ¶ 11. Accordingly, Wisconsin’s document and data productions do not reflect any direct purchases of drugs from Schering or Warrick.

16. As a condition to Medicaid’s reimbursing providers for dispensing Schering and Warrick drugs, Schering and Warrick were required to execute a standard Rebate Agreement with the Federal Center for Medicare and Medicaid Services (“CMS”) (formerly, the Health Care Finance Administration or “HCFA”), which they did in 1991. See 42 U.S.C. § 1396r-8(a)(1); see also 56 Fed. Reg. 7049 (Feb. 21, 1991); see, e.g., Medicaid Drug Rebate Agreement, Warrick Pharmaceuticals Corporation (1993) (Exhibit 8 to the Munson Decl., Filed Under Seal) (“In

order for payment to be made under Medicaid, you must complete and sign this [rebate] agreement, fill in the information on the related documents, and return them to the Health Care Financing Administration (HCFA”).).

17. CMS entered into that Rebate Agreement on behalf of all States, including the State of Wisconsin. *Id.* at Enclosure A (Exhibit 8 to the Munson Decl., Filed Under Seal) (“The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia . . . which have a Medicaid State Plan approved . . . and the Manufacturer, on its own behalf . . . hereby agree to the following [Rebate Agreement].”).

18. Pursuant to that Rebate Agreement, Schering and Warrick are required to report to CMS on a quarterly basis the Average Manufacturer Price (“AMP”) for each of the drugs they market. *See, e.g.*, Medicaid Drug Rebate Agreement, Warrick Pharmaceuticals Corporation (1993) at 1 (Exhibit 8 to the Munson Decl., Filed Under Seal).

19. AMP is defined by statute as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.” 42 U.S.C. § 1396r-8(k)(1). Discounts extended by the manufacturer to customers at the time of sale are included when calculating and reduce a manufacturer’s AMP. *Id.*

20. Once a quarter since 1991, CMS has provided each State (including Wisconsin) with a Unit Rebate Amount or URA based on the AMP for each covered drug, so that the State could calculate and collect the rebates due it by the manufacturers under the Rebate Agreements. *See* 42 U.S.C. § 1396r-8(b)(2)(A). *See e.g.*, Medicaid Drug Rebate Agreement, Warrick Pharmaceuticals Corporation, §§ I(n), (dd) (1993) (Exhibit 8 to the Munson Decl., Filed Under Seal).

21. Pursuant to that Rebate Agreement, Schering and Warrick have paid quarterly rebates to Wisconsin Medicaid based on the AMP reported to CMS for each of the drugs that they marketed and on the level of utilization by Wisconsin Medicaid beneficiaries. *See* 42 U.S.C. § 1896r-8(b)(3)(A); *see e.g.*, Medicaid Drug Rebate Agreement, Warrick Pharmaceuticals Corporation, § II(a) (1993) (Exhibit 8 to the Munson Decl., Filed Under Seal).

22. Through the Rebate Agreement, “state Medicaid agencies obtain access to the lowest price paid for prescription drugs by any purchaser in the United States without having to duplicate the efforts of large private purchasers to earn those discounts.” CBO Papers, How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry (Jan. 1996), at p. ix (Exhibit 9 to the Munson Decl.). Accordingly, “[t]he Medicaid rebate program . . . has succeeded in reducing government spending on outpatient prescription drugs.” *Id.*

23. The Rebate Agreement does not require that a state use any particular reimbursement methodology. *See, e.g.*, Medicaid Drug Rebate Agreement, Warrick Pharmaceuticals Corporation (1993) (Exhibit 8 to the Munson Decl., Filed Under Seal).

24. Neither Schering, nor Warrick receives any reimbursement from the Wisconsin Medicaid Program pursuant to the Rebate Agreement or otherwise. *See Kane Aff.*, at ¶ 11.

Pricing of Schering Drugs

25. Each Schering-brand drug has a Wholesale Acquisition Cost or WAC – *i.e.*, an undiscounted list price – that Schering reports to the drug pricing compendia. WAC is the actual price paid by most Schering direct customers. For example, if a pharmacy chain or wholesaler purchases product directly from Schering, it pays WAC subject to its receiving a customary prompt-pay discount of 2%, if it pays Schering for the drugs within a specified time period. *Id.* at ¶ 14.

26. During the period June 16, 2001 to June 16, 2004,⁷ approximately 83% of the sales of the Schering-brand drugs at issue were made at a price within 5% of WAC. *See* Addanki Aff., at ¶ 12 & Ex. 7. When Schering's sales of these products are analyzed by brand, similar results obtain. *See id.* at ¶ 12 & Ex. 8.

27. The Average Wholesale Prices or AWP's published by the compendia for the Schering-brand drugs at issue reflect an industry standard 20-25% mark-up to Schering's reported WACs. *See* Kane Aff., at ¶ 16; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 91 (“[I]t is undisputed that the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP.”).

28. Based on the existence of this standard relationship between the brand WACs and AWP's, taken in combination with “bona fide” and “routine” discounts off of WAC (such as the prompt-pay discount), in the multi-district AWP litigation, Judge Saris concluded that there is no liability when the “spread” between brand AWP's and the average selling prices for brand drugs did not exceed approximately 30%. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 91-92 (“I conclude . . . that the 30% yardstick . . . is consistent with the undisputed evidence in the market establishing an industry-wide markup between WAC and AWP); *id.* at 108 (“Given the isolated, minor spreads [above 30%] . . . , I find no liability . . .”).⁸

29. The spreads between the AWP's published by FDB for the Schering-brand drugs at issue and the AMP's that Schering reported to CMS under its Rebate Agreement are, with only

⁷ The June 16, 2001 to June 16, 2004 time period is used because this Court has ruled that any DTPA claims accruing prior to June 16, 2001 are time barred due to the relevant three year statute of repose. *See* Mot. to Dismiss Order, May 18, 2006 at 9 (Krueger, J.). The initial complaint in this case was filed on June 16, 2004.

⁸ *See also* May 16, 2007, Hearing Tr. at 22:8-16 (recording a colloquy in which MDL plaintiffs' counsel agrees with the court's assessment that there are other “bona fide” and “routine[]” discounts, besides just the prompt-pay discount, that are not indicative of any “kind of problem” or “violat[ion]”) (Exhibit 10 to the Munson Decl.); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 76 (finding that “[B]y the early 1990's, the more sophisticated payors generally understood that AWP was a 20 to 25 percent markup over WAC, and that some discounting off of WAC was generally available”).

a few limited exceptions, within the 30% “safe harbor” that Judge Saris found in the MDL was generally consistent with industry expectations. *See* Addanki Aff., at ¶ 13 & Ex. 9; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 92.⁹

Pricing of Warrick Drugs

30. In contrast to Schering, Warrick does not have a single list price for any of its drugs. Instead, at any given moment, Warrick has many different arrangements with chain drug stores, wholesalers, and generic distributors, each with different terms and different prices specified for the same drug, and substantial variances among those prices. Thus, Warrick does not – and has never – reported WACs for its drugs. *See* Weintraub Aff., at ¶ 17 (Exhibit 1 to the Munson Decl.).

31. Warrick does announce an AWP for each of its drugs at launch. In order to assure that its drugs are listed in the drug pricing compendia as generic drugs, the launch AWP for a Warrick drug is set at 10-15% below the brand AWP if the Warrick drug is the first to enter the market. When Warrick enters a market that already has other generic competitors, Warrick generally sets its launch AWP at a level consistent with those competitors. Weintraub 9/18/06 Tr. at 149:3-149:11, 166:17-24 (Exhibit 27 to the Munson Decl.); Weintraub 9/20/06 Tr. at 527:6-23, 529:23-530:13 (Exhibit 28 to the Munson Decl.).

32. Following announcement of its launch AWP, Warrick rarely changes the AWP for its drugs. Weintraub 9/18/06 Tr. at 145:10-146:15, 165:23-166:5, 166:17-167:25, 171:21-

⁹ Given the standard 20-25% mark-up between WACs and AWPs for brand-name drugs in conjunction with other “bona fide” and “routine” discounts, defendants contend that 30% is a minimum spread “expected” in the marketplace, and payors were well aware of spreads in excess of 30%, particularly for generic and multi-source drugs. Thus, defendants believe Judge Saris erred in finding that industry “expectations” did not exceed 30%. Whether defendants were right or the court was right, however, the decision makes clear that there would be no basis for concluding that payors such as Medicaid anticipated spreads of less than 30%.

172:23 (Exhibit 27 to the Munson Decl.). During the relevant time period, the AWP's for the seven Warrick drugs at issue did not change. *Id.*

Wisconsin Medicaid's Reimbursement Formula

33. Since at least 1990, Wisconsin Medicaid has reimbursed claims submitted by Medicaid providers for dispensing prescription drugs to Medicaid beneficiaries at the **lower of**: (1) estimated acquisition cost, which Wisconsin has defined for most manufacturers, including Schering and Warrick, as AWP minus some fixed percentage (ranging from AWP-10% to AWP-12% for the period 2001 to 2004) plus a dispensing fee; (2) maximum allowable cost plus a dispensing fee; and (3) the usual and customary charge submitted by the provider. *See* Vavra 8/16/07 Tr. at 53-58 (Exhibit 24 to the Munson Decl.)

Wisconsin's MAC Program

34. For therapeutically equivalent, multiple-source drugs that are readily available from two or more manufacturers, Wisconsin Medicaid has, since the late 1970's, established a Maximum Allowable Cost or MAC. *See* DHCF Current Policy Brand Medically Necessary and Medicaid Maximum Allowable Cost List (WI-Prod-PDF-007885) (Exhibit 11 to the Munson Decl.); Medical Assistance Provider Bulletin, July 20, 1979 (WI-Prod-AWP-030501, 030502) (Exhibit 12 to the Munson Decl.).

35. The MAC established by Wisconsin Medicaid, plus a dispensing fee, is the maximum amount that Wisconsin Medicaid will reimburse a provider for dispensing that drug to a Medicaid beneficiary. *See* DHCF Current Policy Brand Medically Necessary and Medicaid Maximum Allowable Cost List (WI-Prod-PDF-007885) (Exhibit 11 to the Munson Decl.).

36. Wisconsin Medicaid establishes MACs to save money. *See* Q&A about Wisc. Dept. of Health (WI-Prod-PDF-009236) (Exhibit 13 to the Munson Decl.); *see also* Collins 10/30/07 Tr. at 93:10-19; 109:18-21 (Exhibit 20 to the Munson Decl.).

37. MACs allow Wisconsin Medicaid to take advantage of the price competition that ensues when a brand-name drug loses its patent protection and must compete with generic equivalents resulting in lower prices. The same MAC applies to the brand-name and generic equivalents of a drug. *See* Medicaid Briefing Papers, Governor's Pharmacy Reimbursement Commission November 17, 2005, Wisc. Medicaid Drug Pricing: Avg. Wholesale Price and Maximum Allowable Cost (WI-Prod-AWP-111655) (Exhibit 14 to the Munson Decl.).

38. Wisconsin Medicaid has been "aggressive" in establishing MACs and currently sets MACs for approximately 1,300 national drug codes or NDCs. *See* Collins 12/20/07 Tr. at 29:5-30:1 (Exhibit 22 to the Munson Decl.); Collins 10/30/07 Tr. at 112:14 – 113:19 (Exhibit 20 to the Munson Decl.).

39. Wisconsin's MAC program has been successful in saving "probably hundreds of millions" of dollars for Wisconsin Medicaid. *See* Collins 10/30/07 Tr. at 110:7-111:2 (Exhibit 20 to the Munson Decl.); *see also* Collins 10/30/2007 Tr. at 196:4-15 (Wisconsin "beat the crap out of" the federal government's program because "Wisconsin's prices were substantially lower than the federal upper limits in most cases.") (Exhibit 20 to the Munson Decl.).

40. Wisconsin Medicaid has never relied on any AWP or WAC reported by any drug manufacturer to the pricing compendia, or published by any pricing compendium, in establishing MACs. *See* Collins 10/30/2007 Tr. at 101:11-102:10, 128:11-16, 129:3-16, 131:7-132:5, 132:14-22; 160:16-161:15, 184:19-21 (Exhibit 20 to the Munson Decl.); Collins 12/20/07 Tr. at 24:8-25:13 (Exhibit 22 to the Munson Decl.).

41. Instead, in setting MACs, Wisconsin Medicaid has relied on pricing information obtained from various drug wholesalers, including at least two of the three major national drug wholesalers, Cardinal and McKesson, and F. Dohman Company, the largest regional wholesaler operating in Wisconsin; certain group purchasing organizations or cooperative buying groups, such as the Minnesota Multi-State Contracting Alliance for Pharmacy or MMCAP (through which several other Wisconsin state agencies such as the Department of Corrections purchased drugs) and IPC (a buying cooperative serving independent pharmacies in Wisconsin); and various Internet websites. *See Collins 10/30/07 Tr. at 62:15-64:17 (Exhibit 20 to the Munson Decl.).*¹⁰

42. In establishing MACs, Wisconsin Medicaid has also relied on invoices submitted by pharmacists as a part of a formalized process for requesting that a MAC be increased when the pharmacist cannot acquire the drug at or below the MAC price established by Wisconsin Medicaid. *See Collins 12/20/07 Tr. at 23:10-24:7 (Exhibit 22 to the Munson Decl.), Collins 10/30/07 Tr. at 203:19-204:9, 221:9-17, 242:7-11 (Exhibit 20 to the Munson Decl.).*

43. Theodore Collins, R. Ph., Wisconsin's designated witness on the topic of the MAC program, testified that, during the period June 16, 2001 to June 16, 2004, he was the individual responsible for establishing Wisconsin's MAC prices, he did not rely on any AWP or WAC reported by any drug manufacturer, and he likewise did not rely on any AWP or WAC reported by any pricing compendium, including First DataBank, in setting MACs, **except to**

¹⁰ *See also Medicaid Briefing Papers, Governor's Pharmacy Reimbursement Commission November 17, 2005, Wisc. Medicaid Drug Pricing: Avg. Wholesale Price and Maximum Allowable Cost (WI-Prod-AWP-111656) (Exhibit 14 to the Munson Decl.); Collins 10/30/07 Tr. at 225:7-226:5 (regarding McKesson and Cardinal data) (Exhibit 20 to the Munson Decl.); E-mail dated 8/28/00 from Ted Collins to Carrie Gray re: MAC Pricing (WI-Prod-AWP-051607) (regarding McKesson and other data) (Exhibit 15 to the Munson Decl.); Collins 10/30/07 Tr. at 16:3-18 (regarding F. Dohman Company data) (Exhibit 20 to the Munson Decl.); Vavra 9/26/07 Tr. at 433:18-434:13 (regarding Sun Prairie, Wisconsin buying group IPC) (Exhibit 25 to the Munson Decl.); Collins Tr. 10/30/2007 at 193:8-21 (regarding AMP data) (Exhibit 20 to the Munson Decl.); Vavra 9/27/07 Tr. at 588:4-12 (regarding AMP data) (Exhibit 26 to the Munson Decl.).*

confirm that the MAC prices he was setting were lower than the published AWPs for the therapeutically equivalent products subject to the MAC. *See* Collins 10/30/07 Tr. at 8:9-17, 23:14-21, 25:5-16, 160:16-161:15, 245:21-246:16 (Exhibit 20 to the Munson Decl.), Collins 12/20/07 Tr. at 24:8-16 (Exhibit 22 to the Munson Decl.).

44. Mr. Collins further testified that, in setting the MAC, he searched for the lowest price for the drug that was readily available in the marketplace to pharmacies from a wholesaler, buying group, or other distribution source operating in Wisconsin, and then added a 10-25% mark-up to that price to ensure that pharmacies serving Medicaid patients in Wisconsin would be able to acquire the drug for a price at or below the established MAC. *See* Collins 10/30/07 Tr. at 16:3-17:14, 74:9-18, 76:7-22, 95:20-96:3 (Exhibit 20 to the Munson Decl.), Collins 12/20/07 Tr. at 25:14-27:9 (Exhibit 22 to the Munson Decl.); Medicaid Briefing Papers, Governor's Pharmacy Reimbursement Commission November 17, 2005, Wisc. Medicaid Drug Pricing: Avg. Wholesale Price and Maximum Allowable Cost (WI-Prod-AWP-111656) (Exhibit 14 to the Munson Decl.).

45. Put differently, Mr. Collins testified that he added a 10-25% mark-up to ensure access to prescription drugs for Wisconsin Medicaid beneficiaries. *See* Collins 10/30/07 Tr. at 74:9-18 (Exhibit 20 to the Munson Decl.), Collins 12/20/07 Tr. at 27:3-9 (Exhibit 22 to the Munson Decl.).

46. Assuring "equal access" to prescription drugs is a statutory requirement for any state Medicaid program to receive federal reimbursement of a portion of its costs. *See* 42 U.S.C. § 1396a (a)(30)(A) (requiring a state Medicaid program to establish reimbursement rates "sufficient to enlist enough providers so that the 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”). Depending on a state’s per capita income, the federal government pays for anywhere from 50% to 75% of the costs incurred by the state under its Medicaid program (for 2006, the federal government paid 57.65% of Wisconsin Medicaid’s costs. *See* www.cms.hhs.gov).

47. The claims data produced by Wisconsin show that, during the relevant time period, about 55% of all the Medicaid claims for which Wisconsin seeks to recover from Schering and Warrick were paid on the basis of a MAC set by Wisconsin Medicaid, and not an AWP or WAC reported by Schering or Warrick or published by the pricing compendia. *See* Addanki Aff., at ¶ 11 & Exs. 5A & 5B.

48. The vast majority of drugs subject to MAC-based reimbursement are generic drugs such as those marketed and sold by Warrick. Virtually all of the reimbursement for six of the seven Warrick drugs at issue was done on the basis of a MAC – *i.e.*, for those drugs, about 89% of claims reimbursed by Wisconsin Medicaid were reimbursed based on a MAC. *See* Letter from Frank D. Remington, Assistant Attorney General, to Steven F. Barley, Hogan and Hartson (Dec. 13, 2007) and enclosed DHFS Rebate Invoice File/DHFS Pricing File (Exhibit 16 to the Munson Decl.); *see also* Addanki Aff., at ¶ 11 & Exs. 5A & 5B. For the remaining Warrick drug – potassium chloride – only 215 claims were reimbursed by Wisconsin Medicaid during the relevant time period, and Wisconsin did not establish a MAC for this drug. *Id.* at Exs. 5A & 5B.

49. As to those eleven Schering multi-source brand drugs that were subject to a MAC during some portion of the relevant period, during that portion of the period for which a MAC was in place, approximately 32% of claims reimbursed by Wisconsin Medicaid were reimbursed based on a MAC. *See id.* at ¶ 11 & Exs. 6A & 6B. An additional approximately 12% of claims

were reimbursed on the basis of the usual and customary charge that the provider submitted. *See id.* at Exs. 6A & 6B.

Wisconsin's Knowledge That AWP Is Not An Average of Transaction Prices

50. Beginning no later than 1995, officials at Wisconsin Medicaid knew and understood that WACs are an undiscounted list price. *See* White 9/28/07 Tr. at 80:2-80:20 (Exhibit 29 to the Munson Decl.), Vavra 8/16/07 Tr. at 133:10-134:4 (Exhibit 24 to the Munson Decl.), Collins 12/20/07 Tr. at 270:3-15 (Exhibit 21 to the Munson Decl.).

51. At all relevant times, Wisconsin Medicaid officials knew and understood that AWPs did not and do not represent an actual average of wholesale prices. *See, e.g.*, E-mail from Neil Gebhart to Robert Blaine (Jan. 6, 2005 12:34 pm) (WI-Prod-AWP-112268) (some within Wisconsin Medicaid “[REDACTED]”
[REDACTED]”)
(emphasis added) (Exhibit 17 to the Munson Decl., Filed Under Seal); Vavra 8/16/07 Tr. at 160:16-161:15, 164:2-6 (testifying that the State has known for over 30 years that AWP was not an average sales price) (Exhibit 24 to the Munson Decl.).

52. In connection with establishing the reimbursement rate for brand drugs, the Wisconsin Legislature was informed repeatedly that AWPs did not, and do not, represent an actual average of wholesale prices. In 1999, for example, the staff of the Joint Finance Committee, the Legislative Fiscal Bureau, reported to the Legislature that **“AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to a ‘sticker price’ of a car. It does not reflect the actual cost of acquiring the drug.”** *See* LFB Paper # 479, Drug Reimbursement (DHFS – Medical Assistance) at 3 (June 1, 1999) (WI-Prod-AWP-117942) (emphasis added) (Exhibit 18 to the Munson Decl.). In 2005, the Legislative Fiscal Bureau again

reported to the Legislature that AWP's are like the "sticker price on a car" that "very few purchasers actually pay." LFB Paper #371, (May 26, 2005) (WI-Prod-AWP-105412) (Exhibit 19 to the Munson Decl.).

ELEMENTS OF THE CLAIMS

Both Count I and Count II of the Complaint assert claims pursuant to the Deceptive Trade Practices Act. The elements of such claims are clear. As set forth in the Wisconsin Supreme Court's recent decision in *K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 732 N.W.2d 792 (Wis. 2007), to prevail on a claimed violation of the DTPA, "the plaintiff must prove three elements":

First, that with the intent to induce an obligation, the defendant made a representation to "the public." Second, that the representation was untrue, deceptive or misleading. Third, that the representation caused the plaintiff a pecuniary loss.

Id. at 798.¹¹

As to the third element, the court elaborated, "[b]ecause the purpose of the DTPA includes protecting Wisconsin residents from untrue, deceptive, or misleading representation[s] made to induce action," the Act "requires a causal connection between the untrue, deceptive, or misleading representation and the pecuniary loss" suffered. *Id.* at 802. The opinion goes on to explain that, although the "plaintiff does not have the burden of proving reasonable reliance" under the DTPA, "the reasonableness of a plaintiff's reliance may be relevant in considering whether the representation materially induced the plaintiff's pecuniary loss." *Id.* For example, if it would have been patently unreasonable for the plaintiff to rely on the alleged misrepresentation, then a jury may conclude that the plaintiff's loss was not in fact "induced" by the alleged misrepresentation or, put differently, that the alleged misrepresentation did not in fact

¹¹ Wisconsin's recitation of the elements of a claim brought under the Act, set forth in the summary judgment motions filed against other Defendants in this case, appears to be based on outdated case law and fails to acknowledge the *K&S Tool* case.

cause the pecuniary loss allegedly suffered. *See id.* (“proving causation in the context of § 100.18(1) requires a showing of material inducement”).

ARGUMENT

Under Wisconsin law, “summary judgment must be entered ‘if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.’” *Green Spring Farms v. Kersten*, 401 N.W.2d 816, 820 (Wis. 1987) (quoting Wis. Stat. § 802.08(2)). “[O]nce sufficient time for discovery has passed, it is the burden of the party asserting a claim on which it bears the burden of proof at trial to make a showing sufficient to establish the existence of [the] element[s] essential to that party’s case.” *Transport. Ins. Co., Inc. v. Hunzinger Constr. Co.*, 179 Wis. 2d 281, 291-92, 507 N.W.2d 136 (Wis. Ct. App. 1993) (internal quotation marks omitted). If a plaintiff is unable to prove any essential element of its claim, then defendant is entitled to summary judgment. *Id.*

Wisconsin has not only failed to produce the requisite material facts in support of its DTPA claims; such facts in truth could not possibly exist. Wisconsin awkwardly attempts to shoehorn the complex system of Medicaid pharmaceutical reimbursements into the rubric of the “two party transaction” contemplated by the DTPA. But, regardless of how hard Wisconsin pushes, the shoe simply will not fit. Wisconsin cannot possibly make out several crucial elements of its DTPA claims, and accordingly this Court should award Schering-Plough and Warrick summary judgment on Counts I and II of the Complaint.

I. MEDICAID REBATE AGREEMENTS CREATE A “PARTICULAR RELATIONSHIP” SUCH THAT WISCONSIN DOES NOT HAVE STANDING TO ASSERT CLAIMS UNDER THE DTPA.

Schering and Warrick cannot be liable under the DTPA for the simple reason that, by virtue of its unique relationship with drug manufacturers, Wisconsin cannot be considered a member of “the public” for purposes of Section 100.18 and, thus, cannot recover under the statute.

Liability under Section 100.18 requires a showing, among other things, that the defendant made a misrepresentation to “the public.” Wis. Stat. § 100.18(1). While the DTPA itself contains no definition of “public,” Wisconsin courts have interpreted the phrase to exclude situations where the plaintiff and defendant have a “particular relationship . . . which would distinguish the prospective purchasers from ‘the public’ which the legislature intended to protect.” *K&S Tool & Die Corp.*, 732 N.W.2d at 799 (quoting *State v. Automatic Merchs. of Am., Inc.*, 221 N.W.2d 683 (Wis. 1974)). Thus, “a plaintiff is no longer a member of ‘the public’ for the purpose of Section 100.18 once [it] has entered into a contract to purchase” the disputed product. *Id.* at 800.¹² Standard contractual relationships are not the only situation, however, where a relationship between the parties precludes liability under Section 100.18. “The existence of a particular relationship [negating liability] will depend upon its own peculiar facts and circumstances and must be tested by the statute in the light of such facts and circumstances.” *K & S Tool & Die Corp.*, 732 N.W.2d at 800 (internal quotations omitted).

It is just this type of “particular” relationship that prevents application of Section 100.18 in this case. Since 1991, Wisconsin has had an arms-length, contractual relationship with Schering and Warrick specifying the type of pricing information that Schering and Warrick are

¹² See also *Kailin v. Armstrong*, 643 N.W.2d 132, 149 (Wis. Ct. App. 2002) (stating that once a particular relationship is formed through a contract, the possibility of inducing a purchase in violation of §100.18 no longer exists).

required to submit to Medicaid and providing for rebates to be paid by Schering and Warrick to Wisconsin Medicaid based on that pricing information. *See* PUF, at ¶¶ 16-24. Indeed, most drug manufacturers – including Schering and Warrick – are parties to standardized Rebate Agreements with CMS. *Id.* A manufacturer’s entering into a Rebate Agreement is a prerequisite to Medicaid’s agreeing to reimburse providers for dispensing that manufacturer’s drugs. *Id.*

Entered into by CMS “on behalf of” all States (including Wisconsin), these Rebate Agreements establish the framework through which drug manufacturers provide pricing data and make rebate payments to state Medicaid programs, including Wisconsin’s Medicaid program, to help offset some of Medicaid’s cost of offering a prescription drug benefit to Medicaid beneficiaries. *Id.*¹³ The Rebate Agreement requires the drug manufacturer to report to CMS, on an NDC-by-NDC basis, the Average Manufacturer Price or AMP for each Covered Outpatient Drug it markets. *Id.* at ¶ 18. Once a quarter since 1991, CMS has provided each state with a Unit Rebate Amount or URA for each covered drug, so that the state could calculate and collect the rebates that it was due from the manufacturers. *Id.* at ¶ 20.¹⁴

¹³ The Rebate Agreement (and accompanying federal statute) requires participating manufacturers to provide to States quarterly rebates for most “covered outpatient drugs,” based on the total number of units of each dosage, form, and strength paid for under the state plan in the rebate period, multiplied by: (a) in the case of single-source and innovator multiple-source drugs, the greater of (i) the difference between the “Average Manufacturer Price” or AMP and the “Best Price” or (ii) a minimum rebate amount equal to 15.1% of AMP; or (b) in the case of non-innovator multiple-source drugs, a rebate amount equal to 11% of AMP. *See* 42 U.S.C. §§ 1396r-8(c)(1)(B)(i) & (c)(3); PUF, at ¶¶ 16-24.

¹⁴ Thus, the jointly-administered federal/state Medicaid program has had – at a most granular level – what CMS defines as the average selling price of a manufacturer’s products, including relevant discounts, for more than seventeen years; and Wisconsin Medicaid, as the intended third-party beneficiary of the Rebate Agreement has, in fact, received substantial financial benefits under that contract. *See* PUF, at ¶¶ 16-24. This URA information based on such AMPs, which was provided to Wisconsin Medicaid quarterly, not only enabled Wisconsin Medicaid to calculate the rebates due it by the manufacturers, but it also provided Wisconsin Medicaid with sufficient information from which to derive AMPs for each drug at issue on a quarterly basis since 1991. URAs are derived from AMPs by formulae that are set forth in a Federal statute, *see* 42 U.S.C. § 1396r-8(c)(1) and (3), and in the Rebate Agreement, *see* Medicaid Program: Drug Rebate Agreement, 56 Fed. Reg. 7049 (Feb. 21, 1991); CMS Center for Medicaid and State Operations, Medicaid Drug Rebate Operational Training Guide at § H (Sept. 2001). For most generic drugs, URAs are 11% of AMP; for innovator generic drugs and for brands, URA is no less than 15% of AMP. It follows that AMPs for most generics are almost exactly 9 times URAs, and AMPs for other drugs are no greater than 7 times URAs.

The existence of the Rebate Agreements constitutes a “particular relationship” between Wisconsin Medicaid and Schering and Warrick that precludes the application of Section 100.18 in this case. *See K & S Tool & Die Corp.*, 732 N.W.2d at 801 (finding that a jury “could have reasonably found that a particular relationship existed” when the parties had done business in the past and had a history of negotiations regarding the product at issue); *Donisi v. McGann*, 707 N.W.2d 581, slip op. (Wis. Ct. App. 2005) (when an initial offer had been made and the parties enjoyed the “particular relationship of negotiating parties,” a claim under § 100.18 was properly dismissed); *Mayville Die & Tool, Inc. v. Weiler Mach. Co.*, 639 N.W.2d 224, slip op. (Wis. Ct. App. 2001) (when parties have an ongoing business relationship (manufacturer/distributor), the statement was not made to the “public”).

Indeed, in this case, the argument is particularly compelling. The pricing information available to Wisconsin Medicaid pursuant to the Rebate Agreement clearly undermines all of its claims of deception. Equally importantly, the “particular relationship” created by the Rebate Agreement was designed to, and did in fact, defray some of the very same costs to Wisconsin Medicaid that the Attorney General and his private lawyers now seek to recover in this litigation. *See* PUF, at ¶ 22. As summarized in a Congressional Budget Office Report, pursuant to the rebate agreement “state Medicaid agencies obtain access to the lowest price paid for prescription drugs by any purchaser in the United States without having to duplicate the efforts of large private purchasers to earn those discounts.” *Id.* Having receiving the intended benefit of the Rebate Agreement, the State cannot now make a claim that it was harmed under the DPTA.

II. THE DECEPTIVE TRADE PRACTICES ACT WAS NEVER INTENDED TO APPLY AND SHOULD NOT BE APPLIED TO THE CONDUCT AT ISSUE IN THIS CASE.

A. Section 100.18(1) does not cover purchases of drugs reimbursed by Medicaid.

The structure of the Wisconsin Medicaid Program and the history of the DTPA make proof of Wisconsin's DTPA claims impossible. Liability under the DPTA "requires a causal connection between the untrue, deceptive or misleading representation and the pecuniary loss." *K & S Tool & Die Corp.*, 732 N.W.2d at 802; *see also Tim Torres Enters., Inc. v. Linscott*, 416 N.W.2d 670, 675 (Wis. Ct. App. 1987) ("We interpret [the DTPA] as requiring a causal connection between the practices found illegal and the pecuniary losses suffered."). Put another way, the allegedly false or misleading representation must be "a material inducement" to the consumer's purchasing decision, without which the consumer would not have acted. *K & S Tool & Die Corp.*, 732 N.W.2d at 803.

Whether characterized as causation or inducement, the DTPA requirement that a defendant's statement **actually influence** a plaintiff's actions is in perfect keeping with the statute's purpose. Enacted first in 1913, the DTPA was based on a model advertising law drafted by a printers' magazine and was intended to apply to advertisements attempting to induce the sale of goods and services. *See James D. Jeffries, Protection for Consumers against Unfair and Deceptive Business*, 57 MARQ. L. REV. 559, 561 (1974). Then and now, "[t]he purpose of § 100.18 is aimed at untrue, deceptive, or misleading statements *made to induce* certain actions." *Kailin*, 643 N.W.2d at 149 (emphasis added). In short, Section 100.18 is meant to address the unscrupulous advertiser's fraudulently inducing purchases by the average consumer through print and verbal trickery.

Given that the DTPA was intended to address claims where plaintiff was actually induced by the actions of defendant – *i.e.*, transactions involving a direct sale between the parties – the DTPA is particularly ill-suited to address Medicaid reimbursement, a system involving multiple sophisticated parties where the State does not purchase directly or indirectly from the drug manufacturers and, in fact, does not decide which drugs are purchased. It is without dispute that Schering and Warrick do not sell, and have never sold, their products directly to Wisconsin Medicaid or to any Wisconsin Medicaid beneficiary. *See* PUF, at ¶ 15. Schering and Warrick sell to wholesalers, who then resell the drugs to pharmacies, or in a few cases, to doctors.¹⁵ Doctors write prescriptions permitting patients to obtain “self-administered” drugs (which the patient can take without the help of a doctor) from pharmacies. *See id.*, at ¶ 8. When the Medicaid beneficiary fills the prescription at the pharmacy, the pharmacy submits a claim for reimbursement to Wisconsin Medicaid. *Id.* Thus, it is at least one and often times more than one sophisticated intermediary (other than the State) that decides which drugs will be prescribed and, ultimately, reimbursed. This separation of payer from decision-maker is far afield from the vendor-to-consumer exchange envisioned by the DTPA.

More to the point, for virtually all of the Schering and Warrick drugs at issue, Wisconsin simply cannot produce evidence showing that any representation regarding AWP or WAC could have been expected to change, materially induce, or even remotely affect decisions about which drugs would be prescribed and ultimately reimbursed by Wisconsin Medicaid. In the case of self-administered, brand drugs (the vast majority of the Schering drugs at issue here), it is the physician who decides which drug to prescribe, but it is the pharmacy that submits the claim for

¹⁵ Only two of the Schering drugs at issue are “physician-administered” drugs (*e.g.*, intravenous injections that must be given by a doctor). *See* PUF, at ¶¶ 11-12. Thus, as to most of the Schering and Warrick drugs, the doctor does not provide the drug directly to the Medicaid beneficiary or seek reimbursement from Wisconsin Medicaid for dispensing the prescription.

reimbursement and is compensated by Wisconsin Medicaid for dispensing the drug. *See id.*, at ¶¶ 7-8. The doctor is not reimbursed for the drug and, thus, has no interest in any WAC or AWP that may influence reimbursement. *Id.* at ¶ 8.

Similarly, while multi-source self-administered drugs such as those sold by Warrick can be selected by the same entity that receives reimbursement – the pharmacist – it is again impossible for that choice to be “induced” by any multi-source manufacturers’ WAC¹⁶ or AWP. It is undisputed that virtually all of the reimbursement of Warrick’s generic multi-source drugs was done pursuant to a MAC that applied to all manufacturers of the drugs. *See id.*, at ¶ 48. It is also undisputed that those MACs were unrelated to any manufacturer’s WAC or AWP. *See id.* at ¶ 43. Thus, as a simple matter of economics, the pharmacist (or the wholesaler supplying the pharmacist) could not be induced to purchase Warrick’s drugs based on its AWPs because they are irrelevant to the amount of profit that the pharmacist or wholesaler ultimately earns. When therapeutically equivalent drugs are all reimbursed at the same rate, the only thing that should matter to the pharmacist is which manufacturer’s drug can be acquired most cheaply – as a result of good old-fashioned price competition. It is not surprising, then, that Wisconsin has not (nor could it) produce any evidence that those who did make decisions about which generic drugs would be dispensed were materially induced by representations about AWPs or WACs.

B. Section 100.18(10)(b) adds nothing.

Wisconsin’s DTPA claim under Section 100.18(10)(b) serves only as an additional example of the absurdity of attempting to apply the DTPA to the complicated world of Medicaid reimbursement claims. The plain language and the drafting history of 100.18(10)(b) make clear that the Wisconsin Legislature added this subsection to the DTPA specifically to curb advertising abuses by retailers attempting to induce unsuspecting consumers to purchase products by holding

¹⁶ Warrick does not have – and has never had – or published a WAC for its drugs. *See* PUF, at ¶ 30.

themselves out as “wholesalers” or by suggesting that their prices were “wholesale” or “manufacturer’s” prices. The original draft of this subsection explained that: “[t]his bill is designed to specifically prohibit current advertising abuses by some retailers particularly those who operate a ‘mail order’ or ‘catalogue’ business and who either represent themselves or their prices as ‘wholesaler’s’ or ‘manufacturer’s’, or by similar terminology.” Drafting Record, L. 1961, c.376, p.4. As the Defendants’ joint brief points out, Subsection 10(b) was intended to illustrate the conduct prohibited by the DTPA, but still requires proof of each of the three essential elements of a DTPA claim. *See* Def. Joint Br. at Section V.F.

By virtue of the basic structure of the Medicaid reimbursement scheme described above, such a concept has no applicability here. Schering and Warrick **are** manufacturers, and have never held themselves out as anything other than manufacturers. They **do not** advertise their drugs at any price to Wisconsin Medicaid because Wisconsin Medicaid does not decide which drugs are purchased. *See* PUF, at ¶ 15. Moreover, with regard to the vast majority of the Schering and Warrick drugs at issue, the physicians who do decide which drugs to prescribe are generally not reimbursed for dispensing the drugs, so they could not be induced to select drugs based on AWP’s or WAC’s. *See id.*, at ¶¶ 7-8. Likewise, pharmacists could not be induced to select Warrick generic drugs based on their AWP’s because those drugs were overwhelmingly reimbursed at exactly the same rate as competitors’ versions – a rate entirely independent of any manufacturer’s AWP. *Id.* at ¶¶ 34-49.

Simply put, the DTPA was not intended to apply in the way that Plaintiff seeks to exploit it here, and this Court should decline to stretch the DTPA beyond its obvious limits. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 84 (holding that “Deceptive Pricing Guides are directed toward the advertising and promotion of misleading prices to the

‘consuming public’” and are, thus, inapplicable to AWP claims because “[h]ere the manufacturers are not advertising prices to the consuming public, but to doctors and pharmacies”).

III. ANY DPTA CLAIMS BY WISCONSIN ARE DOOMED TO FAIL IN LIGHT OF THE UNDISPUTED RECORD EVIDENCE.

Wisconsin Medicaid reimburses claims submitted by Medicaid providers for dispensing prescription drugs at the **lower of**: (1) estimated acquisition cost (for 2001-2004, AWP-10% to AWP-12%) plus a dispensing fee; (2) maximum allowable cost plus a dispensing fee; or (3) the provider’s usual and customary charge. *See* PUF, at ¶ 33. Functionally, this Wisconsin reimbursement methodology results in generic and multi-source drugs being principally reimbursed based on a MAC and brand-name drugs being principally reimbursed based on AWP less some fixed percentage. While the relevant issues and analyses differ based on the market – generic/multi-source or brand-name – as demonstrated below, Plaintiff cannot prove its claims in either context.

A. Wisconsin cannot show that its reimbursements for generic/multi-source drugs were induced by Schering or Warrick’s WACs or AWPs.

More than half of all claims reimbursed by Wisconsin Medicaid for drugs sold by Schering and Warrick were reimbursed on the basis of a MAC established by Wisconsin Medicaid **without reference to any published price**. The undisputed record evidence shows that such drugs were not in fact reimbursed on the basis of any WAC or AWP published for either company’s drugs. Wisconsin’s designated representative has testified that Wisconsin Medicaid did not rely on AWPs or WACs in setting its MACs. Thus, as to reimbursements based on MACs, Wisconsin cannot prove that any allegedly false, deceptive, or misleading statements made by Schering or Warrick regarding WACs or AWPs caused it any harm.

Schering and Warrick respectfully request summary judgment be entered on their behalf as to these claims.

1. Wisconsin did not rely on AWP or WACs in setting State MACs.

Wisconsin has one of the nation's most extensive and effective MAC programs. *See* PUF, at ¶¶ 38-39. Wisconsin has used its MAC program to shift Medicaid prescriptions from high cost brand-name drugs to lower cost generic drugs, thus saving money for the State. *See id.* at ¶¶ 34-37. According to the State's designated representative, Wisconsin's MAC program is one of the most "aggressive" programs in the country and it has saved "probably hundreds of millions of dollars" for Wisconsin Medicaid. *See id.* at ¶¶ 38-39. In fact, Wisconsin has been even more successful than the federal government in setting price caps in order to save money on generic drugs. Wisconsin's designated witness regarding the MAC program, Theodore Collins, R. Ph., testified that Wisconsin "beat the crap out of" the federal government's program because "Wisconsin's prices were substantially lower than the federal upper limits [price caps enacted for generic drugs] in most cases." *Id.* at ¶ 39.

In implementing its highly-successful MAC program, Wisconsin did not rely on any published prices. *Id.* at ¶¶ 40-43. Mr. Collins set Wisconsin MAC prices for the time period relevant for purposes of this motion. *Id.* at ¶ 43. On behalf of the State, Mr. Collins testified that he did not rely on AWP or WACs reported by any drug manufacturer, and he likewise did not rely on AWP or WACs reported by any pricing compendium, including First DataBank. *Id.* Rather than relying on published prices for multi-source drugs, Wisconsin used various sources of information to investigate the actual purchase prices available to Wisconsin pharmacies. *Id.* at ¶¶ 41-42. Mr. Collins testified that, in setting a MAC, he searched for the lowest price readily available in the marketplace for the drug being offered to pharmacies in Wisconsin by one or

more distribution sources, such as wholesalers or group purchasing organizations, and then added a 10-25% mark-up to that price to ensure that all pharmacies serving Medicaid patients in Wisconsin would be able to acquire the drug for a price at or below the established MAC. *Id.* at ¶ 44. This highly-effective cost savings measure did not rely in any way on prices reported by manufacturers or published by pricing compendia. *Id.* at ¶¶ 40, 43. Thus, Wisconsin cannot prove that any statement made by Schering or Warrick caused it any harm in regard to claims reimbursed on the basis of MACs, and Schering-Plough and Warrick are entitled to summary judgment on these claims.

2. Eighty-nine percent of the claims for Warrick's generic drugs were reimbursed on the basis of a MAC.

Six of the seven generic drugs at issue sold by Warrick were subject to a MAC during some or all of the period 2001 to 2004. *See* PUF, at ¶ 48. A full 89% of all claims for those drugs that were reimbursed by Wisconsin Medicaid were paid on the basis of a MAC. *Id.* With regard to these claims, the material facts are not in dispute. The MAC prices used to determine the reimbursement amount that Wisconsin Medicaid paid providers for dispensing these drugs were entirely unrelated to any statement that Warrick made about AWP or WACs. *Id.* at ¶¶ 40-43. Simply put, nothing Warrick "said" regarding its AWP or WACs (which do not exist) could have induced Wisconsin's MAC-based reimbursement (which was based on a survey of prices actually available in the marketplace), and no harm could have been caused to the State.

Similarly, as to eleven Schering-brand drugs with therapeutically equivalent competition, Wisconsin Medicaid established MACs using the same process as it used to establish MACs for generic drugs. Specifically, its pharmacy consultant, Theodore Collins, R. Ph., would survey the prices available from wholesalers, buying groups, and other distribution sources to determine the lowest price generally available to Wisconsin pharmacies in the marketplace, and then add 10-

25% to that price to arrive at a MAC. *Id.* at ¶¶ 44-45. Doing so ensured that Medicaid beneficiaries had adequate access to these drugs. *Id.* at ¶¶ 44-45. At the times when MACs were in place, approximately 32% or more of claims reimbursed by Wisconsin Medicaid for these eleven Schering multi-source brand drugs were paid on the basis of a MAC. *Id.* at ¶ 49. An additional approximately 12% of claims were reimbursed on the basis of the usual and customary charge that the provider submitted, which means that it was lower than either the MAC or AWP less some fixed percentage and, thus, these claims cannot provide the basis for liability. *Id.* As to the other claims, the arguments in Section B *infra* apply, and there is no basis of liability arising for those claims either.

Based on the overwhelming degree to which generic and multi-source drugs were reimbursed based on MACs and the process used by the State to set those MACs – a process that made it crystal clear that WACs and AWP were not market prices for multi-source drugs, *see* PUF, at ¶¶ 40-43 – it is impossible for the State to meet its burden of proof in the rare instance that the State reimbursed a multi-source drug based on AWP less some fixed percentage. In light of this undisputed record evidence, it is impossible for the State to show that it was induced to do so by any belief that AWP reflected actual transaction prices. Simply put, the scope of Wisconsin’s MAC program and the skill that officials at Wisconsin Medicaid demonstrated in implementing that program belie any causation argument that the State may attempt to make with respect to multi-source drugs. Thus, summary judgment is warranted for all Schering and Warrick multi-source drugs.

B. Wisconsin cannot prove a claim relating to the Schering-brand drugs at issue either.

As noted above, a claim under the Deceptive Trade Practices Act requires proof of three elements:

First, that with the intent to induce an obligation, the defendant made a representation to “the public.” Second, that the representation was untrue, deceptive or misleading. Third, that the representation caused the plaintiff a pecuniary loss.

K & S Tool & Die Corp., 732 N.W.2d at 792. The State cannot meet its burden of proving any of these elements as they relate to the Schering-brand drugs at issue.

1. There is no evidence in the record, nor will the State be able to elicit any, that Schering represented WACs or AWP to the public with an intent to induce drug purchases.

As explained above, Schering had no incentive to make statements about WACs or AWP for the purpose of inducing drug purchases. The vast majority of the Schering brand-name drugs at issue were self-administered drugs.¹⁷ As such, the physician who decides which drug to prescribe has no financial interest in the decision. The spread between the cost of acquiring the drug and the reimbursement paid by Wisconsin Medicaid is, therefore, irrelevant to the doctor. Similarly, where multi-source drugs are all reimbursed at the same rate by Wisconsin Medicaid, and that rate depends on actual market prices, not any price published by the compendia, Schering could not have expected to influence purchasing decisions through statements about WACs or AWP. Notably, in her analysis of the Schering-brand drugs at issue in the MDL Litigation, Judge Saris found “no evidence” of spread marketing by Schering. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 108. It is, therefore,

¹⁷ Schering has two physician-administered drugs at issue in this case. *See* PUF, at ¶ 11. One – Intron-A – was at issue in the AWP MDL, in which the court held that “given the isolated minor spreads . . . I find no liability.” *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 108; *see also* PUF, at ¶ 13. The pattern of spreads for the second – Celestone Soluspan – does not differ materially from that of Intron-A. *See* PUF, at ¶ 14.

entirely unsurprising that Plaintiff has come forward with no evidence to show that Schering represented WACs or AWP to “the public” with an intent to induce drug purchases.¹⁸

2. The State cannot prove that Schering’s AWP or WAC were untrue, deceptive, or misleading.

Separate and apart from any motivation that Schering may have had, the State also fails to show that the WACs and AWP published by the pricing compendia for the Schering-brand drugs at issue were false or misleading. Schering reports a WAC – an undiscounted list price – for each drug to the pricing compendia. *See* PUF, at ¶ 25. Schering sells its brand-name drugs to direct customers at WAC subject to only a few, relatively small industry-standard discounts, such as the widely-available 2% prompt-pay discount. *See* PUF, at ¶ 25; *see also, In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 51 (mentioning the “standard 2% prompt pay discount”). As the court in the MDL Litigation held, it was “widely understood” that the pricing compendia added an industry-standard 20-25% mark-up to brand WACs to arrive at AWP. *Id.* at 91. In fact, an analysis of the “spreads” between the AMPs (or Medicaid’s measure of the average selling price for a drug) that Schering reported pursuant to the Rebate Agreement and the AWP published for the Schering’s brand-name drugs at issue demonstrates that the difference never substantially exceeded the range of what was generally expected by the industry and government. *See* PUF, at ¶ 29. These facts, standing alone, entitle Schering-Plough and Warrick to summary judgment on the State’s brand claims.

¹⁸ For the reasons discussed in Section II.A *supra*, Wisconsin is likewise incapable of proving that Warrick made representations to the public with an intent to induce drug purchases.

- a. **The AWP's published by the pricing compendia for Schering's brand-name drugs reflect the compendia's addition of an industry-standard 20-25% mark-up to Schering's reported WACs.**

Any claim that Schering's AWP's were "untrue, deceptive, or misleading" is without merit, because the term AWP, as it relates to brand-name pharmaceutical products, was widely understood in the industry to be a pricing benchmark typically set at 20-25% above WAC. After half a decade of litigation and a full bench trial, Judge Saris ruled, in the context of the MDL, that everyone in the drug market understood this mark-up. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 91 ("[I]t is undisputed that the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP."). Accordingly, Judge Saris recognized the existence of a 30% "safe harbor" – reflecting the 20-25% industry-standard mark-up imposed by FDB and the other pricing compendia on the WACs reported for all brand-name drugs, plus other relatively small discount such as the 2% prompt pay discount typically extended by the manufacturers to their customers – within which there can be no liability. *Id.* at 92. In assessing defendants' conduct, the MDL court further recognized that "isolated, minor spreads" in excess of 30% do not support a finding of liability. *See id.* at 109.¹⁹

Schering's AWP's are "true" because they were derived in a manner entirely consistent with industry practice and, thus, fall within the recognized "safe harbor" defined by Judge Saris. Schering consistently reported WACs to the pricing compendia such as First DataBank that, as Section B.2.b *infra* demonstrates, were "real" list prices. The AWP's that the pricing compendia published for Schering's brand-name drugs, in turn, reflect an industry standard 20-25% mark-up imposed by the compendia on Schering's reported WACs. *See PUF*, at ¶ 27. An analysis of the

¹⁹ As discussed in Section B.2.b, *infra*, in assessing liability, Judge Saris also considered whether substantial sales were made at the list price from which the AWP's were marked-up. *Id.* at 102 ("Is it a real list price at which substantial sales were made?").

spreads between the AWP's published by First DataBank for the Schering brand drugs at issue in this case and the AMP's that Schering reported to CMS under its Rebate Agreement demonstrates, with only a few limited exceptions, that the Schering AWP's at issue consistently fall within the 30% "safe harbor" that Judge Saris applied in the MDL. *See* PUF, at ¶ 29.²⁰

Under these circumstances, moreover, Wisconsin cannot claim to have been "deceived" or "misled" by the AWP's that the pricing compendia published for the Schering-brand drugs at issue. As other defendants' briefs on summary judgment illustrate, the context in which a statement is made matters. It would be nonsensical to impose liability on a Wisconsin baker who advertises "Danish pastries" or a lumber yard that advertises "2 x 4's." *See* The Johnson & Johnson Defs' Mem. of Law, at Section I.A.(ii); *see also* Defs' Jt. Resp. to Pl's Partial Mot. for Summary Judgment, at Section E.1. Similarly, as Judge Saris recognized, the State's *per se* theory of AWP liability for the drug manufacturers – because AWP's were not an actual average of the prices at which wholesalers resold the manufacturer's products to the wholesaler's retail customers – makes no sense. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 97 ("Because information about the 20 to 25 percent spread was widespread in the industry, a violation of the Medicare statute by publishing an 'AWP' that was not a true average of wholesale prices does not trigger *per se* liability under [the Massachusetts Unfair Trade Practices Act]. Therefore, I reject plaintiffs' zero tolerance approach to liability and damages . . .").

²⁰ Defendants do not mean to suggest that there should be liability for spreads in excess of 30%. Given the State's experience in connection with its MAC program, it is clear that the State understood that competition among drugs caused discounting and might result in spreads between transaction prices and AWP's that exceed 30%. That is why the State adopted its MAC program in the first place.

b. Schering had significant sales at WAC.

In its motion for summary judgment against other defendants, the State suggest that the test for determining whether a list price is deceptive should be whether there are significant sales at that price. *See, e.g.,* Wisconsin's Am. Mot. for Partial Summary Judgment on Liability Against Johnson & Johnson, at pp. 9-11. Schering believes that the State has misconstrued the authority on which it relies, but that is of no moment here. Judged even by the test that the State advances, since Schering makes a significant number of sales at or near its reported WACs, *see* PUF, at ¶ 26, Wisconsin cannot demonstrate that these list prices were untrue, deceptive, or misleading under the DTPA, and Schering is entitled to summary judgment.

Among other things, the State relies on the FTC's Guides Against Deceptive Pricing (the "FTC Guides"), which create a safe harbor for list prices and provide that a list price "will not be deemed fictitious if it is the price at which substantial (that is, not isolated or insignificant) sales are made." 16 C.F.R. § 233.3(d).²¹ The case law interpreting this regulation is "sparse," *see In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp.2d at 105, and sets forth a wide range of standards for a safe harbor precluding liability.²² *See State ex rel. Thornburg v. J.C. Penny*, No. 89 CVS 11819, Slip Op. at 23 (Super. Ct. N.C. July 1992) (finding that a list price falls within the FTC's safe harbor when the percentage of sales at list is as low as 20-25%); *compare Helbros Watch Co. v. FTC*, 310 F.2d 868, 870 (D.C. Cir. 1962) (construing 60% of sales at the list as not sufficiently "substantial" prior to the adoption of the Guides Against Deceptive Pricing) *with Federated Nationwide Wholesalers Serv. v. FTC*, 398 F.2d 253, 261 (2d

²¹ *But see* Resp. of Def. Novartis Pharm. Corp., and Cross-Mot. for Partial Summary Judgment, at p. 41 n.10. (arguing that the FTC Guides do not apply to transactions involving the State and do not reflect current FTC enforcement policy) *and* The Johnson & Johnson Defs' Mem. of Law in Opp. to the State of Wisconsin's Am. Mot. for Partial Summary Judgment, at p. 19 n.4 (same).

²² As with any "safe harbor" provision, conduct falling outside of the safe harbor does not necessarily give rise to liability.

Cir. 1968) (construing 40% of sales as “substantial and significant” prior to the adoption of the Guides Against Deceptive Pricing).²³ For purposes of this motion, however, the standard selected is irrelevant because Schering’s sales at WAC are clearly within any safe harbor. Schering’s total sales made within five percent of WAC were approximately 83%. *See* PUF, at ¶ 26. When Schering’s sales of these products are analyzed by brand, similar results obtain. *Id.* Thus, even under the case law cited by Plaintiff in its own summary judgment motions, *see, e.g.*, Wisconsin’s Mot. For Partial Summary Judgment Against Novartis, at pp. 16 and 24 (citing *Federated Nationwide Wholesalers Service*), Schering’s substantial sales of its brand drugs at or close to its reported WACs foreclose any claim that its reported prices were false, misleading, or deceptive as a matter of law.²⁴ Accordingly, there can be no liability arising from Medicaid’s reimbursement of providers for dispensing any of the Schering-brand drugs at issue in this case.

3. The State cannot prove that Schering’s AWP’s or WAC’s caused it any harm.

Summary judgment should enter in Schering-Plough’s favor as to the claims premised on Wisconsin Medicaid’s reimbursement for the Schering-brand drugs at issue for yet another reason. The undisputed record evidence makes plain that neither the Wisconsin Legislature in setting the reimbursement rate for brand-name drugs, nor the Wisconsin Medicaid agency in paying claims, ever actually considered AWP’s to be an average of transaction prices. With regard to WAC’s, the argument is even simpler. There is no evidence in the record that the reimbursement formula for brand-name drugs ever depended on published WAC’s, nor is there

²³ In the MDL, Judge Saris ruled that “if more than 50 percent of all sales were made at or about the list price, the list price will not be deemed fictitious.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 105. Schering and Warrick believe that this standard is far too restrictive but, as noted above, such a disagreement is irrelevant for purposes of this motion.

²⁴ Since Schering’s WAC’s are “true” list prices and “it is undisputed that the market understood and expected a 20 to 25% formulaic markup from WAC to AWP,” *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 91, it follows logically that Schering’s AWP’s are “true” and cannot be deceptive or misleading.

any evidence that the Wisconsin Legislature even considered establishing a reimbursement formula for brand-name drugs that used WACs as a basis for the reimbursement formula. Thus, Wisconsin will never be able to show that any statement that Schering made caused Wisconsin harm.

a. The Wisconsin Legislature was fully informed as to the meaning of the term AWP in setting the Medicaid reimbursement rate for brand-name pharmaceutical products.

The record evidence showing that the Wisconsin Legislature was fully informed about the meaning of AWP at the time it established the Medicaid reimbursement rate for brand-name drugs is overwhelming. Indeed, this Court need look no further than the undisputable fact that the Legislature has, since 1990, set the reimbursement rate at AWP minus some fixed percentage, to know that the Legislature could not have believed AWP to be an average of actual transactions prices. *See* PUF, at ¶ 33. If the Legislature thought that AWP represented an average of actual transaction prices, then the Legislature presumably would have expected the reimbursement rate it set (at a discount off of AWP) to cause the majority of Wisconsin pharmacists to lose money on each prescription that they dispensed to a Wisconsin Medicaid beneficiary and, in all likelihood, to cause Wisconsin Medicaid to lose its matching federal funds because Wisconsin pharmacies would have refused to dispense drugs to Medicaid beneficiaries and, therefore, Wisconsin Medicaid would not have met its statutory obligation to provide Medicaid beneficiaries “equal access” to prescription drugs. *See* 42 U.S.C. § 1396a (a)(30)(A); PUF, at ¶ 46.

The undisputed evidence that the Legislature was well-informed of the nature of AWP is, however, much more direct. In 1999, for example, in connection with the Legislature considering a proposed reimbursement rate change, the staff of the Joint Finance Committee, the

Legislative Fiscal Bureau, reported to the Legislature that “AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to a ‘sticker price’ of a car. **It does not reflect the actual cost of acquiring the drug.**” *See* PUF, at ¶ 52 (emphasis added). Similarly, in 2005, **after** this lawsuit was filed, the Legislature considered the reimbursement rate for brand-name pharmaceutical products as a part of the biannual budget process – and again was informed by the Legislative Fiscal Bureau that AWP’s are like the “sticker price on a car” that “very few purchasers actually pay,” PUF, at ¶ 52 – and yet the Legislature choose to retain a reimbursement system premised on AWP’s. In light of these undisputed facts, no jury could conclude that the Legislature was induced to believe that AWP’s are an average of transaction prices and set the Medicaid reimbursement rate for prescription drugs in Wisconsin based on that belief.

b. The undisputed record evidence shows that Wisconsin Medicaid could not have been induced to believe that AWP’s are an actual average of wholesale prices.

The evidence with regard to Wisconsin Medicaid is even more overwhelming. As this Court knows, some within Wisconsin Medicaid “

” *See* PUF, at ¶ 51. Wisconsin’s designated representative testified that the State has known for over 30 years that AWP was not an average sales price. *Id.* The Wisconsin Medicaid program could not have been harmed in any way by representations as to AWP because it understood the meaning of this term and its use in the drug industry and made informed decisions based on this understanding to ensure that all Medicaid beneficiaries had access to prescription drugs. Stated more directly, in the face of this undisputed record evidence, Plaintiff will never be able to prove that Wisconsin Medicaid **actually believed** that AWP’s were an average of transactions prices. It follows that Wisconsin Medicaid will never be able to prove

that any alleged harm was induced or caused by any statement by Schering or Warrick regarding AWP.

The method by which Wisconsin Medicaid set its MAC prices perhaps best illustrates this point. As the undisputed record evidence shows, at all relevant times, in establishing MACs, a pharmacy consultant acting for Wisconsin Medicaid would conduct a survey of actual transaction prices. *See id.*, at ¶ 41. He would not rely on published AWPs (except to confirm that the MACs he established were in fact lower than the published AWPs for the drugs subject to the MAC) because he understood that the prices actually available to pharmacists in the marketplace were lower than this published pricing benchmark. *See id.*, at ¶¶ 40, 43. Then, moreover, he would add 10-20% to the lowest transaction price he found to be generally available to Wisconsin pharmacies to ensure adequate access for Medicaid beneficiaries. *See id.*, at ¶¶ 44-45. Put differently, in setting MACs, Wisconsin Medicaid was not simply trying to approximate actual acquisition cost; it was seeking to ensure Medicaid beneficiaries had adequate access. The same was true of Wisconsin Medicaid's decision to reimburse claims for brand-name prescription drugs on the basis of AWP, knowing full-well that actual transaction prices were typically lower than AWP.

RELIEF SOUGHT

Schering-Plough and Warrick respectfully request that this Court grant partial summary judgment in their favor and dismiss Counts I and II of the Complaint as they relate to the Schering and Warrick drugs at issue.

Dated: January 18, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 18, 2008, a true and correct copy of this Motion and Memorandum of Law was served upon all counsel of record via Lexis-Nexis File and Serve.

/s/ Renee A. Coshin
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