

Boehringer Ingelheim

- Individual Memorandum in Support of Motion to Dismiss Defendants Ben Venue Laboratories, Inc., Boehringer Ingelheim Corporation, Boehringer Ingelheim Pharmaceuticals, Inc. and Roxane Laboratories, Inc. for Failure to Plead Fraud with Particularity and for Failure to State a Claim

Dey, Inc.

- Defendant Dey, Inc.'s Supplemental Memorandum of Law in Support of its Motion to Dismiss the Amended Complaint

Johnson & Johnson

- The Johnson & Johnson Defendants' Separate Memorandum in Support of the Motion to Dismiss the Amended Complaint

Merck & Co.

- Separate Memorandum of Defendant Merck & Co., Inc. in Support of its Motion to Dismiss the Amended Complaint

Pfizer Inc.

- Individual Memorandum of Pfizer Inc. in Support of its Motion to Dismiss the Amended Complaint

Pharmacia Corp.

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Sicor Inc.

- Defendant Sicor, Inc.'s Separate Motion to Dismiss the Amended Complaint
- Defendant Sicor Inc.'s Memorandum in Further Support of Defendants' Motion to Dismiss the Amended Complaint

SmithKline Beecham

- Supplemental Memorandum of Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, in Support of its Motion to Dismiss the Complaint

Tap Pharmaceutical

- Defendant Tap Pharmaceutical Products, Inc.'s Supplemental Memorandum in Support of Defendants' Joint Motion to Dismiss the Amended Complaint

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN INC., ET AL.

Defendants.

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Case No 04 CV 1709

Unclassified - Civil: 30703

**DEFENDANT ABBOTT LABORATORIES’
SUPPLEMENTAL MEMORANDUM IN SUPPORT OF
DEFENDANTS’ JOINT MOTION TO DISMISS THE AMENDED COMPLAINT**

Defendant Abbott Laboratories (“Abbott”) submits the following individual memorandum in order to make two additional points: 1) the State has failed to allege fraud against Abbott with the specificity required by Section 802.03 of the Wisconsin Rules of Civil Procedure; and 2) any claims based on the alleged overpayment for multiple-source drugs under Medicare Part B should be dismissed because, according to the State's own allegations, it is impossible for any one defendant to gain a "spread" advantage over another defendant.¹

ARGUMENT

I. The State Fails To Allege Fraud Against Abbott with the Requisite Specificity.

The State’s claims against Abbott lack the specificity required by Section 802.03(2) in several respects. Other than providing Abbott’s business address, the amended complaint makes no particularized allegations against Abbott. Nowhere does the State allege:

- which Abbott products are at issue,

¹ Abbott adopts and incorporates by reference the defendants' joint memorandum and, to the extent applicable, the arguments contained in the other defendants' individual memorandum in support of the motion to dismiss.

- the allegedly fraudulent prices that Abbott submitted for the unidentified products,
- how or why any such price submissions were fraudulent, and
- what prices Abbott should have submitted instead.

The State alleges generally that defendants “have misrepresented the true AWP for *virtually all of their drugs.*” (Am. Compl. ¶ 37.) This broad allegation does not satisfy the requirements of Section 802.03. *See* Defs. Joint Mem. at 12-14; *see also In re Pharmaceutical Industry AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (rejecting AWP complaint and ordering plaintiffs to make specific allegations on a drug-by-drug basis). Significantly, the amended complaint does not even allege that (1) any specific Abbott product is covered under the Wisconsin Medicaid or Medicare programs; or (2) the State or any individual actually paid for a specific Abbott product based on AWP or WAC. These omissions require dismissal of the State’s claims.

The State further fails to identify when Abbott made any alleged misrepresentations. The State’s allegations that the misrepresentations occurred since at least “1992” is insufficient under Section 802.03. (Am. Compl. ¶ 33.) *See Clark v. Robert W. Baird Co.*, 142 F. Supp. 2d 1065, 1071 (N.D. Ill. 2001) (dismissing claim on Rule 9(b) grounds and finding that “for the ‘when’ [element], it is not enough to merely allege a period of months or years, or the duration of the activity”); *see also McCarthy, Wilson & Ethridge v. Provident Life and Accident Ins. Co.*, 2000 WL 1929780 (D. Md. Dec. 18, 2000) (“a general allegation of fraudulent statements occurring over the last nine years without more detail as to the ‘when’ of the fraud fails to meet the specificity requirements of Rule 9(b)”).

Finally, the State also fails to allege *who* at Abbott submitted the allegedly false information to the publications, or *where* and *how* the information was communicated. Those omissions likewise are fatal to the State's claims. See *United States v. EER Systems Corp.*, 950 F. Supp. 130, 132 (D. Md. 1996)(dismissing claims under Rule 9(b) because the plaintiff failed to "(1) name the person(s) who made the representations; (2) specifically state what he or she said; and (3) state what he or she acquired as a result of the representations"); see also *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918 (7th Cir. 1992) (dismissing claim because the plaintiff "[did] not even hint at the identity of those who made the misrepresentations, the time the misrepresentations were made, or the places at which the misrepresentations were made").

As stated in defendants' joint memorandum, the amended complaint repeatedly "lumps" the defendants together in a generalized allegation of fraud. This is precisely the type of pleading that Section 802.03 prohibits. See Defs. Joint Mem. at 10-12.

II. All Medicare Part B Claims for Multiple-Source Drugs Should Be Dismissed.

The State seeks relief on behalf of Medicare-eligible Wisconsin residents who paid, in the State's view, inflated co-payments for prescription drugs under Part B of the Medicare program. Medicare Part B covers multiple-source drugs (drugs that have a therapeutic equivalent) and single-source drugs (drugs that do not have a therapeutic equivalent). Although it is unclear from the amended complaint which Abbott products are at issue in this case, many of Abbott's products covered by Medicare Part B are multiple-source drugs.

As the State concedes, "the methodology for calculating the allowable cost of multiple source drugs and biologicals is 95% of the lesser of the *median average wholesale price* for all sources of the generic forms of the drug or biological or lowest average wholesale price of the brand name form of the drug or biological." (Am. Compl., ¶65)(emphasis added); see also 42 C.F.R. § 405.517. Medicare then pays 80% of the allowable amount, *i.e.*, either 80% of the

provider's actual charges *or*, 80% of 95% of the median AWP or the lowest AWP of the innovator (i.e., "brand-name") multiple-source drug. The Medicare beneficiary pays the remaining 20% as a co-payment. *Id.*

Under this methodology, it is impossible for one drug manufacturer to obtain a "spread" advantage over another manufacturer by increasing the AWP of its version of a multiple-source drug. Any effect that such an increase might have on Medicare reimbursement or co-payments would apply equally to all competing forms of the drug. To illustrate, suppose that three companies manufacture competing forms of a multiple-source drug. Further, suppose that the AWP for Company A's drug is \$10, the AWP for Company B's drug is \$20, and the AWP for Company C's drug is \$30. Regardless how much these three companies increase the AWP for their respective products, all three products will be reimbursed under Medicare Part B based on the *same* AWP, either the lesser of the median AWP for the three products (in this case, \$20) or the AWP of the "brand-name" drug.

Therefore, the State's theory that defendants inflated AWPs for their drugs to create larger "spreads" for their products, and thereby induce providers to purchase their products, simply does not make sense in the case of multiple-source drugs under Medicare Part B. *See Lerma v. Univision Communications, Inc.*, 52 F. Supp. 2d 1011, 1025 (E.D. Wis. 1999) ("the Court 'is not required to don blinders and to ignore commercial reality' ... To survive a motion to dismiss, a claim must make economic and factual sense."); *Brunson Communications, Inc. v. Arbitron*, 239 F. Supp. 2d 550, 564 (E.D. Pa. 2002) (dismissing conspiracy claim because "the conspiracy theorized by Plaintiff is, for several reasons, economically implausible"). For this reason alone, any claims based on the alleged overpayment for multiple source drugs under Medicare Part B should be dismissed.

CONCLUSION

For the foregoing reasons, and those identified in defendants' joint memorandum, Abbott respectfully requests that this Court dismiss the State's amended complaint with prejudice.

Dated: January 20, 2005

Respectfully Submitted,

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Angen Inc.

Amgen Inc. (“Amgen”) is unique among the defendants, standing as the only company to have been dismissed repeatedly on Rule 9(b) grounds from other complaints making similar allegations, even though they were discernibly more detailed than the State of Wisconsin’s Amended Complaint in this case. The result here should be no different. In addition to reasons set forth in the defendants’ consolidated memorandum (in which Amgen joins), the Amended Complaint should be dismissed as to Amgen¹ because: (1) the State fails to provide specific allegations to support its claim that Amgen committed fraud; (2) the alleged “spread” for the single Amgen product mentioned in the Amended Complaint, Epogen, cannot conceivably support the State’s claims; and (3) the State cannot have been misled and its citizens cannot have been injured in their purchases of or reimbursements for Epogen, given that reimbursement for Epogen under Medicare Part B is not based upon AWP.

I. THE STATE HAS FAILED TO MAKE PARTICULARIZED FACTUAL ALLEGATIONS OF FRAUD AGAINST AMGEN.

Amgen has been dismissed, time and again, from complaints asserting allegations and claims similar to those in this case brought not only by private plaintiffs, but also by the attorneys general of at least two other states. Both the Master Consolidated Complaint and the Amended Master Consolidated Complaint in the pending federal consolidated multidistrict litigation were dismissed as to Amgen because the private plaintiffs failed to satisfy the particularity requirements of Fed. R. Civ. P. 9(b), despite substantially more detailed allegations

¹ The State refers to Amgen and Immunex Corporation (“Immunex”) collectively as the “Amgen group.” Am. Compl. ¶5. Although Immunex is now a wholly-owned subsidiary of Amgen, it is a separate corporate entity, was served separately in this action, and is represented by separate counsel. More importantly for purposes of this motion, the State acknowledges that Immunex did not become a subsidiary of Amgen until July 2002. Thus, the State cannot impute to Amgen any pre-July 2002 knowledge or information relating to Immunex.

than those set forth in the State's Amended Complaint.² See *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003)³; *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, 01-12257-PBS (D. Mass. June 7, 2004) (granting motion for reconsideration and dismissing the Amended Master Consolidated Complaint as to Amgen).⁴ Amgen also was and remains dismissed from federal lawsuits brought by the Nevada and Montana attorneys general making allegations of AWP fraud similar to those brought by the State here. In each case, those states were unable to muster sufficiently particularized allegations against Amgen to satisfy Rule 9(b), notwithstanding that those complaints contained allegations significantly more detailed than those in the State's Amended Complaint. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 208 (D. Mass. 2004) (noting court addressed Amgen Motion to Dismiss separately); *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, 01-12257-PBS (D. Mass. June 7, 2004) (granting Amgen motion for reconsideration and dismissing Amended Master Consolidated Complaint as to Amgen).

Wisconsin law requires the State to plead "the time, place, and content of an alleged false misrepresentation." *Friends of Kenwood v. Green*, 239 Wis.2d 78, 87, 619 N.W.2d 271, 276 (Wis. Ct. App. 2000) (quoting *New England Data Serv. Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987)). To satisfy Wis. Stat. § 802.03(2), the State must allege the "who, what, when,

² The language of Wis. Stat. § 802.03(2) and Fed. R. Civ. P. 9(b) are identical. See *Rendler v. Markos*, 154 Wis.2d 420, 428, 453 N.W. 2d 202, 205 (Wis. Ct. App. 1990) ("Section 802.03(2), Stats., is identical to Fed. R. Civ. P. 9(b).").

³ In dismissing the Master Consolidated Complaint, the Court stated in part that, in filing an amended complaint, "plaintiffs shall clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 194.

⁴ Amgen's motion to dismiss the MDL private plaintiffs' latest effort to state a claim against Amgen, which has been fully briefed since August 31, 2004, is currently pending before the federal court in Boston.

where and how” of Amgen’s supposed fraud. *Id.* (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)).

The State does not come close to meeting its burden with respect to Amgen. Of the Amended Complaint’s 97 paragraphs and 36 pages, Amgen is mentioned by name only once – and then merely to identify its principal place of business.⁵ *See* Am. Compl. ¶5. Among other things, the State:

- has failed to identify which Amgen product(s) are at issue;
- has failed to identify even a single specific purchase of, or reimbursement for, any Amgen product by a Wisconsin resident or the amount of any purchase or reimbursement;
- has failed to identify any Amgen specific sales or marketing practices or conduct that it contends are improper; and
- has failed to identify who made the alleged misrepresentations, to whom the alleged misrepresentations were made and when the alleged misrepresentations were made, and what the specific misrepresentations were.

The failure to plead the specifics of these and other fundamental aspects of their case surely does not comport with Wis. Stat. § 802.03(2).

The two exhibits attached to the Amended Complaint do not cure its deficiencies.

Exhibit A purports to reflect the results of the Department of Justice’s (“DOJ”) investigation into fraudulent AWP’s, but it does not help the State as to Amgen. The exhibit makes no mention of Amgen or any of its products.

Exhibit B, which includes a reference to an Amgen product (Epogen), purports to set forth examples of drugs with inflated AWP’s and the alleged “spreads” between the drug’s

⁵ As the Defendants’ consolidated brief points out, the State is required to allege specific conduct as to each defendant. Group pleading does not satisfy Wisconsin’s pleading requirements.

published AWP and its “available price.”⁶ However, merely listing a product’s published AWP next to an undefined and unsupported “available price” – which is all the State has done insofar as Amgen is concerned – does not do the trick. There is nothing in the Amended Complaint providing an explanation of why Amgen’s supposed “spread” is fraudulent.⁷ And, while the exhibit mentions Epogen and purports to set forth a “spread” for that product, neither the Amended Complaint nor Exhibit B provides any information regarding why the supposed “spread” is the result of fraud, or even how the State went about calculating the “2000 Available Price” for Epogen. There is no explanation of what data the State used, how the data were selected, whether the “2000 Available Price” represents a median or mean price, or some other mathematical computation, or whether the 2000 AWP listed in Exhibit B for Epogen represents an average AWP for the entire year, the median AWP for the year, or something else.⁸ Similar reliance on unexplained calculations have been rejected by Judge Saris in the consolidated federal proceedings. *See In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, 1:03-cv-10643, 2004 WL 2387125, at *2 (D. Mass. Oct. 26, 2004).

⁶ At a minimum, should its case against Amgen be allowed to continue, the State should be barred from pursuing claims against Amgen for products other than Epogen, which are neither mentioned in the Amended Complaint nor listed in its attached exhibits.

⁷ Although not relied upon for purposes of this motion, the State’s alleged “2000 Available Price” for Epogen (\$1,960) is nearly identical to the published and publicly available 2000 wholesale acquisition cost (“WAC”) for the same NDC code of Epogen (\$2,000), differing by a mere 2%. Even accepting the State’s calculation of Epogen’s “2000 Available Price,” virtually the same price was referenced in the published industry compendia to which many states refer for purposes of Medicaid reimbursement. As such, it is difficult to discern how the State intends to prove how it, or the citizens it represents, were misled by Amgen regarding the pricing or reimbursement of its product.

⁸ The State, for example, does not specify the source of its data, other than to indicate that the information was gathered from: (1) materials obtained by *qui tam* relator Ven-A-Care (to its knowledge, Amgen is not a party to the *Ven-A-Care* litigation); (2) complaints filed by unnamed states (presumably referring to the State of Montana’s complaint, from which Amgen has been dismissed); and (3) “prices available to buyers other than Wisconsin’s Medicaid program” (without identifying the sources, the prices or the buyers). Am. Compl. ¶43.

In the absence of such specifics, the Amended Complaint should be dismissed as to Amgen.

II. AMGEN'S ALLEGED "SPREAD" CANNOT SUPPORT THE STATE'S CLAIMS.

Exhibit B, which purports to set forth the supposed "spreads" between the "2000 Available Price" and the "2000 AWP" for various products, reflects alleged "spreads" ranging from a low of 20% to a high of 4,525%. As to Amgen, the State alleges that there was a "spread" of 22% for a particular dosage and NDC for Epogen.

Even accepting the State's calculations at face value, a 22% "spread" cannot support allegations of AWP fraud against Amgen because such a difference is well within the range that the federal government has acknowledged is both expected and intended. As the Defendants' consolidated brief discusses in detail, the government has long understood that AWPs exceed provider acquisition costs. Indeed, in the recent prosecution of individuals flowing out of the TAP Pharmaceuticals investigation in Boston, the government acknowledged that purchasers of pharmaceuticals are "able to obtain a 'list price' for the drug which was lower than average wholesale price (AWP), and the spread between list price and AWP was known to the government in various ways, and assumed by the Medicare reimbursement system."

Government's Mem. Regarding [Return to Practice] as a Kickback Under Paragraph 55(b) of the Conspiracy Charged in Count I, *United States v. MacKenzie*, No. 01-CR-10350-DPW (D. Mass. filed June 24, 2004) at 1. Moreover, the government quantified what it considered to be an acceptable "spread" stating, "everybody got the spread between AWP and list price, the same 25 percent [. . .] And the 25 percent, everyone gets that. That's there. That's what Congress expected with AWP." Transcript, Jury Trial – Day 39, *United States v. MacKenzie*, 01-CR-10350-DPW (D. Mass. June 24, 2004) at 67:25 – 68:6 (emphasis added).

Here, the State alleges a “spread” of 22% between the “available price” for Amgen’s product Epogen and its published AWP. In view of the government’s specific acknowledgment that a “spread” of 25% is appropriate and intended, the alleged 22% “spread” simply cannot serve as the underpinning for the State’s claims of fraud against Amgen.

III. THE STATE’S CLAIMS BASED ON EPOGEN SHOULD BE DISMISSED.

Lastly, the State’s claims relating to Epogen should be dismissed because reimbursement for Epogen under Medicare Part B is not even based on AWP. Instead, Epogen is reimbursed at a statutory rate under Medicare Part B (\$10 per 1,000 units administered) that has remained unchanged for nearly a decade. *See* 42 U.S.C. § 1395rr(b)(11)(B). Thus, to the extent that the State’s claims seek to recover Medicare Part B co-payments (either on behalf of citizens who made Medicare Part B co-payments or in its own right for Medicare Part B co-payments made on behalf of Medicaid eligible citizens), such payments were plainly not based on AWP and cannot support a claim against Amgen.⁹

Even to the extent the State seeks to recover for non-Medicare Part B payments for Epogen, the Medicare Part B reimbursement rate set by Congress and CMS for Epogen is both publicly available and widely known. Thus, whatever Amgen’s reported price for purposes of AWP, the State cannot reasonably claim that it has been deceived into paying falsely inflated payments for Epogen by relying on Epogen’s published AWP.

⁹ According to OIG reports, roughly 90% of Amgen’s market for Epogen consist of Medicare Part B patients. *See, e.g., Review of Epogen Reimbursement*, Office of Inspector General, Dep’t of Health and Human Services, A-01-92-00506, at 1 (Jan. 1993).

CONCLUSION

For the foregoing reasons, and for the reasons set forth in the defendants' consolidated motion and memorandum, Amgen requests that the Amended Complaint filed against it in this action be dismissed with prejudice.

Respectfully submitted,

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Dated: January 19, 2005

AstraZeneca

STATE OF WISCONSIN

CIRCUIT COURT
BRANCH 7

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

Case No. 04-CV-1709

AMGEN, INC., et al.,

Defendants.

**INDIVIDUAL MEMORANDUM OF LAW OF DEFENDANTS ASTRAZENECA
PHARMACEUTICALS LP AND ASTRAZENECA LP IN SUPPORT OF THEIR
MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

INTRODUCTION

AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AstraZeneca") respectfully submit this supplemental brief in support of their motion to dismiss the Amended Complaint. If the Amended Complaint is not dismissed in its entirety as to all defendants, pursuant to the points raised in Defendants' Memorandum of Law in Support of their Joint Motion to Dismiss, all claims against AstraZeneca should nevertheless be dismissed because the State has not satisfied Wis. Stat. § 802.03(2) with respect to its allegations of fraud against AstraZeneca, as set forth below. In addition, to the extent that the State is pursuing claims as a Medicaid payer with respect to Zoladex® (goserelin acetate), an AstraZeneca drug identified in an attachment to the Amended Complaint, those claims are barred by a 2003 settlement agreement.

ALLEGATIONS OF THE COMPLAINT

The Amended Complaint contains just two references to AstraZeneca: with respect to jurisdictional allegations (Compl. ¶ 6) and to note the existence of a settlement with the federal government relating to Zoladex® (Compl. ¶ 51). The *only* other allegation against AstraZeneca is contained not within the four corners of the Amended Complaint, but in an attachment thereto (Exhibit B) in which the State identifies NDC codes for 29 drugs, one of which is AstraZeneca's product, Zoladex®. The allegations concerning this attachment, however, concern all defendants and are entirely vague and general in nature (Compl. ¶ 43 & Exhibit B).

ARGUMENT

I. THE STATE'S CLAIMS AGAINST ASTRAZENECA
MUST BE DISMISSED PURSUANT TO THE HEIGHTENED
PLEADING REQUIREMENTS OF WIS. STAT. § 802.03(2)

The State cannot satisfy the particularity requirements of § 802.03(2) without specifically pleading the "who, what, when, where, and how" of the alleged fraud. *See Friends of Kenwood v. Green*, 239 Wis. 2d 78, 87 (Wis. Ct. App. 2000). Exhibit B to the Amended Complaint merely sets forth a list of drug prices that were "available" in 2000 for a price that was less than AWP. One AstraZeneca product, Zoladex®, is included on the list. Yet, the fact that a product's AWP differs from its "available price" does not constitute anything close to a sufficient allegation of fraud. Nor are the allegations in paragraph 43 of the Amended Complaint, which references Exhibit B, sufficiently particularized. Accordingly, the State's generalized allegations of fraud against AstraZeneca are inadequate to satisfy the particularity requirements of Wis. Stat. § 802.03(2).

II. WISCONSIN'S CLAIMS AS A MEDICAID PAYER
WITH RESPECT TO ZOLADEX® ARE BARRED BY
SETTLEMENT AGREEMENT

Furthermore, the State purports to bring certain claims on its own behalf as a Medicaid payer (Compl. ¶¶ 1, 35, 57-61). However, with respect to Zoladex® (the only drug referenced in the Amended Complaint, at Exhibit B), such claims are barred by a 2003 settlement agreement between AstraZeneca and the State, which provides in relevant part:

The State of Wisconsin, on behalf of itself, and its officers, agents, agencies, and departments, releases and discharges Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parent and affiliates, predecessors, successors and assigns, and their current and former directors, officers and employees from any civil or administrative claims for Medicaid damages or penalties that the state of Wisconsin has or may have relating [sales, marketing and pricing practices concerning Zoladex®]. The payment of the Settlement Amount fully discharges Zeneca from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the state of Wisconsin for the [aforementioned conduct].

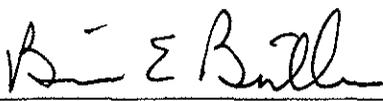
See Settlement Agreement and Release by and among AstraZeneca Pharmaceuticals LP, AstraZeneca LP and the Office of the Attorney General of the State of Wisconsin (Medicaid Fraud Control Unit), effective date September 4, 2003, at 7-8 ¶ III.2 (Attached hereto as Exhibit A) (emphasis added).

The State's Medicaid-related claims relating to Zoladex® are thus barred by the valid and binding settlement agreement. See, e.g., *Fair v. Intn'l Flavors & Fragrances*, 905 F.2d 1114, 1116 (7th Cir. 1990) (finding that plain language of settlement agreement precluded plaintiff from bringing suit on claim arising from same facts); see also *Dietrich v. Trek Bicycle Corp.*, 297 F. Supp. 2d 1122, 1129 (W.D. Wis. 2003) (finding that parties' settlement agreement barred defendant from "revisiting" claim).

CONCLUSION

For the foregoing reasons, as well as those set forth in Defendants' Memorandum of Law in Support of their Joint Motion to Dismiss, the Amended Complaint should be dismissed as to AstraZeneca, with prejudice.

Dated: January 20, 2005

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EXHIBIT A

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement ("Agreement") is entered into this ____ day of _____, 2003. The parties to the Agreement are the state of Wisconsin and Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively and hereinafter referred to as "Zeneca"), which has its headquarters in Wilmington, Delaware, and is a successor to the pharmaceutical business of Zeneca, Inc., and are collectively referred to as the parties. The Parties now agree as follows:

II. PREAMBLE

A. WHEREAS, Zeneca is entering into a civil settlement with the United States of America, acting through and/or on behalf of its Department of Justice and the United States Attorney's Office for the District of Delaware, and the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); TRICARE Management Activity ("TMA") (formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense; the Defense Supply Center Philadelphia, of the Defense Logistics Agency, the United States Department of Defense ("DSCP"); the Railroad Retirement Board ("RRB") (the "Federal Settlement"), and relator in a certain federal False Claims Act lawsuit, as well as settlement agreements with the state of Wisconsin and numerous other states (hereinafter the "Participating States"), all of which are intended to resolve civil claims for the conduct alleged in Preamble Paragraph F below;

B. WHEREAS, this Agreement addresses the state of Wisconsin's claims against Zeneca for the conduct alleged in Preamble Paragraph F below;

C. WHEREAS, on such date as may be determined by the Court, Zeneca will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one count Information alleging a violation of Title 18, United States Code, Section 371, namely, a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 333(b) and 331(t) by causing the billing of free drug samples (hereinafter the "Criminal Action");

D. WHEREAS, at all relevant times, Zeneca marketed and sold the drug Zoladex in various dosages to physicians, health maintenance organizations, hospitals, wholesalers, and others for use in treatment of prostate cancer;

E. WHEREAS, the state of Wisconsin alleges that Zeneca caused to be submitted claims for payment for Zoladex to the state's Medical Assistance Program ("Medicaid") established pursuant to Title XIX of the Social Security Act;

F. WHEREAS, the state of Wisconsin contends that it has Medicaid-related civil claims against Zeneca under various statutes and the common law for engaging in the following alleged conduct from January 1991 through the present, involving the marketing, sale and pricing of Zoladex for treatment of prostate cancer;

(i) The state of Wisconsin contends that certain employees of Zeneca provided free samples of the drug Zoladex to certain physicians, knowing and expecting that those physicians would prescribe and administer the free drug samples to their patients and thereafter illegally bill those free samples to its Medicaid program;

(ii) The state of Wisconsin contends that Zeneca knowingly and willfully offered and paid illegal remuneration to certain physicians, physicians' practices, and others in various forms including, for example, free Zoladex, unrestricted educational grants, business assistance grants and

services, travel and entertainment, consulting and audit services, and honoraria, to obtain unlawfully orders to purchase the drug Zoladex for treatment of prostate cancer from Zeneca, knowing that reimbursement for the drug would be made by the state's Medicaid program;

(iii) The state of Wisconsin contends that Zeneca knowingly and willfully offered and paid illegal remuneration to physicians by marketing Zeneca's "Return-to-Practice" program to physicians to unlawfully induce orders to purchase the drug Zoladex for treatment of prostate cancer, knowing that reimbursement for the drug would be made by the state's Medicaid program. The state of Wisconsin further contends that Zeneca's Return-to-Practice program consisted of inflating the Average Wholesale Price ("AWP") used by Medicaid and others for reimbursement of the drug, deeply discounting the price paid by physicians to Zeneca for the drug ("the discounted price"), and marketing the spread between the AWP and the discounted price to physicians as additional profit to be returned to the physician's practice from Medicaid's reimbursements for Zoladex. The state of Wisconsin further contends that Zeneca falsely advised physicians that the discounted price could not and should not be reported to Medicaid;

(iv) The state of Wisconsin contends that Zeneca engaged in a marketing scheme where it set an AWP for Zoladex at levels far higher than the majority of its physician customers actually paid for the drug when purchasing from Zeneca. As a result, the state of Wisconsin contends that Zeneca's customers received reimbursement from the state of Wisconsin's Medicaid program at levels significantly higher than the physicians' actual costs or the wholesalers' average price;

(v) The state of Wisconsin contends that Zeneca knowingly misreported and underpaid its Medicaid rebates for Zoladex used for treatment of prostate cancer, i.e., the amounts

that it owed to the states under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. The state of Wisconsin further contends that Zeneca was generally required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price ("AMP") and its "Best Price," as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C). The state of Wisconsin alleges that Zeneca falsely reported to the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) its Best Price for Zoladex used for treatment of prostate cancer because Zeneca calculated its Best Prices for Zoladex without accounting for off invoice price concessions provided in various forms including, for example, cash discounts in the form of grants, services, free goods contingent on any purchase requirement, volume discounts and rebates. As a result, the state of Wisconsin contends that Zeneca misreported and underpaid its Medicaid rebates to the states under the Medicaid Rebate Program.

Zeneca's conduct alleged in Preamble Paragraph F is hereinafter referred to as the "Covered Conduct." The state of Wisconsin contends that its Medicaid program was damaged as a result of the Covered Conduct;

G. WHEREAS, the state of Wisconsin contends that it has administrative and civil claims against Zeneca for administrative and monetary penalties under state and federal law for the Covered Conduct;

H. WHEREAS, other than such admissions as Zeneca makes in connection with its plea in the Criminal Action, Zeneca denies the remaining allegations of the state of Wisconsin as set forth herein and in any civil action filed by the state of Wisconsin;

I. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Zeneca agrees to pay to the United States and the Participating States, collectively, the sum of two hundred ninety one million, twenty-seven thousand, eight hundred forty-four dollars (\$291,027,844), as set forth below ("Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States and the Participating States on the effective date of this Agreement. This debt is to be discharged by payments to the United States and the Participating States, under the following terms and conditions:

A. Zeneca shall pay to the United States the sum of two hundred seventy nine million, eight hundred twenty-two thousand, eight hundred forty dollars (\$279,822,844), plus simple interest at the rate of 6% in an amount of (\$45,998.28) for each day following the effective date of this Agreement before complete payment is made (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the civil settlement agreement entered between Zeneca and the United States (the "Federal Agreement").

B. Zeneca shall pay to the Participating State Medicaid programs the sum of eleven million, two hundred five thousand dollars (\$11,205,000), plus simple interest at the rate of 6% in an amount of (\$1,841.92) for each day following the effective date of the Federal Agreement

until complete payment is made (the "State Settlement Amount"). This State Settlement Amount shall be paid to an escrow account pursuant to the State Settlement Agreement no later than seven business days after Zeneca receives written payment instructions from the negotiating team for the Participating States and following the latest date on which the following occurs: (1) the Federal Agreement is fully executed by the Parties and delivered to Zeneca's attorneys, (2) the stipulated dismissals described in the Federal Agreement are filed and copies provided to Zeneca's attorneys, or (3) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph C and imposes the agreed-upon sentence. The escrow account into which Zeneca shall deposit the State Settlement Amount shall be an account under the custody and control of a Medicaid Fraud Control Unit, which shall be designated by the state negotiating team. This Medicaid Fraud Control Unit shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in subparagraph D below.

C. The total portion of the Settlement Amount paid by Zeneca in settlement for alleged injury to the Medicaid program for the state of Wisconsin is \$224,050.16, consisting of a portion paid to the state of Wisconsin under this agreement and another portion paid to the federal government as part of the Federal Settlement Agreement. The individual portion of the State Settlement Amount allocable to the state of Wisconsin, and which may be withdrawn by the state of Wisconsin from escrow pursuant to this Agreement is \$94,811.38 (the "Individual State Settlement Amount"), plus any accrued interest on that portion of the State Settlement Amount. The portion of the Federal Settlement Amount allocable to the state of Wisconsin is \$129,238.78.

D. The state of Wisconsin shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after the Escrow Agent has received fully

executed state settlement agreements from all of the participating states, or, in the alternative, when the state negotiating team and Zeneca agree that the Individual State Settlement Amounts shall be disbursed.

E. If Zeneca's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the state of Wisconsin or Zeneca. If either the state of Wisconsin or Zeneca exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten business days of the date on which the party receives actual notice of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Zeneca agrees that the period of time between January 10, 2003, and thirty days after rescission of this Agreement shall be excluded for the purpose of considering any time-related defenses, including but not limited to those defenses based in whole or in part on a statute of limitation or on a theory of laches.

2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3, the state of Wisconsin, on behalf of itself, and its officers, agents, agencies, and departments, releases and discharges Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns, and their current and former directors, officers and employees from any civil or administrative claims for Medicaid damages or penalties that the state of Wisconsin has or may have relating to the Covered Conduct as defined in Preamble Paragraph F. The payment

of the Settlement Amount fully discharges Zeneca from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the state of Wisconsin for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the state of Wisconsin specifically does not herein release any person or entity, including Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns, and their current and former directors, officers, and employees from any and all of the following: (a) any criminal, civil or administrative claims arising under state of Wisconsin revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any liability to the state of Wisconsin (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Zeneca; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Zeneca, its predecessors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, who, related to the Covered Conduct, receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement; or (j) any reporting of AWP for Zolodex to First Data Bank or any other national reporting service for use in Medicaid reimbursement submitted subsequent to the effective date of this Agreement.

4. In consideration of the obligations of Zeneca set forth in this Agreement and conditioned upon Zeneca's payment in full of the Settlement Amount, the state of Wisconsin agrees to release and refrain from instituting, directing, recommending or maintaining any administrative claim or any action seeking exclusion from the state of Wisconsin's Medicaid program against Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, their corporate parents and affiliates, predecessors, successors and assigns for the Covered Conduct or for Zeneca's conviction in the Criminal Action. Nothing in this Paragraph precludes the state of Wisconsin from taking action against Zeneca in the event that Zeneca is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. Zeneca acknowledges that the state of Wisconsin does not have the authority to release Zeneca from any claims or actions which may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to the state's Medicaid program.

5. This agreement is expressly conditioned upon resolution of the Criminal Action. In consideration of the Criminal Action, the Medicaid Fraud Control Unit of the state of Wisconsin agrees that it shall not prosecute or refer for investigation or prosecution to any agency Zeneca, its predecessors, successors, subsidiaries, partners, joint venture owners, and their corporate parents and affiliates, predecessors, successors and assigns for the Covered Conduct.

6. Zeneca fully and finally releases the state of Wisconsin, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Zeneca has asserted, could have asserted, or may assert in the future against the state of Wisconsin, its agencies, employees, servants, and agents, related to or

arising from the investigation and prosecution of Covered Conduct up to the effective date of this Agreement.

7. Zeneca waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Zeneca agrees that this Agreement is not punitive in purpose or effect.

8. The Settlement Amount that Zeneca must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the state of Wisconsin's Medicaid program where such denial resulted from the Covered Conduct. If applicable, Zeneca agrees not to resubmit to the state of Wisconsin's Medicaid program any previously denied claims, which denials were based on the Covered Conduct and agrees not to appeal any such denials of claims.

9. Zeneca agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf on Zeneca, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement and the related plea agreement; (2) the United States' and the state of Wisconsin's audit and civil and criminal investigation of the matters covered by this Agreement; (3) Zeneca's investigation, defense,

and any corrective actions undertaken in direct response to the United States' and the state of Wisconsin's audit and civil and criminal investigation in connection with the matters covered by this Agreement (including attorney's fees); (4) the negotiation and performance of this Agreement and the plea agreement; (5) the payment Zeneca makes to the United States and the Participating States pursuant to this Agreement and any payments that Zeneca may make to relators; (6) the negotiation of the Corporate Integrity Agreement (CIA), and the obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the HHS-OIG, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, Railroad Retirement, TRICARE, DOD, and Federal Employees Health Benefits Program (FEHBP). However, nothing in this paragraph affects the status of costs that are not allowable based on any other authority applicable to Zeneca. (All costs described or set forth in this Paragraph 9(a) are hereafter, "unallowable costs").

(b) Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by Zeneca, and Zeneca will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Zeneca or any of its subsidiaries to the Medicare, Medicaid, TRICARE, DOD, Railroad Retirement or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Zeneca further agrees that within 60 days of the effective date of this Agreement, it will identify to applicable Medicare, Railroad Retirement and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DOD, VA and FEHBP fiscal agents, any unallowable costs (as

defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Zeneca or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Zeneca agrees that the United States and the state of Wisconsin, at a minimum, will be entitled to recoup from Zeneca any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States or the state of Wisconsin pursuant to the direction of the Department of Justice, and/or the affected agencies. The state of Wisconsin reserves its rights to disagree with any calculations submitted by Zeneca or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Zeneca or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States or the state of Wisconsin to examine or reexamine the unallowable costs described in this Paragraph.

10. If applicable, Zeneca agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Zeneca waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

11. Zeneca expressly warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. Section 547(b)(3), and will remain solvent

following its payment to the state of Wisconsin hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (i) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Zeneca, within the meaning of 11 U.S.C. Section 547(c)(1), and (2) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

12. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Zoladex from Zeneca.

13. Nothing in any provision of this Agreement constitutes an agreement by the state of Wisconsin concerning the characterization of the Settlement Amount for purposes of state internal revenue codes or the United States Internal Revenue Code.

14. In addition to all other payments and responsibilities under this agreement, Zeneca agrees to pay all reasonable travel costs and expenses (including distribution costs) of the state negotiating team. Zeneca will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after all Participating States execute this Agreement, or as otherwise agreed upon by the state negotiating team and Zeneca.

15. Zeneca agrees to cooperate completely and truthfully with the state of Wisconsin's on-going investigation of third parties for alleged violations of state and federal law arising out of its investigation. Zeneca understands and agrees that such cooperation shall include the following:

(a) prompt production of any non-privileged document or record in the possession, custody or control of Zeneca relating to the subject matter of the investigation. In

connection with this, Zeneca shall provide such technical assistance as is necessary and reasonable to facilitate the state of Wisconsin's access to any non-privileged computerized information covered by this subparagraph:

(b) taking all reasonable measures available to Zeneca to ensure that present and former officers, directors, agents and employees of Zeneca cooperate truthfully and completely in connection with the on-going investigation; and

(c) taking all reasonable measures available to Zeneca to make all present and former employees of Zeneca available for interviews by law enforcement personnel, upon reasonable notice.

Provided, however, notwithstanding any provision of this Agreement, that Zeneca is not required to request of its present or former employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice, and that Zeneca is not and will not be required to waive the attorney-client privilege, the protection of the work product doctrine, or any other privilege or protection from disclosure.

16. Zeneca represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

17. Zeneca has entered into a CIA with HHS-OIG. Zeneca acknowledges that the state of Wisconsin may gain access to and use pricing information provided by Zeneca under the CIA, provided that the state of Wisconsin meets its obligations relating to the use and confidentiality of that information as set forth in this Agreement. Zeneca acknowledges that the CIA does not preclude the state from taking any appropriate action against Zeneca for future conduct under the state of Wisconsin's laws. The state of Wisconsin hereby agrees to abide by all confidentiality provisions

and restrictions contained in the CIA as allowed by state law and afford all such information the maximum degree of confidentiality permitted by law.

18. Zeneca shall report directly to the Medicaid Program for the state of Wisconsin the average sale price, as defined below, for the following currently marketed drugs: Cefotan, Elavil Injection¹, Faslodex, Foscavir, Merrem, Tenormin Injection, Xylocaine Injection, Zolodex, and all other newly developed injectible products which are primarily marketed and sold by Zeneca to individual medical practitioners/clinics for in-office administration and directly billed by the practitioner/clinic to health care insurers, including federal health care programs (hereinafter "Covered Products").

(a) Average Sale Price Definition: For purposes of this Agreement, "Average Sale Price" means, with respect to each dosage form, strength and volume of the Covered Products (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by Zeneca for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding identifiable direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the "Relevant Purchasers.") The prices identified in the calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; charge backs; short-dated product discounts; free goods; rebates²; and all other price concessions provided by Zeneca to any Relevant Purchaser that result in a reduction of

¹ As of February 2003, AstraZeneca no longer makes or sells Elavil injection. Consequently, AstraZeneca may be limited or unable to report average sale price for this product in the future.

the ultimate cost to the purchaser. Notwithstanding the foregoing, the Average Sale Price shall not include the value of bona fide charity care or bona fide grants.

Zeneca shall report the Average Sale Price by National Drug Code ("NDC") for each Covered Products identified by Zeneca's NDC. The Average Sale Price reported shall be properly weighted to reflect the volume of sales at each sale price, *i.e.*, for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by Zeneca to a Relevant Purchaser, net of all price reductions identified above, for a Covered Products in a quarter by the total number of units of that product sold in that quarter.

(b) Time Frame: Except as otherwise noted below, forty five (45) days after the last day of each calendar quarter, Zeneca shall report, in accordance with section 18(a) above, the average sale prices of each of its Covered Products identified by Zeneca's NDC to: (1) the Medicaid programs of those States who have executed a State Settlement Agreement with Zeneca; and (2) First DataBank Inc.³ solely for the purpose of reporting pricing information based on those Average Sale Prices to the Medicaid Programs of those States that have executed a state settlement agreement. The first such report of Average Sale Prices shall be made no later than 45 days after the end of the first full calendar quarter following the Effective Date of the CIA. The Average Sale Price reporting obligations under this agreement may be subject to modification consistent with a change in federal

² The term "rebate" as used in this paragraph does not include any payments made by Zeneca to the States pursuant to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).

³ If appropriate to reflect changes in the sources from which the Medicaid programs for the Participating States receive pricing information, Zeneca agrees that, upon the receipt of a written request by any of the Participating States, Zeneca will report the required information to a drug pricing reporting source other than, and in addition to, FirstDataBank, provided that the price reporting source agrees to protect the confidentiality of Zeneca's pricing information in a written agreement containing reasonable provisions equivalent to the confidentiality provisions governing the submission of pricing information to First DataBank.

or state statutory or regulatory requirements for the submission of price information by pharmaceutical manufacturers.

(c) **Certification:** With each report of Average Sales Price information Zeneca sends to the Medicaid Program for the state of Wisconsin, an appropriate employee or agent of Zeneca will certify that price information reported has been reported to First DataBank, or any successor or alternative reporting agency, and that the information has been calculated in accordance with the methodology described in this Agreement. Said certification shall be in the form annexed to this Agreement as Exhibit "A." Zeneca agrees that this certification by an appropriate employee or agent of Zeneca constitutes a certification by Zeneca.

(d) **Document Retention:** Zeneca shall retain all supporting work papers and documentation relating to the average sale price of its Covered Products for six years after the effective date of the CIA, and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the MFCU for the state of Wisconsin, or a duly authorized representative of the MFCU, pursuant to the confidentiality provisions set forth in paragraph 20 below.

(e) **Time Period:** Zeneca agrees to submit Average Sale Price in accordance with this Agreement for a period of five years from the effective date of the CIA.

19. (a) Zeneca and the state of Wisconsin acknowledge that Zeneca considers the pricing information provided by Zeneca to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of Zeneca. It is further understood that all information provided by Zeneca shall be made available to the state of

Wisconsin's MFCU upon request. The state of Wisconsin hereby agrees to afford to the pricing information disclosed by Zeneca the maximum degree of confidentiality permitted by law.

(b) The Medicaid Program of the state of Wisconsin has been advised by the MFCU of the purpose and use of this information. Without surrendering any legal right to contest the use of this information, Zeneca acknowledges that this information may be relied upon by the state of Wisconsin in establishing reimbursement rates for Zeneca's products, provided however the state of Wisconsin will not change reimbursement rates for any Zeneca product based on this information without conducting meaningful review for all government-reimbursed therapeutically similar products.

20. Unless otherwise stated in writing subsequent to the execution of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

STATE PHARMACY MANAGER
[For the submission of Average Sale Price Data]:

Division of Health Care Financing
P.O. Box 309
Madison, WI 53701-0309

STATE MEDICAID FRAUD CONTROL UNIT
[For legal notices and other purposes]:

MFCU of Wisconsin
Office of the Attorney General
P.O. Box 7857
Madison, WI 53707-7857

ZENECA

Glenn Engelmann

Vice President, General Counsel
And Secretary
Zeneca, Inc.

21. This Agreement is governed by the laws of the state of Wisconsin. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the appropriate court having jurisdiction and venue in the state of Wisconsin.

22. The undersigned Zeneca signatory represents and warrants that he is authorized by the Board of Directors of AstraZeneca PLC, the parent corporation of AstraZeneca Pharmaceuticals, LP, to execute this Agreement. The undersigned state of Wisconsin signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the state of Wisconsin through their respective agencies and departments.

23. This Agreement is effective on the date of signature of the last signatory to the Agreement.

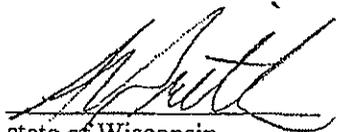
24. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

25. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

26. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

THE STATE OF WISCONSIN

DATED: 6/24/03

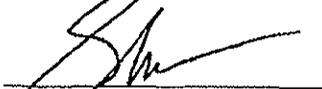


state of Wisconsin
Office of the Attorney General
Medicaid Fraud Control Unit

BY: Amy R. Smith

Title: Director and Assistant Attorney General

DATED: 6-24-2003

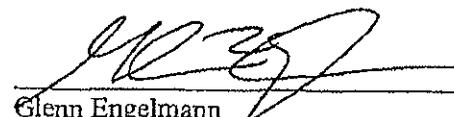


state of Wisconsin
Medicaid Program

BY: Alan S. White

Title: Director, Program Integrity

ASTRAZENECA PHARMACEUTICALS LP

By: 

Glenn Engelmann
Vice President, General Counsel
And Compliance Officer
AstraZeneca Pharmaceuticals LP

Dated: 9/04/03

By: 

JOHN C. DODDS
Morris, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
Counsel to AstraZeneca Pharmaceuticals, LP

Dated: 8/18/03

ZENECA, INC.

By: _____

Dated: _____

Glenn Engelmann
Vice President, General Counsel
And Secretary
Zeneca, Inc.

By: _____

Dated: _____

John C. Dodds
Morgan, Lewis & Bockius, LLP
1701 Market Street
Philadelphia, PA 19103-2921
Counsel to Zeneca, Inc.

EXHIBIT 'A' CERTIFICATION FORM

CERTIFICATION

The undersigned, an agent of AstraZeneca Pharmaceuticals LP, hereby certifies that the attached average sale price information has been communicated to First Databank or any successor or alternative reporting agency, and that it has been calculated in accordance with the methodology described in the State Settlement Agreement and as further described in AstraZeneca Pharmaceuticals LP's Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services.

Signed _____

Title _____

Date _____

Baxter International

ARGUMENT

Wisconsin courts can only exercise personal jurisdiction over Baxter International, a non-resident defendant, under the State's long-arm statute. Wis. Stat. § 801.05. The burden is on the plaintiff to establish jurisdiction under that statute. *Lincoln v. Seawright*, 104 Wis. 2d 4, 9, 310 N.W.2d 596, 599 (1981). Wisconsin's long-arm statute provides, in relevant part:

801.05 Personal jurisdiction, grounds for generally. A court of this state having jurisdiction of the subject matter has jurisdiction over a person served in an action pursuant to s. 801.11 under any of the following circumstances:

(1) Local Presence or Status. In any action whether arising within or without this state, against a defendant who when the action is commenced:

...

(d) Is engaged in substantial and not isolated activities within this state, whether such activities are wholly interstate, intrastate, or otherwise.

(4) Local Injury: Foreign Act. In any action claiming injury to person or property within this state arising out of an act or omission outside this state by the defendant, provided in addition that at the time of the injury, either:

(a) Solicitation or service activities were carried on within this state by or on behalf of the defendant; or

(b) Products, materials or things processed, serviced or manufactured by the defendant were used or consumed within this state in the ordinary course of trade.

Wis. Stat. § 801.05.

Here, the plaintiff cannot satisfy the requirements of Wisconsin's long-arm statute to establish personal jurisdiction over Baxter International.

A. Baxter International Is Not Engaged In Substantial Activities Within Wisconsin

Plaintiff cannot meet the requirements of Wis. Stat. § 801.05(1)(d) because Baxter International is not “engaged in substantial ... activities within” Wisconsin. Among other things, Baxter International is neither authorized nor licensed to do business in Wisconsin and has never maintained any offices in Wisconsin, rented or owned any real or personal property in Wisconsin, maintained any bank accounts in Wisconsin, or paid taxes in Wisconsin. Exhibit A, (“Persky Aff.” ¶¶ 5-14). See *Bushelman v. Bushelman*, 246 Wis. 2d 317, 338, 629 N.W.2d 795, 807 (Ct. App. 2001) (sending money and letters into Wisconsin insufficient to satisfy the “engaged in substantial” activities requirement of Section 801.05(1)(d)).

B. Baxter International Has Never Engaged In Any Service or Solicitation Within Wisconsin And Has Never Manufactured Or Sold Any Products That Were Used Or Consumed Within Wisconsin In The Ordinary Course Of Trade

Even assuming, *arguendo*, an “injury to person or property” occurred in Wisconsin, Plaintiff still fails to meet the requirements of § 801.05(4) because Baxter International has never engaged in any service or solicitation in Wisconsin (Persky Aff., ¶ 7) and has never manufactured, promoted, marketed, advertised, developed, designed, packaged, labeled, sold, distributed, or placed into the stream of commerce any products in Wisconsin. (Persky Aff., ¶ 4). See *Lincoln v. Seawright*, 104 Wis. 2d 4, 12, 310 N.W.2d 596, 600 (1981) (personal jurisdiction lacking where defendant neither solicited nor manufactured goods consumed in Wisconsin).

CONCLUSION

Because this Court has no personal jurisdiction over Baxter International, as well as for those reasons stated in Defendants’ Joint Motion to Dismiss the Amended Complaint and those individual Defendants’ memoranda that apply to Baxter International, this Court should dismiss Wisconsin’s Amended Complaint in its entirety as to Baxter International.

Respectfully submitted,

<p></p> <p>Merle M. DeLancey, Jr. (<i>Pro hac vice motion pending</i>) Tina D. Reynolds (<i>Admitted pro hac vice</i>) Tim A. O'Brien (<i>Admitted pro hac vice</i>) DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 2101 L St. NW Washington, DC 20037 Telephone: (202) 785-9700 Facsimile: (202) 887-0689</p>	<p></p> <p>Bruce Schultz (SBN # 1016100) COYNE, SCHULTZ, BECKER & BAUER, S.C. 150 E. Gilman Street Madison, WI 53703 Telephone: (608) 255-1388 Facsimile: (608) 255-8592</p>
---	--

Counsel for Defendant
BAXTER INTERNATIONAL INC.

5. Baxter International Inc. is not authorized or licensed to do business in Wisconsin.
6. Baxter International Inc. does not do any business in Wisconsin.
7. Baxter International Inc. does not engage in any service or solicitation in Wisconsin with respect to any product.
8. Baxter International Inc. does not maintain any offices in Wisconsin.
9. Baxter International Inc. does not rent or own any real or personal property in Wisconsin.
10. Baxter International Inc. does not have any employees in Wisconsin.
11. Baxter International Inc. does not have any bank accounts in Wisconsin.
12. Baxter International Inc. does not have any telephone listing in Wisconsin.
13. Baxter International Inc. does not have a registered agent in Wisconsin.
14. Baxter International Inc. does not pay taxes in Wisconsin.
15. Baxter International Inc. maintains no distributors, wholesalers, or other representatives in Wisconsin.
16. Baxter International Inc. does not purposefully avail itself of the privilege of conducting activities in Wisconsin.
17. To the best of my knowledge the facts set forth herein are true and correct.

Executed this 13TH day of January, 2005.

Marla S. Persky

Subscribed and sworn to before me this 13TH day of January, 2005


Notary Public

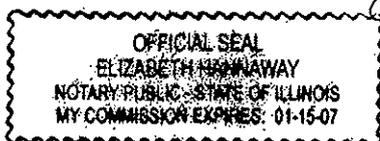


Exhibit A

II. LAW AND ARGUMENT

A. Plaintiff's Claims Must Be Dismissed Because Plaintiff Has Failed to Adequately Plead Fraud.

1. Fraud Must be Pleaded with Particularity.

For most claims, the Wisconsin Rules of Civil Procedure require only a “short and plain statement of the claim” supported by “simple, concise, and direct” averments. WIS. STAT. §§ 802.02(1)(a) & (5)(b). Fraud claims, however, are different and must be pled with particularity. See WIS. STAT. § 802.03(2).

The Wisconsin courts have explained the policy behind WIS. STAT. § 802.03(2)'s particularity pleading requirements: “our statute is ‘designed to protect defendants whose reputation could be harmed by lightly made charges of wrongdoing involving moral turpitude, to minimize ‘strike suites,’ and to discourage the filing of suits in the hope of turning up relevant information during discovery.’” Friends of Kenwood v. Green, 239 Wis.2d 78, 87 (Ct.App.2000) (citation omitted). Consistent with both the prose and policy of WIS. STAT. § 802.03(2), Wisconsin courts have dismissed fraud and misrepresentation claims for insufficiently particular allegations. See, e.g., Friends of Kenwood, 239 Wis.2d at 91; Rendler, 154 Wis.2d at 428-429.

In short, fraud claims are special matters. The Wisconsin Civil Rules and the Wisconsin Courts require that they be pleaded with particularity or be dismissed.

2. Plaintiff Has Failed to Plead Fraud With Sufficient Particularity.

This action was filed by the State of Wisconsin, through its Attorney General, “on its own behalf and acting in its parens patriae capacity on behalf of its citizens and

Wisconsin organizations who pay the prescription drug costs of their members.” Amend. Compl. ¶ 2. Plaintiff alleges that Defendants—including Defendants Ben Venue, BIC, BIPI, and Roxane¹— have “taken advantage of the enormously complicated and non-transparent market for prescription drugs” by publishing “phony ‘average wholesale prices,’” (Amend. Compl. ¶ 1) and using “secret discounts and rebates to providers and the use of various devices to keep secret the prices of their drugs currently available in the market place.” Amend. Compl. ¶ 1. Plaintiff claims that “Defendants have illegally misrepresented the true AWP for virtually all of their drugs.” Amend. Compl. ¶ 37. Additionally, Plaintiff claims that Defendants have “similarly illegally and deceptively misrepresented and inflated wholesale acquisition cost (“WAC”) of their drugs making it appear that any reduction in the purchase price beyond the listed WAC would result in a loss to the wholesaler . . . when in fact the WAC was secretly discounted to purchasers . . . through an elaborate chargeback system.” Amend. Compl. ¶ 44.

Each of Plaintiff’s five separate counts² incorporates and is based upon these basic allegations. WIS. STAT. § 802.03(2) applies to all ‘averments’ of fraud and requires that the circumstances constituting the alleged fraud be stated with particularity. Because all of Plaintiff’s claims incorporate by reference and are based on the same general allegations of “fraudulent” inflation of average wholesale price (“AWP”) and wholesale acquisition cost (“WAC”), Plaintiff’s failure to satisfy the requirements of WIS. STAT. § 802.03(2) dooms all of its claims.

¹ Plaintiff lumps these disparate entities into something it designates as the “Boehringer Group” (Amend. Compl. ¶ 11), a designation the Defendants expressly reject.

² Plaintiff claims that each of the twenty defendants have violated the Wisconsin Deceptive Trade Practices Act (Counts I and II), the Wisconsin Trust and Monopolies Act (Count III), the Wisconsin Medical Assistance statute (Count IV), and have been “unjustly enriched” (Count V).

The Wisconsin courts have interpreted particularity to mean “who, what, when, where, and how.” Friends of Kenwood, 239 Wis.2d at 95; see also Rendler, 154 Wis.2d at 428. Plaintiff peppers the Amended Complaint with terms like “illegal” and “unlawful” but omits much that is required by WIS. STAT. § 802.03(2). For example:

1. Plaintiff ignores corporate distinctions by insisting on referring to each of the separate entities – Ben Venue, BIC, BIPI, and Roxane -- as belonging to a “Boehringer Group.”
2. Plaintiff repeatedly attributes conduct to every Defendant – Ben Venue, BIC, BIPI, and Roxane (in addition to those other companies named in the caption) – without particularizing a specific act to a particular Defendant.
3. Plaintiff repeatedly fails to identify with particularity the specific times at which a Defendant was alleged to have made a false representation.
4. Plaintiff fails to identify with particularity each Defendants’ role in the alleged fraud.

Similar failures have been fatal in the context of conclusory fraud or misrepresentation claims against multiple defendants over time. See Friends of Kenwood 239 Wis.2d at 89-90 (explaining that “[i]t is insufficient to lump the defendants together” and agreeing that “[t]he complaint must inform each defendant of the nature of his alleged participation in the fraud and specify who was involved in what activity”)

Similarly, in the case at bar, when the conclusory allegations of Plaintiff’s Amended Complaint are compared to the legal requirements of WIS. STAT. § 802.03(2), it is evident that Plaintiff has failed to plead fraud with sufficient particularity: For example, without specifying any defendants or identifying any specific instances of such conduct, plaintiff alleges that “Defendants have illegally misrepresented the true AWP

for virtually all of their drugs.” Amend. Compl. ¶ 37 (emphasis added). Plaintiff’s fraud claims are legally deficient.

Moreover, Plaintiff’s conclusory allegations of fraud invite the harm which WIS. STAT. § 802.03(2) was designed to prevent. The fraud claims impugn the reputation of Defendants with only conclusory and dubious allegations of moral turpitude. If the particularity requirement is not enforced, hardly any business dispute would be immune from such a fraud claim. Further, Plaintiff’s conclusory allegations do not provide Defendants with notice necessary to determine the conduct of which each one is accused, the time or place of the alleged conduct, its role in the alleged fraud, or even the nature of the allegedly fraudulent conduct. The claims in Plaintiff’s Amended Complaint, all of which are based upon allegations of fraud, are inconsistent with both the requirements of, and the reasons for, WIS. STAT. § 802.03(2). This deficiency warrants dismissal of the Complaint.

B. Plaintiff’s Complaint Against BIC Must Be Dismissed For Failure To State a Claim Upon Which Relief Can Be Granted

A motion to dismiss for failure to state a claim tests whether the complaint is legally sufficient to state a cause of action for which relief may be granted. Watts v. Watts, 137 Wis. 2d 506, 512, 405 N.W. 2d 303 (1987). A complaint is to be dismissed as legally insufficient when it appears certain that a plaintiff cannot recover under any circumstances. Id.

Counts I to V of Plaintiff’s Complaint allege that BIC made fraudulent representations and engaged in unfair trade practices related to the production, sale, marketing, pricing, or distribution of pharmaceutical products. (Amend. Compl. ¶¶ 77, 81, 85, 91, 95). However, Plaintiff cannot establish any legal basis for these claims

because BIC does not manufacture, distribute, or sell any drugs, nor has it ever done so. (Tetzner Aff. ¶ 3) (attached as BIC Exhibit A). Moreover, neither BIC nor any of its employees reports the AWP or WAC of drugs to the public for publication in medical compendia. (Tetzner Aff. ¶ 4). Because BIC does not engage in the activities that form the basis of Plaintiff's Complaint, recovery would be a legal impossibility. Plaintiff's Complaint should thus be dismissed.

III. CONCLUSION

As set forth in the foregoing discussion, the claims in Plaintiff's Amended Complaint, all of which are based upon allegations of fraud, have not been pled with sufficient particularity and are thus inconsistent with both the requirements of, and the reasons for, WIS. STAT. § 802.03(2). Furthermore, Plaintiff has failed to state a claim against upon which relief can be granted. Accordingly, for the foregoing reasons, and those in Defendants' Joint Motion to Dismiss the Amended Complaint incorporated herein by reference, Defendants respectfully request that this Court dismiss them from the instant action.

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Dey, Inc.

business in Napa, California. (Complaint ¶ 13.) Plaintiff's other mention of Dey – two sentences which refer to a lawsuit Dey initiated against a publisher of average wholesale prices – is completely irrelevant to the issues in this action. *See, infra*, Point III. Nor does the reference to a single Dey drug in an exhibit to the Complaint allege facts sufficient to support a claim against Dey. *See, infra*, Point II. These fleeting mentions of Dey contain absolutely no substantive allegations against Dey to support Plaintiff's claims.

As set forth in greater detail in Section I of the Joint Memorandum, Wis. Stat. 802.03(2) requires Plaintiff to plead facts specifically relating to Dey, which, if proven, are sufficient to recover on that claim against Dey, and which provide Dey with enough information to prepare a defense. Plaintiff's Complaint, which merely makes passing reference to Dey in a few sentences over the course of nearly 100 paragraphs, does not meet this standard. Instead, Plaintiff resorts to exactly the type of vague and conclusory group pleading held to be inadequate under Wisconsin law. Plaintiff's claims against Dey should, therefore, be dismissed.

II. **ALL CLAIMS RELATING TO DRUGS REIMBURSED BASED UPON DOJ RECOMMENDED PRICES OR MAC PRICES FAIL AS A MATTER OF LAW**

As discussed in more detail in the Joint Memorandum, Plaintiff reimburses a vast number of drugs without any reference to the published average wholesale prices ("AWP") which purportedly underlie Plaintiff's claims. For these drugs, Plaintiff utilizes certain prices supplied by the United States Department of Justice ("DOJ") or Plaintiff's own maximum allowable cost ("MAC") prices. (*See* Joint Memorandum, Section II(C).) Defendants, including Dey, have no part in the creation or dissemination of either of these non-AWP reference prices.

As Plaintiff's own Complaint demonstrates, several drugs manufactured by Dey are subject to reimbursement by Plaintiff based on the DOJ prices or Plaintiff's MAC prices. For

example, the DOJ price list annexed to Plaintiff's complaint supplies prices for various formulations of Dey's generic drugs acetylcysteine, albuterol sulfate, cromolyn sodium, and metaproterenol sulfate. *See* Complaint, Ex. A, at 4, 5-6, and 10. Indeed, the DOJ price list references Dey by name. *Id.* Plaintiff has established MAC prices for these drugs as well as for ipratropium bromide, another of Dey's generic drugs. *See* Wisconsin Medicaid Legend Drug MAC List, at 1-2, 9, 18, and 21 (available at http://dhfs.wisconsin.gov/medicaid4/pharmacy/data_tables/index.htm). A copy of the MAC list is included in Defendants' Joint Appendix. *See* Joint Memorandum, Section II(C).

As to these drugs, Plaintiff's claims fail as a matter of law since Plaintiff does not rely on the published, allegedly fraudulent AWP for these drugs. Indeed, no alleged conduct, representation, or omission by Dey could have any effect of the reimbursement for these drugs since Dey has no role – and Plaintiff does not allege that Dey has a role – in the creation of the DOJ and MAC prices.

The futility of Plaintiff's claims as they concern those drugs reimbursed based upon a DOJ or MAC price is illustrated by Plaintiff's own Complaint. In an attempt to give its allegations a veneer of substance, Plaintiff annexes to the Complaint an exhibit purportedly containing "Examples of Spreads from Defendants". *See* Complaint, Ex. B. This exhibit sets forth a handful of drugs and purports to show a "spread" between the published AWP (called "2000 AWP" in Plaintiff's exhibit) and something Plaintiff refers to as the "2000 Available Price".

In the case of Dey, the only drug Plaintiff points to is metaproterenol sulfate. As noted above, this is a drug for which the DOJ supplies a price and for which Plaintiff has also

assigned a MAC price. Although one would not know it from Plaintiff's exhibit, the "2000 Available Price" noted for Dey's metaproterenol sulfate is \$11.29, precisely the same as the DOJ price for this drug. *See* Complaint, Ex. A, at 10. Two conclusions follow from this example. First, since Plaintiff reimburses for metaproterenol sulfate based upon the DOJ or MAC prices, and not the published AWP for Dey's metaproterenol sulfate, there is *no spread* for this drug. Moreover, since the DOJ and MAC prices are not based on published AWPs, Plaintiff cannot establish a causal link between alleged misconduct by Dey and any injury allegedly suffered by Plaintiff or its residents.

III. **DEY'S ACTION AGAINST FIRST DATABANK IS IRRELEVANT TO THIS ACTION**

Plaintiff attempts to bolster the vague and conclusory allegations in the Complaint by making a passing reference to a lawsuit Dey initiated against a publisher of AWP data named First DataBank (the "FDB Action"). Plaintiff alleges that Dey initiated the FDB Action because First DataBank "published the *actual* average wholesale price of Dey's drugs" (Complaint ¶ 40.) The FDB Action is irrelevant to the issues here. Dey did not initiate the FDB Action because First DataBank reported "actual average wholesale prices". Rather, the FDB Action was initiated because First DataBank began publishing AWP numbers for Dey's drugs which First DataBank made up by applying a methodology it had not used before and which was completely different from that used to arrive at the AWPs of Dey's competitors. Nothing in the FDB Action supports the assertion that Dey (or any other defendant) engages in AWP manipulation or any other fraudulent scheme involving AWP data.

CONCLUSION

For the foregoing reasons, Plaintiff's Complaint should be dismissed in its entirety
as against Dey with prejudice.

Dated: January 20, 2005

Respectfully submitted,

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STATE OF WISCONSIN

CIRCUIT COURT
Branch 7

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN, INC., ET AL.,

Defendants

Case No. 04 CV 1709

Unclassified-Civil: 30703

**THE JOHNSON & JOHNSON DEFENDANTS'
SEPARATE MEMORANDUM IN SUPPORT OF THE
MOTION TO DISMISS THE AMENDED COMPLAINT**

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Introduction

The State appears to have sued Johnson & Johnson and four of its operating subsidiaries (the “J&J Defendants”) for no reason other than the fact that they sell pharmaceuticals. Indeed, except for the jurisdictional allegations in paragraph 15, the only place the J&J Defendants are even mentioned in the Amended Complaint is in Exhibit B. That exhibit lists three NDC Codes for three Johnson & Johnson company products—Nizoral® (ketoconazole), Procrit® (epoetin alfa) and Polycitra® (potassium citrate & citric acid)—that the State says were “available” to the Wisconsin Department of Corrections at prices that were 20% to 25% below AWP. These references aside, the State fails to make any particularized allegations relating to the J&J Defendants. Instead, the J&J Defendants are simply swept into an undifferentiated mass of companies, all of whom are alleged to have participated in an “unlawful scheme” to “inflate” drug prices and “defraud” the State and its citizens.

As noted in the defendants’ main brief, the State’s claims rest on the demonstrably false premise that payers were duped into believing that “AWP” was an average of the prices at which pharmacies acquire drugs from wholesalers. The State does not allege that the J&J Defendants or any other manufacturer ever said that that is what AWP means, and numerous government reports over the years have made it abundantly clear that pharmacies routinely purchase drugs for less than AWP. Indeed, the State itself, through its Medicaid program, reimburses pharmacies at less than AWP. Given this practice, it is inconceivable that the State ever believed that AWP was an average of pharmacy acquisition prices. Indeed, the State admits that if reimbursement is set at a level that is “below that which providers actually pay for drugs,” providers will “simply stop” supplying drugs under the State’s Medicaid program. (Am. Cmpl’t., ¶ 55). Because the State’s claims are at odds with its own reimbursement practices, they are disingenuous on their face.

The State will undoubtedly respond by claiming that the Court is required to accept the allegations in the Amended Complaint as true, no matter how implausible and absurd the allegations may be. Perhaps so. But this Court is not required, or even permitted, to accept the complete lack of particularity in the State's pleading. A complaint that sounds in fraud must specify "details" sufficient to show the "who, what, when, where, and how" of each alleged misrepresentation. It is not enough merely to allege that diverse "defendants" have engaged in unspecified AWP-related misrepresentations, with respect to an unstated number of products, over an indeterminate course of years.

Argument

Wis. Stat. § 802.03(2) requires that all pleadings sounding in fraud must be pled with particularity. *See Friends of Kenwood v. Green*, 239 Wis.2d 78, 87, 619 N.W.2d 271, 276 (Ct. App. 2000), quoting *New England Data Services, Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987). In cases against multiple defendants, involving multiple misrepresentations, the role of each defendant in the alleged scheme must be specifically alleged. *Friends of Kenwood*, 239 Wis.2d at 89, 619 N.W.2d at 277, citing *Vicom, Inc. v. Harbridge Merchant SerSrvs., Inc.*, 20 F.3d 771, 777–778 (7th Cir. 1994); *K-S Pharmacies, Inc. v. Abbott Labs.*, 1995 WL 1922010 (Wis. Cir. 1995) (complaint against 27 manufacturers dismissed because it was "devoid of specifics" concerning the alleged wrongful conduct of each defendant). A plaintiff may not allege that a particular defendant engaged in wrongdoing simply because other defendants may have done so. *See, e.g., Albright v. The Upjohn Co.*, 788 F.2d 1217 (6th Cir. 1986) (counsel sanctioned for suing nine tetracycline manufacturers without a factual basis to allege that plaintiff received tetracycline from all nine companies); *Kinee v. Abraham Lincoln Fed. Sav. & Loan Assoc.*, 365 F. Supp. 975 (E.D. Pa. 1973) (counsel sanctioned for suing 177 mortgage

lending institutions without a factual basis to allege that all of them engaged in the challenged lending practice).

The Amended Complaint fails to plead fraud with particularity against the J&J Defendants. As mentioned above, except for jurisdictional allegations, the body of the complaint never even mentions the J&J Defendants, or any of their products. In addition, no J&J Defendant or product is listed in Exhibit A, which the State says is a “list of drugs ... that the U.S. Department of Justice, after an extensive investigation, found to have inflated AWP.” (Am. Cmplt, ¶ 41). To the contrary, the *only* substantive reference in the Amended Complaint to any J&J Defendant or product is in Exhibit B, which identifies three NDC codes for three products, sold by three of the five J&J Defendants that the State is attempting to sue. That exhibit merely sets forth a list of drug prices that were “available” in 2000 to Wisconsin’s Department of Corrections for a price that was less than AWP.¹ These cryptic references are inadequate to sustain a claim under Wis. Stat. § 802.03(2).

To begin, it may be noted that Exhibit B does not list any product that is sold by two of the five J&J Defendants that the State is attempting to sue. In particular, Exhibit B does not identify any product sold by Johnson & Johnson itself, or any product sold by its subsidiary, McNeil-PPC, Inc. (In the case of Johnson & Johnson, this omission undoubtedly stems from the fact that Johnson & Johnson is a holding company that does not sell drugs.) Because the Amended Complaint fails to allege any misconduct with respect to products sold by Johnson & Johnson or by McNeil-PPC, Inc., these two companies must be dismissed.

Exhibit B does reference three NDC Codes for three products sold by three different J&J Defendants, including:

¹ The State’s reliance on prices available to the Wisconsin Department of Corrections was disclosed in the version of Exhibit B that was attached to its initial Complaint. (See Attachment C to the Complaint dated 6/03/04). The State appears to have deleted this reference in the revised exhibit.

1. **Nizoral®** (ketoconazole), NDC Code 50458-0220-10, a dandruff shampoo which, according to Wisconsin, is sold by Janssen Pharmaceutica Products, L.P.;
2. **Procrit®** (epoetin alfa), NDC Code 59676-0302-01, an anemia treatment sold by Ortho Biotech Products, L.P.; and
3. **Polycitra®** (potassium citrate & citric acid), NDC Code 17314-9322-01, a potassium supplement sold by Ortho-McNeil Pharmaceutical, Inc.

Even as to these three products, however, the State only alleges that they were “available” for purchase in 2000 at prices below AWP. In the case of Nizoral®, Wisconsin’s Department of Corrections was apparently able to purchase the product for 20% less than AWP (the AWP being 25% more than the “Available Price”). Similarly, the Department of Corrections was able to purchase Polycitra® for 25% less than AWP (the AWP being 33% more than the “Available Price”), and it was able to purchase Procrit® for about 25% less than AWP (the AWP being about 34% more than the “Available Price”).²

The foregoing allegations are insufficient under Wis. Stat. § 802.03(2). Just because a product’s AWP differs from its “Available Price” does not mean that there has been fraud. There is no particularized allegation suggesting that the J&J Defendants ever “concealed” or lied about the fact that these medicines could be purchased for less than AWP. Indeed, the State knew that they were available at a discount below AWP, because its own Department of Corrections appears to have acquired them for less than AWP.

Had the State attempted to plead specific facts concerning the J&J Defendants it would have been apparent that the conduct of the J&J Defendants cannot be squared with the State’s allegations. For example, the State alleges that it has continued to gather evidence

² The State reports the higher percentages in Exhibit B, because it calculates the percentage difference between AWP and Available Price by dividing the so-called “\$ Spread” by the “Available Price,” rather than by the “AWP.” This manner of expressing the percentage difference between the AWP and the Available Price is misleading because Wisconsin’s Medicaid program reimburses for medications at a percentage discount off AWP, not at a percentage premium over the Available Price.

relating to its claims, including evidence from Ven-A-Care, a company that the State describes as “the original qui tam whistleblower.” (Am. Cmpl’t., ¶ 43). According to the Amended Complaint, this evidence “uniformly supports” the State’s claims. (*Id.*).

At least as to the J&J Defendants, nothing could be further from the truth. Ven-A-Care has indeed been critical of certain pharmaceutical pricing practices, but it has never asserted any sort of claim against the J&J Defendants. Indeed, in testimony before the House Committee on Energy and Commerce, Ven-A-Care’s President, Mr. Zachary T. Bentley, testified that Johnson & Johnson does *not* abuse the AWP-based reimbursement system:

Q: So who created the AWP, then? Is it created by HCFA, by HHS—

A: It’s been around, sir, for the better part, that I’m aware of 40 years. And for a great number of those years, it’s always worked, and there are still a great number of companies, Merck, Lilly, Johnson & Johnson, DuPont, who do not engage in this type of gaming the system. When they make a representation about the price of a drug, you may not like it because it may be high, but that’s the price they sell it for.

“Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers,” Joint Hearing Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, September 21, 2001, Serial No. 107-65, at 54 (available at <http://www.access.gpo.gov/congress/house/house05ch107.html> and attached for the Court’s convenience as Appendix A).

This testimony underscores the fatal defect in the Amended Complaint. By ignoring its obligation to plead fraud with particularity, the State has obscured the differences among the defendants with respect to the practices alleged in the Amended Complaint. That is precisely what Wis. Stat. § 802.03(2) was designed to prevent. The J&J Defendants should not be dragged into a massive, unwieldy and costly litigation simply because, in 2000, the State’s

Department of Corrections paid less than AWP for three drugs, especially since there is no claim that the J&J Defendants ever represented that AWP includes discounts. If the State does not like the prices that the J&J Defendants charge for their products, it is under no obligation to purchase them. If it wishes to reform its Medicaid reimbursement program, it is free to do so. But without particulars demonstrating that the J&J Defendants have committed a fraud on the State or its citizens, the claims against the J&J Defendants must be dismissed.

Conclusion

For the foregoing reasons, and for the reasons set forth in the Defendants' Joint Motion to Dismiss the Amended Complaint, the State's claims against the J&J Defendants should be dismissed in their entirety with prejudice.

Dated: January 20, 2005

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PPC, INC.

**MEDICARE DRUG REIMBURSEMENTS: A BROKEN
SYSTEM FOR PATIENTS AND TAXPAYERS**

JOINT HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
AND THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTH CONGRESS
FIRST SESSION

SEPTEMBER 21, 2001

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file is significantly superior to that of etoposide. Now, what they were concerned about was there was a big spread already in etoposide, so how were they going to market and sell the better, in their own words, clinically superior, second-generation drug?

Now, they admit right here, currently physician practices can take advantage of the growing disparity between Vepesid—that's etoposide—list price and subsequently the average wholesale price, AWP, and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished.

And they go through some different scenarios. And I can tell you right now that the spread differential on etoposide, as was pointed out earlier, Medicare is reimbursing approximately \$135 for the old version of etoposide, and it costs less than \$10. And literally we have a, quote, clinically superior drug that Bristol-Myers Squibb has been unable to market because of the spread on the older version of the drug.

Mr. GREENWOOD. Your time is—

Mr. DEUTSCH. Can I just ask a very short follow-up question?

Mr. BENTLEY. Sure.

Mr. DEUTSCH. And I know my time is expired. I guess I have a copy of this, and it's up there. I'm just curious. You were able to ascertain this information through your whistleblower lawsuit. How were you able to—

Mr. BENTLEY. This—I obtained this from the Justice Department, cooperating with them. They obtained this by an OIG subpoena issued to Bristol-Myers Squibb.

Mr. GREENWOOD. The time of the gentleman has expired.

The Chair recognizes for 10 minutes the gentleman from Florida, the chairman of the Health Subcommittee, Mr. Bilirakis.

Mr. BILIRAKIS. Thanks, Mr. Chairman.

Mr. Bentley, the Mitomycin that's on that chart, 40 milligram, and the dollar figures attached thereto, how many doses is that? Is that one dose?

Mr. BENTLEY. Well, that's one vial. Depending on how it is administered, that could take two or three vials to equate to a dose.

Mr. BILIRAKIS. All right. So if it took 2 or 3 vials for one dose—

Mr. BENTLEY. You multiply all of those figures times 2 or 3. And if I can interject to shine some light on some previous remarks that were made, the Mitomycin, that AWP, that was established by the drug manufacturers, and that is what Medicare is relying on to determine the reimbursement. And I can tell you I have examined tens of thousands of internal drug company documents, and there is not one scintilla of evidence that shows that the drug companies established an inflated price for Mitomycin in order to offset practice expense for oncologists or to give the pharmacists any more money. It just—that is not the focus.

Mr. BILIRAKIS. So who created the AWP, then? Is it created by HCFA, by HHS, by—

Mr. BENTLEY. It's been around, sir, for the better part, that I'm aware of, about 40 years. And for a great number of those years, it's always worked, and there are still a great number of companies, Merck, Lilly, Johnson & Johnson, DuPont, who do not engage

in this type of gaming the system. When they make a representation about the price of the drug, you may not like it because it may be high, but that's the price they sell it for.

Mr. BILIRAKIS. Let me ask you, about the \$180 figure which is the Ven-A-Care cost. Is HCFA, in your opinion, aware that that's really all that it cost?

Mr. BENTLEY. I think they are now, sir.

Mr. BILIRAKIS. Mr. Scanlon, are they aware of it?

Mr. SCANLON. Yes, Mr. Chairman.

Mr. BILIRAKIS. Have they been aware of it?

Mr. SCANLON. They have been aware of it, and last year they did take steps to try and change this, but then because of concerns raised by providers, they backed off and—

Mr. BILIRAKIS. Concerns raised by providers to HCFA?

Mr. SCANLON. About the imbalance between the drug prices and the drug administration compensation.

Mr. BILIRAKIS. Concern was raised by providers, being—

Mr. SCANLON. Yes, sir.

Mr. BILIRAKIS. [continuing] let us say in that case the oncologists?

Mr. SCANLON. Yes, sir.

Mr. BILIRAKIS. Mr. Grob, do you agree with that?

Mr. GROB. That's correct.

Mr. BILIRAKIS. Because concerns were raised by providers, it just remained status quo?

Mr. GROB. The status quo has remained. In fact, the Congress required that it remain that way.

Mr. BILIRAKIS. That's what I want to get to. The Congress did what?

Mr. GROB. The Health Care Financing Administration had advocated making available more realistic drug prices to the carriers, but because of the concerns that were raised, the Congress placed a moratorium on any reductions in those prices, and it commissioned the study of the General Accounting Office.

Mr. BILIRAKIS. And that's what we have today. I'm almost speechless.

Is there a substitute or an equivalent drug that will do the same job Mitomycin will do? Mr. Bentley?

Mr. BENTLEY. I'm not a pharmacist. I'm not—I don't know. Really my expertise is on pharmaceutical pricing and the economics.

Mr. BILIRAKIS. Do any of you know?

Mr. GROB. I don't know, Mr. Chairman.

Mr. SCANLON. Nor do I.

Mr. BILIRAKIS. Mr. Grob, do you know, can HCFA, the administration, HHS, et cetera, et cetera, can they fix this in a way that it should be fixed? You know, and I'm not—I realize this is more complex. It's certainly not a simple situation, but can they fix this? Do they have the power to fix this, or does it have to be Congress?

Mr. GROB. Theoretically, CMS does have the power through an authority called their "inherent reasonableness" power, which allows them to conduct studies to determine what the true prices are, and if there is a price that is, as the phrase says, inherently unreasonable, they can reduce it. However, that's a very lengthy process to conduct the studies. The studies are almost—

Merck & Co.

STATE OF WISCONSIN

CIRCUIT COURT
BRANCH 7

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

vs.

AMGEN, INC., et al.

Defendants.

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Case No. 04-CV-1709

Unclassified - Civil: 30703

**SEPARATE MEMORANDUM OF DEFENDANT
MERCK & CO., INC. IN SUPPORT OF ITS MOTION
TO DISMISS THE AMENDED COMPLAINT**

Defendant Merck & Co., Inc. (“Merck”) submits this separate memorandum in support of its motion to dismiss the Amended Complaint. Merck also joins in the Defendants’ Joint Motion to Dismiss the Amended Complaint and the Memorandum of Law in support of that motion (the “Joint Memorandum”).

Aside from Merck’s address (Am. Compl. ¶ 16), there is not a single specific reference to Merck in the Amended Complaint. The Amended Complaint contains no particularized factual allegation of fraud that would allow Merck to determine what conduct by Merck is at issue, when it occurred, or which of Merck’s drugs might be involved. These defects warrant dismissal. Wis. Stat. § 802.03(2); see Friends of Kenwood v. Green, 239 Wis. 2d 78, 87-91, 619 N.W.2d 271, 276-77 (Ct. App. 2000).

No Merck product is even mentioned in the Amended Complaint itself. Exhibit B to the Amended Complaint, entitled “Examples of Spreads from Defendants,” identifies Merck as the manufacturer of a single product – “famotidine 10 mg/ml.” But this inclusion of a single Merck product in Exhibit B does not remedy the lack of specificity in

the Amended Complaint, because the general allegations of how AWP is purportedly misused do not, as a matter of law, apply to famotidine.¹

Famotidine (for which Merck's brand name is Pepcid®) is an intravenously-administered H-2 receptor antagonist used by hospitals and physicians to treat stomach and intestinal ulcers.² As explained in the Joint Memorandum (and in the Amended Complaint), the Medicare Part B reimbursement methodology differs depending on whether a drug is available only from a single source or from multiple sources. Intravenous famotidine is available from multiple sources.³ The Amended Complaint concedes that reimbursement for multiple source drugs is based on 95% of the lesser of (1) "the median [AWP] of all sources of the generic forms of the drug" . . . or (2) "the lowest [AWP] of the brand name form of the drug . . ." Am. Compl. ¶ 65. Medicare reimbursement for famotidine is thus not based on the AWP for Merck's version of this drug.

Nor can plaintiff state a claim against Merck with respect to payments under the Medicaid program. As described in the Joint Memorandum, Wisconsin (and other states) establish their own Maximum Allowable Cost ("MAC") for providers with respect to multi-source drugs like famotidine, and that MAC price is not based on AWP.

Finally, Wisconsin's assertion that it has no way to control provider charges for drugs in the Medicare and Medicaid programs is demonstrably not true as to

¹ Paragraph 43 of the Amended Complaint describes Exhibit B and mentions sources of information, without actually explaining what sources Exhibit B is based upon. It identifies no source for the reference in Exhibit B to famotidine.

² A tablet form of famotidine, also sold under the brand name Pepcid®, is available but is not covered by Medicare Part B.

³ The FDA's Orange Book of Approved Drug Products establishes that at least since 2001 there have been more than three alternative sources of IV famotidine. The Orange Book is available electronically at <http://www.fda.gov/cder/ob/default.htm>.

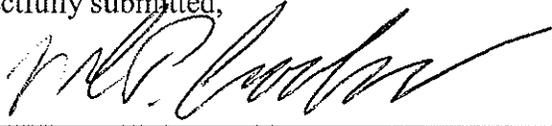
famotidine. Wisconsin has the authority to require preauthorization before any Medicaid provider can obtain reimbursement for particular drugs, see Wis. Admin. Code HFS § 107.10(2) (2004), and it has used this authority in the past for famotidine. Wisconsin Medicaid Update No. 99-41 (July 1999). The Amended Complaint's allegations (at ¶¶ 55-56) that the State is "powerless" to control pricing or to ensure that providers comply with their obligations are thus contradicted by the State's own conduct as to the only Merck product identified in any part of the Amended Complaint.

Conclusion

In addition to the deficiencies of the Amended Complaint as to all defendants set forth in the Joint Memorandum, the Amended Complaint fails to comply with Wis. Stat. § 802.03(2) as to Merck and should therefore be dismissed.

Dated: January 19, 2005

Respectfully submitted,

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Attorneys for Defendant Merck & Co., Inc.

Pfizer Inc.

STATE OF WISCONSIN

CIRCUIT COURT
Branch 7

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN INC., ET AL.,

Defendants.

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Case No.: 04 CV 1709

**INDIVIDUAL MEMORANDUM OF PFIZER INC.
IN SUPPORT OF ITS
MOTION TO DISMISS THE AMENDED COMPLAINT**

STATE OF WISCONSIN

CIRCUIT COURT
Branch 7

DANE COUNTY

STATE OF WISCONSIN,)

Plaintiff,)

v.)

AMGEN INC., ET AL.,)

Defendants.)

Case No.: 04 CV 1709

**INDIVIDUAL MEMORANDUM OF PFIZER INC. IN SUPPORT OF ITS
MOTION TO DISMISS THE AMENDED COMPLAINT**

Defendant Pfizer Inc. ("Pfizer"), joins in the Joint Motion to Dismiss the Amended Complaint and the Memorandum of Law supporting that motion (the "Joint Memorandum"), and submits this Individual Memorandum to address certain deficiencies in the Amended Complaint that pertain specifically to Pfizer.

As discussed in the Joint Memorandum, where a plaintiff claims fraud, section 802.03(2) requires the "the circumstances constituting fraud or mistake shall be stated with particularity." Wis. Stat. Ann. § 802.03(2). The complaint must therefore set forth with particularity the "who, what, when, where and how" of the allegedly false representation. *Friends of Kenwood v. Green*, 2000 WI App 217, ¶ 14, 239 Wis. 2d 78, 619 N.W.2d 271 (explaining similarity between applicability and pleading requirements of section 802.03(2) and Rule 9(b) of the Federal Rules of Civil Procedure). Furthermore, section 802.03(2) requires that a plaintiff plead with particularity as to each defendant in a case - not merely lump all allegations against all defendants together in a multi-defendant complaint. *Id.* at ¶¶ 14, 16.

The State's Amended Complaint fails this test as to Pfizer. The Amended Complaint contains only generalized allegations describing allegedly fraudulent conduct by "Defendants." The Amended Complaint lacks any allegation that describes how Pfizer participated in this alleged conduct, or any facts that would indicate that Pfizer's conduct was fraudulent at all. In fact, that State's lengthy Amended Complaint contains only two scant paragraphs directly related to Pfizer; one merely sets forth Pfizer's state of incorporation and principal place of business, and the other mischaracterizes an unrelated investigation involving a drug that the State has not even placed in issue here. *See* Paragraphs 17 and 51. Indeed, the Amended Complaint fails to allege any misconduct with respect to any drug manufactured by Pfizer.¹⁷

For these reasons, and those further explained in the Joint Memorandum, the Amended Complaint lacks any particularized allegations against Pfizer, and should be dismissed.

Dated: January 20, 2005

Respectfully submitted)

By: 

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¹⁷ Azithromycin (Zithromax) is buried in a chart entitled, "Examples of Spreads from Defendants" as Exhibit B to the Amended Complaint. However, the State does not allege that it paid for this drug, nor does it plead any facts necessary to state a claim as to this drug.

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STATE OF WISCONSIN

CIRCUIT COURT
Branch 7

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN INC., ET AL.,

Defendants.

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Case No.: 04 CV 1709

**INDIVIDUAL MEMORANDUM OF PHARMACIA CORPORATION
IN SUPPORT OF ITS MOTION
TO DISMISS THE AMENDED COMPLAINT**

STATE OF WISCONSIN

CIRCUIT COURT
Branch 7

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN INC., ET AL.,

Defendants.

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Case No.: 04 CV 1709

**INDIVIDUAL MEMORANDUM OF PHARMACIA CORPORATION IN
SUPPORT OF ITS MOTION TO DISMISS THE AMENDED COMPLAINT**

Defendant Pharmacia Corporation (“Pharmacia”), joins in the Defendants’ Joint Motion to Dismiss the Amended Complaint and the Memorandum of Law in support of that motion (the “Joint Memorandum”), and submits this Individual Memorandum to address certain deficiencies in the Amended Complaint that pertain specifically to Pharmacia.

As discussed in the Joint Memorandum, where a plaintiff claims fraud, section 802.03(2) requires the “the circumstances constituting fraud or mistake shall be stated with particularity.” Wis. Stat. Ann. § 802.03(2). The complaint must therefore set forth with particularity the “who, what, when, where and how” of the allegedly false representation. *Friends of Kenwood v. Green*, 2000 WI App 217, ¶ 14, 239 Wis. 2d 87, 619 N.W.2d 271 (explaining similarity between applicability and pleading requirements of section 802.03(2) and Rule 9(b) of the Federal Rules of Civil Procedure).

Furthermore, section 802.03(2) requires that a plaintiff plead with particularity as to each

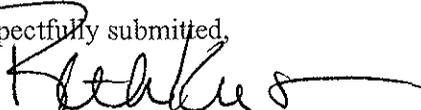
defendant in a case - not merely lump all allegations against all defendants together in a multi-defendant complaint. *Id.* at ¶¶ 14, 16.

The State has not met its pleading burden with respect to Pharmacia. The Amended Complaint refers generally to a “scheme” among the “Defendants” but provides no allegations explaining how Pharmacia participated in the alleged conduct, or any facts that would indicate that Pharmacia’s alleged conduct was fraudulent. The Amended Complaint refers to two Pharmacia drugs, Adriamycin (¶ 39) and Solu-Medrol (¶ 42), but does not allege facts showing any wrongful conduct even as to these two drugs. Further, the Amended Complaint fails to allege any facts showing any connection between any conduct by Pharmacia and reimbursement for these drugs by the State of Wisconsin.^{1/}

For these reasons, and those further explained in the Joint Memorandum, the Amended Complaint lacks any particularized allegations against Pharmacia, and therefore should be dismissed.

Dated: January 20, 2005

Respectfully submitted,

By: 

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^{1/} As explained in the Joint Memorandum (Section I.B), Wisconsin has relied on the U.S. Department of Justice’s alternative pricing data for Solu-Medrol since 2000 and therefore cannot claim to have paid for Solu-Medrol and various other Pharmacia drugs based on published AWP’s since that date.

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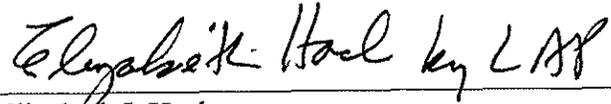
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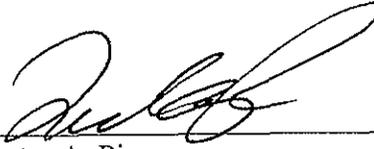
Dated: January 19, 2005

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ARGUMENT

In the Amended Complaint the State brings claims on behalf of private third-parties who were allegedly victimized by PBMs. Specifically, the State alleges that in the 1990s the drug reimbursement process became increasingly complicated and expensive, and so “most organizations turned to PBMs to manage their drug reimbursement.” Am. Compl. ¶ 69. The State then asserts that “defendants” provide PBMs with hefty, secret economic inducements to secure placement of defendants’ drugs on formularies. *Id.* ¶ 71.

With regard to Sicor, not only does the State fail to identify any alleged fraudulent conduct identified above on the part of Sicor, it also fails to identify a single private third-party payer or PBM or a single contract or contract term or alleged fraudulent conduct involving PBMs. The State will never be able to plead such conduct on the part of Sicor since Sicor has never sold any of its drugs to PBMs. Thus, the State has failed to state a claim on which relief may be granted under both Wisc. Stat. § 802.03(2) and § 802.06(a)(6).

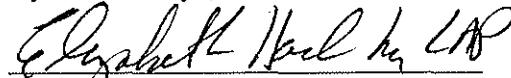
CONCLUSION

For the foregoing reasons, and for the reasons set forth in Defendants’ Motion to Dismiss and accompanying memoranda in support thereof, Sicor respectfully requests that the Court dismiss the Amended Complaint against Sicor in its entirety.

Dated: January 19, 2005

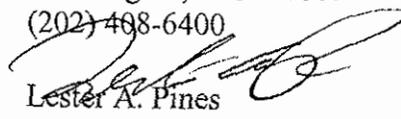
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SmithKline Beecham

STATE OF WISCONSIN

CIRCUIT COURT

DANE COUNTY

STATE OF WISCONSIN,

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Case No.: 04 CV 1709

Plaintiff,

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v.

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AMGEN INC, ET AL.,

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Defendants.

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**SUPPLEMENTAL MEMORANDUM OF DEFENDANT
SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE,
IN SUPPORT OF ITS MOTION
TO DISMISS THE AMENDED COMPLAINT**

Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (“GSK”) has joined in the Defendants’ Joint Motion to Dismiss the Amended Complaint and the Memorandum of Law in support of that motion (the “Joint Memorandum”). GSK is submitting this short supplemental brief to make one simple point: the State’s Complaint is woefully lacking in particularity with respect to its allegations against GSK.

GSK is identified as a defendant in paragraph 23 of the Complaint, but it is not mentioned by name anywhere else in the body of the Complaint. Not a single GSK drug is identified in the body of the Complaint as having an “inflated” AWP or WAC (whatever “inflated” means). There are thus no allegations in the body of the Complaint about the particular “who, what, when, where and how” of GSK’s alleged fraud or the specific basis for any claim against GSK. In the Appendices to the Complaint, only two drugs made by GSK or its predecessor companies are identified -- namely Zofran® and Kytril®, both physician-administered brand name drugs covered by Medicare Part B. For both drugs, a purported AWP

for one year (2000) is listed, and it is alleged that there was a “spread” for one formulation of Zofran® for that year. On the basis of these meager allegations concerning one year’s prices for two drugs, the State seeks to litigate sweeping fraud and other claims against GSK as to some unidentified number of the hundreds of drugs that GSK or its predecessors have sold since 1992. There is a major difference between (a) claims concerning pricing and reimbursement for one or two drugs for one year and (b) claims filed without any articulated basis concerning potentially hundreds of unnamed drugs for a thirteen-year period.

As set forth in the Joint Memorandum, Wisconsin’s pleading rules require far more specificity than the Complaint provides in order to support sweeping claims concerning a potentially huge number of the defendants’ drugs. The State should not be permitted to proceed against GSK as to any of its products due to the Complaint’s lack of particularity concerning GSK, as well as for the numerous other reasons set forth in the Joint Memorandum. At a minimum, the Wisconsin pleading rules preclude the State from proceeding with any claims against GSK as to any drug other than those (1) identified by name in the Complaint or its Appendices, (2) as to which the state has specifically identified an allegedly fraudulent reported price, and (3) as to which the state has specifically articulated why it contends the reported price for that drug was fraudulent.

Dated: January 20, 2005

Respectfully submitted,

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STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN INC., ET AL.,

Defendants.

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Case No 04 CV 1709

Unclassified - Civil: 30703

**DEFENDANT TAP PHARMACEUTICAL PRODUCTS, INC.'S
SUPPLEMENTAL MEMORANDUM IN SUPPORT OF DEFENDANTS'
JOINT MOTION TO DISMISS THE AMENDED COMPLAINT**

Defendant TAP Pharmaceutical Products, Inc. (“TAP”) moves for dismissal of the State’s claims for one additional reason not identified in defendants' joint memorandum: in 2001, the State settled and released all claims against TAP based on Lupron®. The only TAP drug identified in the exhibits to the amended complaint is Lupron®. Furthermore, the State’s claims should be dismissed against TAP because they fail to allege fraud against TAP with the specificity required by Section 802.03 of the Wisconsin Rules of Civil Procedure.¹

ARGUMENT

I. Any Claims Regarding The Marketing, Pricing, and Sale of Lupron® Should Be Dismissed Because The State Has Settled and Released Them.

On December 3, 2001, the State of Wisconsin reached a settlement with TAP that released TAP from any liability involving the marketing, sale and pricing of Lupron® (the “Settlement Agreement”). The Settlement Agreement provides:

¹ TAP adopts and incorporates by reference the defendants' joint memorandum and, to the extent applicable, the arguments contained in the other defendants' individual memoranda in support of the motion to dismiss.

[T]he state of Wisconsin on behalf of itself, its officers, agents, agencies and departments shall release and forever discharge TAP . . . and their corporate parents and affiliates . . . from any civil or administrative claims for damages or penalties that the state of Wisconsin has or may have related to the Covered Conduct. (See Settlement Agreement, attached as Ex. A, at 8, ¶ 2.)

The Settlement Agreement defines “Covered Conduct” to include “alleged conduct from January 1991 through the present involving the marketing, sale and pricing of Lupron[®] . . . ,” including, for instance, conduct that TAP allegedly (1) inflated the AWP of Lupron[®] in order to establish and market the spread; (2) provided free samples of Lupron[®] knowing and expecting that medical providers would charge for them; (3) provided financial incentives, including grants, travel and entertainment, to induce providers to purchase Lupron[®]; and (4) concealed the discounted price from governmental agencies. *Id.* at ¶ F(i)-(iv). The conduct alleged here mirrors the conduct covered by the Settlement Agreement. (See Am. Compl., ¶¶ 1-2, 28-74.) Therefore, the State's claims based on TAP's conduct regarding Lupron[®], those claims should be dismissed with prejudice.

Furthermore, even if the State had not released all claims relating to the pricing, marketing or sale of Lupron[®], the State would nevertheless be prohibited from pursuing any Lupron[®] claims on behalf of its citizens because of a nationwide injunction issued by the Honorable Richard G. Stearns of the United States District Court for the District of Massachusetts. On November 24, 2004, Judge Stearns entered an Order preliminarily approving a nationwide class settlement and certified for settlement purposes a nationwide class of “[a]ll individual persons or entities who, during the Class Period, made Lupron[®] Purchases” See *In re: Lupron[®] Marketing and Sales Pract. Litig.*, 345 F. Supp. 2d 135, 139 (D. Mass. 2004). In order to preserve his jurisdiction and to oversee the orderly administration of the nationwide settlement, Judge Stearns directed in the Order that all members of the Lupron[®] Purchaser Class, which include all Lupron[®] purchasers in Wisconsin, are immediately enjoined stating, “[p]ending Final Approval, no nationwide Lupron[®]

Purchaser Class Member, either directly, representatively, or in any other capacity . . . shall commence, continue or prosecute against any or all Releasees any action or proceeding in any court or tribunal asserting any of the matters . . . to be released upon Final Approval . . . and are hereby enjoined from so proceeding.” *Id.* at 146. Thus, even if the State had not released all claims in this case related to the pricing, marketing, and sale of Lupron®, the injunction would stay any proceedings relating to the State’s claims on behalf of its citizens insofar as they relate to Lupron®.

II. The State Fails To Allege Fraud Against TAP with the Requisite Specificity.

The State’s claims against TAP lack the specificity required by Section 802.03(2) of the Wisconsin Rules of Civil Procedure. Other than Lupron, a drug for which the State settled and released all claims in 2001, the amended complaint (including its exhibits) fails to identify a single TAP product. Nowhere does the State allege:

- which TAP products are at issue,
- the allegedly fraudulent prices that TAP submitted for the unidentified products,
- how or why any such price submissions were fraudulent, and
- what prices TAP should have submitted instead.

The State alleges generally that defendants “have misrepresented the true AWP for *virtually all of their drugs.*” (Am. Compl. ¶ 37.) Such a broad allegation does not satisfy the requirements of Section 802.03. *See* Defs. Joint Mem. at 12-14; *see also In re Pharmaceutical Industry AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (rejecting AWP complaint and ordering plaintiffs to make specific allegations on a drug-by-drug basis). Significantly, the amended complaint does not even allege that (1) any specific TAP product is covered under Medicare or the Wisconsin Medicaid programs; or (2) the State or any individual actually paid for a specific TAP product based on AWP or WAC. These omissions require dismissal of the State’s claims.

The State further fails to identify when TAP made any alleged misrepresentations. The State's allegations that the misrepresentations occurred since at least "1992" is insufficient under Section 802.03. (Am. Compl. ¶ 33.) See *Clark v. Robert W. Baird Co.*, 142 F. Supp. 2d 1065, 1071 (N.D. Ill. 2001) (dismissing claim on Rule 9(b) grounds and finding that "for the 'when' [element], it is not enough to merely allege a period of months or years, or the duration of the activity"); see also *McCarthy, Wilson & Ethridge v. Provident Life and Accident Ins. Co.*, 2000 WL 1929780 (D. Md. Dec. 18, 2000) ("a general allegation of fraudulent statements occurring over the last nine years without more detail as to the 'when' of the fraud fails to meet the specificity requirements of Rule 9(b)").

Finally, the State also fails to allege *who* at TAP submitted the allegedly false information to the publications, or *where* and *how* the information was communicated. These omissions likewise are fatal to the State's claims. See *United States v. EER Systems Corp.*, 950 F. Supp. 130, 132 (D. Md. 1996)(dismissing claims under Rule 9(b) because the plaintiff failed to "(1) name the person(s) who made the representations; (2) specifically state what he or she said; and (3) state what he or she acquired as a result of the representations"); see also *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918 (7th Cir. 1992) (dismissing claim because the plaintiff "[did] not even hint at the identity of those who made the misrepresentations, the time the misrepresentations were made, or the places at which the misrepresentations were made").

As stated in defendants' joint memorandum, the amended complaint repeatedly "lumps" the defendants together in a generalized allegation of fraud. This is precisely the type of pleading that Section 802.03 prohibits. See Defs. Joint Mem. at 10-12.

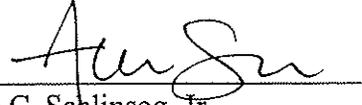
CONCLUSION

For the foregoing reasons, and those identified in defendants' joint memorandum, TAP respectfully requests that this Court dismiss the State's amended complaint with prejudice.

Dated: January 20, 2005

Respectfully Submitted,

DEFENDANT TAP PHARMACEUTICAL
PRODUCTS, INC.



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STATE SETTLEMENT AGREEMENT AND RELEASE

I. THE PARTIES

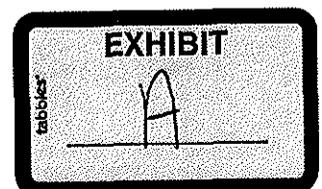
This Settlement Agreement ("Agreement") is entered into this 3rd day of December, 2001. The parties to the Agreement are the state of Wisconsin and TAP Pharmaceutical Products Inc. (formerly known as TAP Holdings Inc. and TAP Pharmaceuticals Inc.) ("TAP"), a Delaware corporation with a principal place of business in Lake Forest, Illinois, and are collectively referred to as the "Parties". The Parties now agree as follows:

II. PREAMBLE

A. WHEREAS, TAP is entering into a civil settlement agreement with the United States of America, acting through and/or on behalf of its Department of Justice and the United States Attorney's Office for the District of Massachusetts, and the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); TRICARE Management Activity ("TMA")(formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense, the United States Department of Defense, and relators in certain federal False Claims Act lawsuits, as well as settlement agreements with the state of Wisconsin and numerous other states, all of which are intended to resolve civil claims for the conduct alleged in Paragraph F below;

B. WHEREAS, this Agreement addresses the state of Wisconsin's claims against TAP for the conduct alleged in Preamble Paragraph F below;

C. WHEREAS, on or before October 16, 2001, or such other date as the Court may set in United States of America v. TAP Pharmaceutical Products Inc., Criminal



Action No. [to be assigned](District of Massachusetts) (the "Criminal Action"), or such other date as may be determined by the Court, TAP has agreed to enter a plea of guilty pursuant to Fed. R. Crim. P. 11(e)(1)(C) to a one count Information alleging a violation of Title 18, United States Code, Section 371, namely, a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. § 331(f) and 333(b) by causing the billing of free drug samples;

D. WHEREAS, at all relevant times, TAP marketed and sold the drugs Lupron⁷ and Lupron Depot⁷ (collectively "Lupron") in various dosages to physicians, health maintenance organizations, hospitals, wholesalers, distributors and others for use in treatment of prostate cancer;

E. WHEREAS, the state of Wisconsin contends that TAP caused to be submitted claims for payment for Lupron to the state's Medical Assistance Program ("Medicaid") established pursuant to Title XIX of the Social Security Act;

F. WHEREAS, the state of Wisconsin contends that it has Medicaid-related civil claims against TAP under various statutes and the common law for engaging in the following alleged conduct from January 1991 through the present, involving the marketing, sale and pricing of Lupron for treatment of prostate cancer:

(i) The state of Wisconsin contends that TAP, through certain of its employees, provided, and conspired to provide, free samples of the drug Lupron to certain providers (including physicians), knowing and expecting that those providers would prescribe, distribute and/or administer the free drug samples to patients and that those free samples would be illegally billed to the Medicaid program. The state of Wisconsin further contends that the

purpose of providing these free drug samples varied, but that among those purposes were: permitting Medicaid providers to obtain money from the reimbursement for the samples of Lupron; inducing Medicaid providers to order Lupron; providing a source of money for Medicaid providers to pay past-due balances owed to TAP; and increasing the income of Medicaid providers.

(ii) The state of Wisconsin contends that TAP knowingly and willfully offered and/or paid illegal remuneration to certain providers, physicians, physician practices, health maintenance organizations and others in various forms, including, for example, grants, free Lupron, debt forgiveness, travel and entertainment, consulting and audit services, administration fees, nominally priced drug, and VCRs and TVs, for the purpose of either unlawfully obtaining orders to purchase the drug Lupron from TAP or causing Lupron to be placed on formulary by a provider, which drug TAP knew was paid for by the Medicaid program.

(iii) The state of Wisconsin contends that TAP knowingly and willfully offered and/or paid illegal remuneration to providers by marketing TAP's Return-to-Practice program to providers to induce unlawful orders to purchase the drug Lupron for treatment of prostate cancer, which drug TAP knew was paid for by the Medicaid program. The state of Wisconsin further contends that TAP's Return-to-Practice program consisted of inflating the Average Wholesale Price (AWP) used by Medicaid for reimbursement of the drug Lupron, deeply discounting the price paid by providers to TAP for the drug (the discounted price), and marketing the spread between the AWP and the discounted price to providers as additional profit to be returned to the providers from Medicaid reimbursements for Lupron. The state of

Wisconsin further contends that TAP concealed the discounted price from Medicaid and other governmental agencies by omitting material information about providers' actual cost, by falsely advising providers that the discounted price could not and should not be reported to Medicaid, and by auditing providers to ensure the claims for payment were submitted at the inflated AWP rather than the discounted price paid by the provider. The state of Wisconsin also contends that as a consequence of this conduct, its Medicaid program was damaged.

(iv) The state of Wisconsin contends that TAP manipulated reported prices, including AWP, to increase reimbursement from the Medicaid program. Specifically, the state of Wisconsin contends that TAP engaged in a marketing scheme where it set AWPs of Lupron at levels far higher than the majority of its customers actually paid for the drug when purchasing either directly from TAP or through a wholesaler or distributor. As a result, the state of Wisconsin contends that TAP's customers received reimbursement from the Medicaid program at levels significantly higher than the providers' actual costs or the wholesalers' average price. The state of Wisconsin further contends that certain providers submitted claims for payment to the Medicaid programs that were subsequently paid, based upon falsely inflated AWPs, to the financial detriment of the Medicaid program;

(v) The state of Wisconsin contends that TAP knowingly misreported and underpaid its Medicaid rebates for Lupron used for treatment of prostate cancer, *i.e.*, the amounts that it owed to the state under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. The state of Wisconsin further contends that TAP was generally required on a quarterly basis to rebate to its state Medicaid program the difference between the Average Manufacturer Price

(AAMP) and its Best Price, as defined by 42 U.S.C. § 1396r-8(k)(1) and 1396r-8(c)(1)(C). The state of Wisconsin alleges that TAP falsely reported to the Center for Medicare and Medicaid Services ("CMS") (formerly the "Health Care Financing Administration" or "HCFA") its Best Price for Lupron used for treatment of prostate cancer because TAP calculated its Best Prices for Lupron without accounting for off-invoice price concessions provided in various forms, including, for example, grants, free Lupron, debt forgiveness, travel and entertainment, consulting and audit services, administration fees, nominally priced drugs, and VCRs and TVs. As a result, the state of Wisconsin contends that TAP misreported and underpaid its Medicaid rebates to the states under the Medicaid Rebate Program.

TAP's conduct alleged in Preamble Paragraph F is hereinafter referred to as the "Covered Conduct."

G. WHEREAS, the state of Wisconsin contends that it has administrative claims against TAP for administrative and monetary penalties under state and federal law for the Covered Conduct.

H. WHEREAS, other than such admissions as TAP makes in connection with its guilty plea in the Criminal Action, TAP denies the remaining allegations of the state of Wisconsin set forth herein.

I. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final compromise of the civil and administrative Medicaid-related claims the state of Wisconsin has against TAP.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. TAP agrees to pay to the United States, to the individual states, to the relators in certain federal False Claims Act lawsuits and to any relators in any pending state court *qui tam* or “whistleblower” lawsuits, collectively, the maximum collective sum of five hundred eighty five million dollars (\$585,000,000) (the “Settlement Amount”). Payments to the United States and to the individual states shall be made pursuant to the following terms and conditions:

A. TAP has agreed to pay to the United States the sum of five hundred fifty nine million four hundred eighty three thousand five hundred sixty dollars (\$559,483,560) (the AFederal Settlement Amount), which represents the federal share of the Settlement Amount and the share of the Settlement Amount payable to the relators in certain federal False Claims Act lawsuits. The Federal Settlement Amount shall be paid pursuant to the civil settlement agreement entered between TAP and the United States (the “Federal Agreement”).

B. TAP agrees to deposit into an escrow account the sum of twenty five million, five hundred sixteen thousand, four hundred forty dollars (\$25,516,440) (the AState Settlement Amount), which represents the state-funded portions of the claims settled for the Medicaid programs of all fifty states and the District of Columbia (“the Participating States”). TAP shall pay the State Settlement Amount into an escrow account within seven business days after the

latest date on which all of the following have occurred: (1) the Federal Agreement is fully executed by the Parties and delivered to TAP=s attorneys, (2) the stipulated dismissals described in the Federal Agreement are filed and copies provided to TAP=s attorneys, and (3) the Court accepts the Fed. R. Crim. P. 11(e)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph (B), and imposes sentence. The escrow account into which TAP shall deposit the State Settlement Amount shall be an interest bearing escrow account under the custody and control of a Medicaid Fraud Control Unit, which shall be designated by the negotiating team for the National Association of Medicaid Fraud Control Units and which shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in subparagraph E below.

C. The total portion of the Settlement Amount paid by TAP in settlement for alleged injury to the Medicaid Program for the state of Wisconsin is \$1,433,271.10, consisting of a portion paid to the state of Wisconsin under this Agreement and another portion paid to the federal government as part of the Federal Settlement Amount. The individual portion of the State Settlement Amount allocable to the state of Wisconsin, and which may be withdrawn by the state of Wisconsin from escrow pursuant to this Agreement, is \$596,196.45 (the "Individual State Settlement Amount"), plus any accrued interest on that portion of the State Settlement Amount. The portion of the Federal Settlement Amount allocable to the state of Wisconsin is \$837,074.65.

D. The state of Wisconsin shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after the Escrow Agent has received fully executed state settlement agreements from all of the Participating States. Any escrowed funds

not disbursed within 200 days after the Escrow Agent has received the State Settlement Amount shall be disbursed to TAP.

E. If TAP=s agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(e)(1)(C) in the Criminal Action described in Preamble Paragraph B is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the state of Wisconsin or TAP. If either the state of Wisconsin or TAP exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within four business days of the Court=s decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, TAP waives any affirmative defense based in whole or in part on the statute of limitations for the period of time between April 17, 2001, and thirty days after rescission of this Agreement.

2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3 below, the state of Wisconsin on behalf of itself, its officers, agents, agencies and departments shall release and forever discharge TAP, its predecessors, subsidiaries, joint venture owners, and their corporate parents and affiliates, successors and assigns, and their current and former directors, officers, and employees from any civil or administrative claims for damages or penalties that the state of Wisconsin has or may have relating to the Covered Conduct as defined in Preamble Paragraph F. The payment of the Settlement Amount fully discharges TAP from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the State for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the state of Wisconsin specifically does not herein release TAP, its predecessors, subsidiaries, joint venture owners, and their corporate

parents and affiliates, successors and assigns, and their current and former directors, officers, and employees from any and all of the following: (a) any potential criminal, civil or administrative claims arising under state of Wisconsin revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any potential liability to the state of Wisconsin for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) any reporting of AWP for Lupron to First Data Bank or any other national reporting service for use in Medicaid reimbursement submitted subsequent to the effective date of this agreement; (f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (g) any express or implied warranty claims or other claims for defective or deficient products and services provided by TAP; (h) any claims for personal physical injury or property damage or for other consequential damages arising from the Covered Conduct; (i) any claim based on a failure to deliver items or services due; or (j) any civil or administrative claims against individuals, including current and former directors, officers, and employees of TAP, its predecessors, subsidiaries, joint venture owners, and their corporate affiliates, who receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement related to the Covered Conduct.

4. In consideration of the obligations of TAP set forth in this Agreement, conditioned upon TAP's payment in full of the Settlement Amount and except as reserved in paragraph 3 above, the state of Wisconsin agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusions from the state of Wisconsin's Medicaid program against TAP, its predecessors, subsidiaries, joint venture owners,

their corporate parents and affiliates, successors and assigns, for the Covered Conduct or for TAP's conviction in the Criminal Action. Nothing in this Agreement precludes the state of Wisconsin from taking action against TAP in the event that TAP is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. The Medicaid Fraud Control Unit for the state of Wisconsin further agrees to refrain from recommending, causing or attempting to cause any administrative action or sanction, including debarment, by any other government agency of the state of Wisconsin for the Covered Conduct or for the conviction in the Criminal Action. TAP acknowledges that the state of Wisconsin does not have the authority to release TAP from any claims or actions which may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to the States' Medicaid programs.

5. This Agreement is expressly conditioned upon resolution of the Criminal Action. In consideration of the Criminal Action, the state of Wisconsin agrees that it shall not investigate, prosecute, or refer for prosecution or investigation to any agency, TAP, its predecessors, subsidiaries, joint venture owners, and their corporate parents and affiliates, successors and assigns for the Covered Conduct.

6. TAP fully and finally releases the state of Wisconsin, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which TAP has asserted, could have asserted, or may assert in the future against the state of Wisconsin, its agencies, employees, servants, and agents, related to or arising from the investigation and prosecution of the Covered Conduct up to the effective date of this Settlement Agreement.

7. TAP waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal prosecution or administrative action. Provided, however, that nothing in this paragraph is intended to, or will operate to, limit the scope of paragraph 5, in which the state of Wisconsin agrees not to prosecute or investigate TAP for certain conduct.

8. The Settlement Amount that TAP must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the state of Wisconsin's Medicaid program where such denial resulted from the Covered Conduct. If applicable, TAP agrees not to resubmit to the program any previously denied claims where such denial resulted from the Covered Conduct and agrees not to appeal any such denials of claims.

9. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Lupron from TAP.

10. Nothing in any provision of this Agreement constitutes an agreement by the state of Wisconsin concerning the characterization of the Settlement Amount for purposes of the state internal revenue laws.

11. In addition to all other payment and responsibilities under this Agreement, TAP agrees to pay all reasonable travel costs and expenses of the state negotiating team. TAP will

pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after all Participating States execute this Agreement.

12. TAP covenants to cooperate fully and truthfully with the state of Wisconsin in any ongoing investigation or investigation commenced within five years of the execution of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom TAP has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct. More specifically, upon reasonable request from the state of Wisconsin:

(a) TAP will make reasonable efforts to facilitate access to, and encourage the cooperation of, its current and former directors, officers, and employees for interviews and testimony relating to the Covered Conduct, consistent with the rights and privileges of such individuals. To encourage the cooperation of such individuals, TAP agrees to advise such individuals in writing that the state of Wisconsin wishes to interview them or seek their testimony, and that the individuals' cooperation is in the best interest of TAP. Cooperation provided pursuant to this subparagraph will include identification of witnesses who, to TAP's knowledge, may have material information related to the state of Wisconsin's inquiry. The testimony referred to in this paragraph includes, but is not limited to, testimony deemed necessary by the state of Wisconsin or a court to identify or establish the source, original location, authenticity, or other evidentiary foundation for any documents and to authenticate such documents in any criminal, civil and administrative investigations and proceedings in which the state of Wisconsin is involved.

(b) TAP will provide copies of non-privileged documents and records in its possession, custody or control relating to the Covered Conduct and relating to the subject of the state of Wisconsin's inquiry. In connection with this, TAP shall provide such technical assistance as is necessary and reasonable to facilitate the state of Wisconsin's access to any computerized information covered by this Paragraph.

Nothing in this agreement shall be construed as a waiver by TAP of its attorney-client privilege or work product privilege. Notwithstanding that fact, the existence of any such privilege does not affect TAP's obligation to comply with this Agreement.

13. Notwithstanding any provision of this Agreement, TAP is not required to (1) request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its directors, employees or agents for following their attorney's advice or for failing to submit to an interview or otherwise cooperate with the state of Wisconsin; or (3) waive any privilege or claim of work product. The failure of any individual to submit to an interview or otherwise to refuse to cooperate with the state of Wisconsin shall not constitute a breach of this agreement by TAP.

14. The state of Wisconsin acknowledges TAP's cooperation in the state of Wisconsin's investigation of drug pricing practices and agrees to communicate the nature and extent of this cooperation to other parties upon the request of TAP. The making of this Agreement, and TAP's provision of information pursuant to it, shall not be construed by the state of Wisconsin as a basis for the exclusion of any of TAP's products from the state of Wisconsin's formulary.

15. TAP represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

16. TAP has entered into a Corporate Integrity Agreement ("CIA") with HHS-OIG. TAP acknowledges that the state of Wisconsin may gain access to and use the pricing information provided by TAP under the CIA, provided that the state of Wisconsin meets its obligations relating to the use and confidentiality of that information as set forth in this Agreement. TAP acknowledges that the CIA does not preclude the state from taking any appropriate action against TAP for future conduct under the state of Wisconsin's laws. The state of Wisconsin hereby agrees to abide by all confidentiality provisions and restrictions contained in the CIA and to afford all such information the maximum degree of confidentiality permitted by law.

17. TAP shall report directly to the Medicaid Program for the state of Wisconsin the average sale price, as defined below, for pharmaceutical and other products for which the Medicaid Program for the state of Wisconsin provides reimbursement (hereafter "Government Reimbursed Products").

(a) AVERAGE SALE PRICE DEFINITION: For purposes of this Agreement, "average sale price" means, with respect to each dosage form, strength and volume of the Government Reimbursed Product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by TAP for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of average sale price are hereafter referred to as the "Relevant Purchasers".) The prices identified in the calculation of the average sale price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-

dated product discounts; free goods; rebates¹; and all other price concessions provided by TAP to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser.

Notwithstanding the foregoing, the average sale price shall not include the value of bona fide charity care or grants.

TAP shall report the average sale price by National Drug Code ("NDC") for each Government Reimbursed Product identified by TAP's NDC. The average sale price reported shall be properly weighted to reflect the volume of sales at each sale price, *i.e.*, for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by TAP to a Relevant Purchaser, net of all price reductions identified above, for a Government Reimbursed Product in a quarter by the total number of units of that product sold in that quarter.

(b) TIME FRAME: Except as otherwise noted below, thirty (30) days after the last day of each calendar quarter, TAP shall report, in accordance with section 17.a. above, the average sale prices of each of its Government Reimbursed Products identified by TAP's NDC to: (1) the Medicaid programs of those States who have executed a state settlement agreement with TAP; and (2) First DataBank Inc.² solely for the purpose of reporting pricing information based on those average sale prices to the Medicaid Programs of those States that have executed a state

¹ The term "rebate" as used in this paragraph does not include any payments made by TAP to the States pursuant to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8)

² If appropriate to reflect changes in the sources from which the Medicaid programs for the Participating States receive pricing information, TAP agrees that, upon the receipt of a written request by any of the Participating States, TAP will report the required information to a drug pricing reporting source other than, and in addition to, First DataBank, provided that the price reporting source agrees to protect the confidentiality of TAP's pricing information in a written agreement containing reasonable provisions equivalent to the confidentiality provisions governing the submission of pricing information to First Data Bank.

settlement agreement. The first such report of average sale prices shall be made no later than 30 days after the end of the first full calendar quarter following the Effective Date of the CIA.

(c) CERTIFICATION: With each report of price information TAP sends to the Medicaid Program for the state of Wisconsin, an appropriate employee or agent of TAP will certify that the price information reported has been reported to First DataBank, or any successor or alternative reporting agency, and that the price information has been calculated in accordance with the methodology described in this Agreement. Said certification shall be in the form annexed to this Agreement as Exhibit "A". TAP agrees that this certification by an appropriate employee or agent of TAP constitutes a certification by TAP.

(d) DOCUMENT RETENTION: TAP shall retain all supporting work papers and documentation relating to the average sale price of its Government Reimbursed Products for eight years after the effective date of the CIA, and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the MFCU for the state of Wisconsin, or a duly authorized representative of the MFCU, pursuant to the confidentiality provisions set forth in paragraph 18 below.

(e) TIME PERIOD. TAP agrees to submit average sale price in accordance with this Agreement for a period of seven years from the effective date of the CIA.

18. (a) TAP and the state of Wisconsin acknowledge that the pricing information provided by TAP is considered to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of TAP. It is further understood that all information provided by TAP shall be made available to the state of

Wisconsin's MFCU upon request. The state of Wisconsin hereby agrees to afford to the pricing information disclosed by TAP the maximum degree of confidentiality permitted by law.

(b) The Medicaid Program of the state of Wisconsin has been advised by the MFCU of the purpose and use of this information. The parties acknowledge that this information may be relied upon by the state of Wisconsin in establishing reimbursement rates for TAP products, provided however the state of Wisconsin will not change reimbursement rates for any TAP product based on this information without conducting meaningful review for all government-reimbursed therapeutically similar products.

19. Unless otherwise stated in writing subsequent to the execution of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

STATE PHARMACY MANAGER
[For the submission of Average Sale Price Data]:

Division of Health Care Financing
P.O. Box 309
Madison, WI 53701-0309

STATE MEDICAID FRAUD CONTROL UNIT
[For legal notices and other purposes]:

MFCU of Wisconsin
Office of the Attorney General
P.O. Box 7857
Madison, WI 53707-7857

TAP

Legal Department

TAP Pharmaceutical Products Inc.
675 N. Field Drive
Lake Forest, IL 60045

20. The undersigned TAP signatory represents and warrants authorization by the Board of Directors to execute this Agreement. The undersigned state of Wisconsin signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the state of Wisconsin through their respective agencies and departments.

21. This Agreement is governed by the laws of the state of Wisconsin.

22. This Agreement is effective on the date of signature of the last signatory to the Agreement.

23. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties; provided, however, this Agreement shall not apply to the products of an acquiring company or a company merging with TAP except to the extent such company, as a result of the acquisition of or merger with TAP, becomes involved in the sales, marketing or pricing of, or Medicaid Drug Rebate program obligations associated with, Government Reimbursed Products (as defined in this Agreement) originally manufactured by TAP prior to the merger or acquisition, in which case the obligations of this agreement shall apply only to those products which had been Government Reimbursed Products when they were manufactured by TAP.

24. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties. As to Paragraph 1 only, TAP and the NAMFCU TAP Negotiating Team may agree in

writing to amend this Agreement by (1) extending beyond 200 days the time in which all Participating States must execute settlement agreements and/or (2) reducing the number and identity of Participating States that must return executed state settlement agreements before funds are disbursed from escrow.

25. Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

For the state of Wisconsin:

By: [Signature] Dated: 9/27/01

Title: Director, Wisconsin MFLU

For the state of Wisconsin Medicaid Program:

By: [Signature] Dated: 9/27/01

Title: Deputy Administrator, DHSF

TAP PHARMACEUTICAL PRODUCTS INC.

By: [Signature] Dated: 12/3/01

H. THOMAS WATKINS
President
TAP Pharmaceutical Products Inc.

By: [Signature] Dated: 12/4/01

DANIEL REIDY
Jones, Day, Reavis & Pogue
77 West Wacker
Chicago, Illinois 60601
Counsel to TAP Pharmaceutical Products Inc.

By: [Signature] Dated: 12/4/01

JOSEPH SAVAGE
Testa, Hurwitz & Thibeault, LLP
125 High Street
Boston, MA 02110
Counsel to TAP Pharmaceutical Products Inc.

EXHIBIT 'A' CERTIFICATION FORM

CERTIFICATION

The undersigned, an agent of TAP Pharmaceutical Products Inc., hereby certifies that the attached average sale price information has been communicated to First Databank or any successor or alternative reporting agency, and that it has been calculated in accordance with the methodology described in the State Settlement Agreement and as further described in TAP's Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services.

Signed _____

Title _____

Date _____