STATE OF WISCONSIN | CIRCUIT COURT BRANCH 7 | DANE COUNTY

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

CIRCUIT COURT
05 MAR 10 PM 3:30
DANE COUNTY, WI

THE STATE OF WISCONSIN'S MEMORANDUM IN RESPONSE TO THE INDIVIDUAL MOTIONS TO DISMISS OF CERTAIN DEFENDANTS

THIS IS AN AUTHENTICATED COPY OF THE ORIGINAL DOCUMENT FILED WITH THE DANE COUNTY CLERK OF CIRCUIT COURT.

JUDITH A. COLEMAN
CLERK OF CIRCUIT COURT

THE STATE OF WISCONSIN'S MEMORANDUM IN RESPONSE TO THE INDIVIDUAL MOTIONS TO DISMISS OF CERTAIN DEFENDANTS

A minority of the defendants have filed individual motions to dismiss this case. The memoranda in support of these motions generally echo (unnecessarily) the argument in the Joint Brief that Wisconsin's complaint must meet the pleading requirements for common law fraud, even though the complaint contains no such claim. In addition, some of these defendants – Abbott, Amgen, AstraZeneca, Baxter, Boehringer Ingelheim, Dey, Johnson & Johnson, Sicor, and TAP – raise other arguments as well.

With respect to the redundant pleading argument contained in virtually all these additional pleadings, Wisconsin adopts the discussion at pp. 37-43 of its main brief. As shown there, Wis. Stat §802.03(2) does not require heightened pleading requirements for any of the consumer protection claims brought in the complaint. Moreover, the complaint would meet §802.03(2) even if that statute applied. The discussion of these points in Wisconsin's main brief disposes of the individual submissions of Merck, Pfizer, Pharmacia and Smith Kline Beecham, which merely repeat the §802.03(2) arguments made in defendants' main brief.

Wisconsin will now briefly discuss the additional issues raised by the remaining defendants.

I. ABBOTT LABORATORIES

Abbott attacks the Medicare Part B claims in Wisconsin's amended complaint. Abbott appears to assert that many of the prescription drugs manufactured by Abbott and covered by Medicare Part B are "multisource" drugs, and that because of the formula used for determining reimbursement levels under Medicare for multisource drugs, Abbott would find it impossible to obtain a "spread" advantage over another manufacturer. This argument has been frequently made

in other average wholesale price ("AWP") cases and has been routinely rejected as a basis for dismissing the complaint on the pleadings. *See, e.g., State of Nevada v. Baxter International, Inc. et al.,* No. CV02-00260 (Washoe Cty. NV, July 16, 2004), at pp. 7-8 (reprinted in Wisconsin's Appendix of Authorities filed with its main brief). Abbott is free to make this argument at trial.

When it does, however, Abbott will run into rough sledding. Even if Abbott did not have a "market the spread" motive as to Medicare for publishing false AWP prices, that will not save it from liability under Wisconsin's claims. Abbott's particular motive for deceiving Wisconsin is not even an element of a violation of Wisconsin's Deceptive Trade Practices Act, Wis. Stat. §100.18. §100.18 involves misrepresentations in connection with a sale. Whether Abbott inflated its AWPs to market the spread or for some other reason, it is still liable for any resulting damage. Abbott has published false AWPs of its Medicare Part B medicines. Even where those products are multisource products and the federal reimbursement is based on the median price of three multisource products, the consumer is paying 20 % of a number that has been inflated by false AWPs. It is true that consumers' payment represents 20 % of a median; however, that median is still based upon the AWPs of the products, which prices were used to calculate the median.

II. AMGEN, INC.

Most of Amgen's separate memorandum is devoted to defendants' argument that the state has failed to plead with enough specificity. As discussed above, Wisconsin has adequately addressed these claims in its primary memorandum. Amgen makes much of the fact that several

other jurisdictions dismissed it from AWP cases on account of those jurisdictions' analogues to Wis. Stat. 802.03(2). However, as Wisconsin's main brief discusses, in Wisconsin, the "particularity" requirement does not apply. As to Amgen, the complaint satisfies the test laid down by this Court in *K-S Pharmacies v. Abbott Laboratories,* No. 94 CV 2384 (Dane Cty. Cir. Ct. 1996), which insisted that the complaint provide enough detail so that "the court can obtain a fair idea of what the plaintiff is complaining, and can see that there is some basis for recovery against each defendant." *Id.* at 5. This standard does not "require that extensive details be included." Rather, the Court required only "a single occurrence linking each defendant to the alleged scheme." *Id.* at 6. As Amgen concedes, Exhibit B to the complaint provides such an example as to Amgen.

Amgen also asserts that if the spread for its product Epogen is "only" 22%, Wisconsin cannot allege that Amgen has falsely reported the AWP of Epogen, since "such a difference is well within the range that the federal government has acknowledged and expected." Amgen Mem., 5. This is simply a rehash of the "no causation" argument in defendants' Joint Memorandum, in which defendants ask the Court to ignore the allegations of the complaint and to take judicial notice of a huge compendium of documents. Wisconsin has answered this argument at length at pp. 22-29 of its main brief.

Amgen claims that Wisconsin's claims relating to Medicare Part B must be dismissed as against Amgen, because Amgen's product Epogen is reimbursed at a statutory rate under Medicare Part B that has remained unchanged for nearly a decade. Amgen Mem. 6. Such assertions by lawyers, unsupported by evidence, cannot be considered on a motion to dismiss. Even if Amgen had supported this assertion by evidence, it would not justify dismissal of the

complaint against Amgen. There is no assertion that Epogen is Amgen's only Medicare Part B product. And as Amgen admits, for non-Medicare payments for Epogen, the AWP-based formula does apply. *Id.*

III. THE ASTRAZENECA DEFENDANTS

Defendants Astrazeneca Pharmaceuticals LP and Astrazeneca LP (hereafter jointly called "Astrazeneca") argue that any claims by Wisconsin as to the drug Zoladex would be barred by a 2003 Settlement Agreement and Release which Astrazeneca attaches as an exhibit. This is an agreement which Astrazeneca made with Wisconsin at the same time as it settled civil and criminal charges brought by the United States based on its practices with respect to Zoladex. Paragraph E2 of the 2003 settlement agreement released Astrazeneca only for only "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," and further says that this results in the discharge of Astrazeneca from "any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the state of Wisconsin for the Covered Conduct." Preamble Paragraph F describes a series of alleged actions by Astrazeneca, most of which are covered by the allegations of the present complaint.

Wisconsin agrees that any claims covered by this release cannot be asserted in the present lawsuit against AstraZeneca. However, that does not result in dismissing all claims asserted in the amended complaint relating to Zoladex. Since the release only covers "Medicaid-related" damages, it does not cover the claim made in the amended complaint on behalf of individuals and third parties who paid in whole or part the Medicare Part B twenty percent co-pay for the

drug Zoladex. Moreover, the settlement agreement leaves undisturbed the State's consumer and antitrust claims to the extent they assert damages that are not "Medicaid-related."

IV. BAXTER INTERNATIONAL, INC.

Defendant Baxter argues that it is not subject to personal jurisdiction in Wisconsin. This is an evasive motion that merely plays games with Wisconsin and with the Court. What Baxter is really arguing is that it sells its drugs in Wisconsin through subsidiaries.

Wisconsin has been attempting to moot this motion by obtaining a stipulation from Baxter that would identify the Baxter subsidiaries that market Baxter's products in Wisconsin and would substitute those subsidiaries as parties. However, as of this writing, Baxter has neither agreed nor refused to agree to such a stipulation. So this unnecessary motion merely adds to this Court's pile of work.

There is no question that the Baxter complex of companies massively markets drugs in Wisconsin. According to Baxter International's Form 10-K Annual Report filed with the Securities and Exchange Commission for the fiscal year ended December 31, 2003:

> Baxter operates as a global medical products and services company with expertise in medical devices, pharmaceuticals and biotechnology to assist health-care professionals and their patients with the treatment of complex medical conditions, including hemophilia, immune disorders, infectious diseases, cancer, kidney disease, trauma and other conditions. The company's products are used by hospitals, clinical and medical research laboratories, blood and plasma collection centers, kidney dialysis centers, rehabilitation centers, nursing homes, doctors' offices and by patients at home under physician supervision. Baxter manufactures products in 29 countries and sells them in over 100 countries.
>
> Baxter International Inc. was incorporated under Delaware law in 1931. As used in this report, except as otherwise indicated in information incorporated by reference, "Baxter International" means Baxter International Inc. and "Baxter" or the "company" means Baxter International and its subsidiaries.

See http://www.sec.gov/Archives/edgar/data/10456/000119312504040579/d10k.htm.

Baxter International's 10-K report details its extensive manufacture and sales of health care-related products through its subsidiaries and also contains extensive references to its business in the United States. *Id.*, pp. 1-9. The report also identifies Baxter Healthcare Corporation as one of its two principal operating subsidiaries. *Id.,* Part III. Baxter Healthcare Corporation is registered to do business in Wisconsin with the State of Wisconsin Department of Financial Institutions. *See* the Department's website, http://www.wdfi.org/apps/ cris/ ?action =details&entityID=2T01115&searchText=baxter&searchBy=searchByEntityNameAlphasort.

On Baxter's company website, the company proclaims:

> Baxter International Inc. (NYSE: BAX) is a global health-care company that, *through its subsidiaries* assists health-care professionals and their patients with treatment of complex medical conditions including hemophilia, immune disorders, kidney disease, cancer, trauma and other conditions. With 2003 sales of $8.9 billion, and approximately 51,000 employees, Baxter applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

See Corporate Overview, http://www.baxter.com/about_baxter/company_profile/sub/corporate_ overview.html. The company's website notes that approximately half of Baxter's sales are in the U.S. and goes on to detail the company's extensive manufacture and sales of pharmaceutical and other health care-related products:

> **Business Overview**
>
> **BioScience**
>
> **2003 Sales: $3.3 billion**
>
> Baxter is a leading producer of plasma-based and recombinant proteins used to treat hemophilia, immune deficiencies and other blood-related disorders. Other biopharmaceutical products include vaccines for the prevention of diseases, and

biosurgery products like fibrin sealant and others used in hemostasis and wound-sealing in surgery. Baxter also is a leading manufacturer of products used to collect, process and store blood for use in transfusion therapies. These include manual blood-collection systems, automated instruments for collecting and separating blood and blood components, leukoreduction filters and pathogen-inactivation systems.

Medication Delivery

2003 Sales: $3.8 billion

Baxter is a leading manufacturer of intravenous (IV) solutions and a range of specialty products. These products meet customer needs across the spectrum of injectable medication delivery, from formulation, packaging and administration through medication management. Specialty products include pharmaceuticals such as critical-care generic injectables, anesthetic agents, nutrition and oncology products. These products work with devices such as drug-reconstitution systems, IV infusion pumps, nutritional compounding equipment and medication management systems to provide fluid replenishment, general anesthesia, parenteral nutrition, pain management, antibiotic therapy, chemotherapy and other therapies.

Renal

2003 Sales: $1.8 billion

Baxter provides a range of products for people with kidney disease. The company is the world's leading manufacturer of products for peritoneal dialysis (PD), a home-based therapy that Baxter helped pioneer in the early 1970s. PD products include specialty solutions, container systems, solution-exchange devices and automated PD cyclers. Baxter also provides products for hemodialysis (HD), a therapy Baxter pioneered in the 1950s, which generally takes place in a hospital or clinic. HD products include HD machines and dialyzers as well as instruments for continuous renal replacement therapy, an acute therapy that represents the fastest growing segment of the HD market.

Id.

In addition, data regarding Wisconsin Medicaid drug reimbursements obtained from the federal Centers for Medicare and Medicaid Services and its predecessor the Health Care Financing Authority drug rebate utilization files indicates that for the period 1995-2004, an entity

referred to as "Baxter Healthcare" was reimbursed a total of $8.681 million, and an entity referred to as "Baxter Healthcare Corporation" was reimbursed a total of $4.035 million.

In short, Baxter's motion to dismiss is a shell game. Baxter belongs in this lawsuit, whether through Baxter International or through the appropriate subsidiaries. If Baxter does not withdraw this motion, this Court should defer ruling on it and require Baxter to submit to discovery as to which of its subsidiaries does the manufacturing and marketing of drugs in Wisconsin. Of course, in the alternative, Baxter might spare everyone this game of hide-and-seek by executing an appropriate stipulation, just as defendant Boehringer Ingelheim, discussed below, did.

V. THE BOEHRINGER INGELHEIM DEFENDANTS

The Boehringer Ingelheim defendants (Boehringer Ingelheim Corporation, or "BIC")) originally made an argument like Baxter's, arguing that it does not manufacture, distribute, or sell any drugs. However, this argument has been mooted by a stipulation between Wisconsin and BIC that will substitute the proper defendants.

VI. DEY, INC.

Defendant Dey's individual memorandum consists mostly of assertions that the complaint's allegations as to it are wrong. Specifically, Dey argues that Wisconsin has no claim against it because Wisconsin uses prices calculated by the U.S. Department of Justice and disseminated by the U.S. Department of Health and Social Services on September 8, 2000, as well as Maximum Allowable Cost ("MAC") prices set by the Wisconsin Department of Health

and Family Services for Medicaid reimbursement purposes, and that Dey had no part in setting these prices. Dey Mem. pp. 2-3. This argument, unsupported by evidence, is improper on a motion to dismiss. It should be ignored by the Court.

If Dey ever introduces evidence in support of these arguments, Wisconsin will introduce evidence to show that Dey's assertions are false. Wisconsin disputes Dey's specific claim that Wisconsin directly adopted the Justice Department prices for Medicaid reimbursement for Dey's drugs, including those listed by Dey at p. 3 of its Memorandum. Wisconsin will prove that (1) Dey's drug with the most utilization under Wisconsin Medicaid, Ipratroprium [Bromide] ($2,920,000 for 1998-2003), was reimbursed until 2001 by reference to the AWP *set by Dey itself;* (2) three of the four Dey drugs with the largest utilization reimbursed by Wisconsin Medicaid were *also* reimbursed at various times based on the falsely inflated AWPs reported by Dey; and (3) of those few Dey drugs which were reimbursed based upon a MAC figure determined by Wisconsin, the reimbursements were not set at the amounts of the Justice Department figures, which Dey represents to this Court to have been the sole basis for Wisconsin Medicaid reimbursement. Dey Mem., pp. 2-3.

Dey next disputes the complaint's description of its lawsuit against First DataBank. See First Amended Complaint ¶40. Again, this is no basis for dismissing the amended complaint.

Dey has already got itself into enough trouble with its drug pricing practices. It does not help itself by filing briefs like this one in which it tries to explain away, without offering any evidence, what it has done in the past. With respect to Dey's lawsuit against First DataBank, Inc., at the appropriate time, Wisconsin will introduce evidence showing that (1) in *Dey, Inc. v. First DataBank, Inc., et al.*, Napa County California, Superior Court, Case No. 26-21019, Dey

sought an *ex parte* order to enjoin defendants from publishing true and accurate AWPs for Dey's products and to force defendants to publish Dey's false inflated AWPs; (2) in the complaint in that case, Dey argued that First DataBank ("FDB") should have listed Dey's AWP for Ipratopium Bromide in 609 vial cartons at $105.60, instead of the lower figure of $29.25 which FDB published, ostensibly to reflect the *true* average wholesale price Dey was actually charging its customers; (3) that Dey's own Manager of Sales/Marketing Services, Russell Johnson, made the following statement in support of its application for an *ex parte* restraining order in that case:

> Because of the prominence of AWP in the reimbursement formulas throughout the country, a disproportionately low AWP will jeopardize the sale of a generic manufacture's product because that manufacturer's products will be reimbursed at a lower rate than competitors' products that have a higher AWP. (¶ 15). * * *
>
> Since third party reimbursement now accounts for approximately 85% of the total payments made for pharmaceuticals nationally, as a result of the reporting of AWP by First DataBank and Medi-Span, pharmacies will simply refuse to buy Dey's products because they cannot be adequately reimbursed for Dey's products as compared to Dey's competitors' products. (¶ 36).

To sum up: Dey's individual motion could stand as a symbol of what is wrong with defendants' entire approach to this case. The complaint's allegations control this motion, not what defendants' lawyers choose to say about those allegations.

VII. JOHNSON & JOHNSON

Johnson & Johnson argues that since Wisconsin reimburses pharmacies at less than defendants' inflated AWPs, it is "inconceivable" that the State ever believed Defendants' AWPs were accurate. J&J Mem., p. 1. This argument is a rehash of the "no causation" arguments in defendants' Joint Memorandum. It is fully answered at pp. 22-29 of Wisconsin's response to that Joint Memorandum.

Defendants' next argument is that Johnson & Johnson "does not sell drugs." J&J Mem., p. 3. This appears to be another Baxter-style argument, discussed above, except in that this case, Johnson & Johnson does not even offer evidence. The short answer is that the complaint alleges that Johnson & Johnson does sell drugs. On this motion to dismiss, the complaint governs.

Without offering any evidentiary support, Johnson & Johnson asserts that Wisconsin knew that three products sold by Defendants could be purchased at prices below the AWPs that Defendants caused to be published, because the Wisconsin Department of Corrections had purchased these products at one point for less than Johnson & Johnson's reported AWPs. The answer is the same: the complaint governs, not unsupported lawyers' statements in briefs on a motion to dismiss.

Moreover, it would not matter even if Johnson & Johnson had supported its motion with evidence. As Wisconsin's main brief discusses in detail, the issue is not whether Wisconsin knew that AWPs can be discounted; indeed, the complaint specifically states that at various times Wisconsin did receive information that certain drugs could be discounted. Moreover, the attempt to charge Wisconsin agencies with knowledge of defendants' scheme is particularly tenuous in the present situation, because Wisconsin's Department of Corrections does not do the actual buying of Johnson & Johnson products. Instead, the Department of Corrections is a sub-member of a multi-state purchasing organization composed of the majority of states who make direct pharmaceutical purchases for the needs of specialized state agencies or facilities (i.e., Corrections, Central Wisconsin Center for the Developmentally Disabled, Mendota Mental Health Institute, etc.). The organization seeks to obtain the lowest prices possible for its members by using their collective purchasing power in price negotiations with manufacturers.

The J & J defendants attach a hearing report from Congress showing that an employee of Ven-A-Care in Florida apparently told a Congressional subcommittee in 2001 that he did not believe Johnson & Johnson "engaged in this type of gaming the system." Wisconsin does not understand this argument. The opinion of a third party's official cannot possibly control this motion to dismiss. As Wisconsin pointed out in its main brief (p. 19), this is a particularly egregious example of the misuse of evidentiary materials in a motion to dismiss.

VIII. SICOR, INC.

Defendant Sicor, Inc. argues that it does not contract with pharmacy benefit managers and, hence, that particular aspect of the complaint should not apply to it. Once again, this kind of argument is improper at the motion to dismiss stage because it relies on facts outside the complaint. If the complaint says something about a defendant that the defendant thinks is factually incorrect, then the defendant should deny the allegation in its answer, not raise the issue in a motion to dismiss.

In any event, even if Sicor is right, this allegation would not lead to any ruling on a motion to dismiss. The allegations about pharmacy benefit managers are just a part of the entire scheme attributed to Sicor, among other defendants, and Sicor does not address these other aspects of the scheme pled against it.

IX. TAP PHARMACEUTICAL PRODUCTS

TAP Pharmaceutical Products, Inc. makes the usual duplicative argument that the amended complaint fails to plead with the requisite particularity. Wisconsin's main brief sufficiently answers this argument. The argument is particularly silly with respect to TAP, who

has pled guilty to criminal indictments based on conduct alleged in the amended complaint. First Amended Complaint, ¶51. If any defendant in this case knows exactly what it is accused of doing wrong, it is TAP.

In an argument similar to that made by defendant Astrazeneca (see above), TAP argues that the State should be barred from seeking further monies for the Medicaid Program relating to its drug Lupron. As support, TAP quotes from and attaches a copy of a settlement agreement. TAP claims that the agreement released it from "any liability involving the marketing, sale and pricing of Lupron." TAP Mem. p. 1.

This argument is essentially identical to AstraZeneca's, and the answer is the same. The TAP Agreement settled the state's Medicaid claim, but by its very language it did not release TAP from all liability, especially to other persons defrauded by its admittedly wrongful and criminal conduct. Thus, it does not affect the claims made on behalf of individuals and third parties who paid in whole or part the Medicare Part B twenty percent co-pay for the drug Lupron nor the State's consumer and antitrust claims.

TAP is a current defendant in a class action lawsuit filed in federal court in Massachusetts. TAP appears to argue (1) that a settlement has been reached in this federal case that settles the claims both of Wisconsin and of all Wisconsin citizens on whose behalf Wisconsin brings claims; (2) that Judge Stearns, who is hearing that case, has issued an injunction that prevents Wisconsin from proceeding with those claims in this lawsuit; and (3) hence all claims in this suit based on Lupron should be dismissed. This argument has no merit.

First, TAP has utterly failed to provide this Court with evidence to support this argument, much less sufficient information to justify enjoining a sovereign state from proceeding in

Wisconsin courts. TAP does not attach the settlement document, so there is no way of telling whether the claims that have purportedly been settled are the same as Wisconsin's. It does not attach Judge Stearns' order, so there is no way of telling whether that order purports to enjoin Wisconsin or not, much less to enjoin it from pursuing the particular claims it pursues here.

Second, TAP gives no information as to whether this purported class action settlement has been finally *approved* by the federal court. A class action settlement requires the approval of the federal court pursuant to F. R. Civ. P. 23(e) before it becomes binding on any class member. In actual fact, it is Wisconsin's understanding that Judge Stearns has given only *preliminary* approval to the class action settlement in the MDL litigation; that a hearing will not occur until at least April 13, 2005 to consider whether to give final approval; and that the First Circuit Court of appeals has granted a petition for leave to appeal pursuant to 28 U.S.C. §1292(b) by two class members who are contesting even the *preliminary* approval. Thus, as of this time, there is no final order approving any settlement in that case, much less an order that binds Wisconsin.

Third, even if TAP were to introduce the actual court order in question, and even if that court order purported to enjoin a sovereign State from proceeding with its own claims in a Wisconsin State court, there would be a gigantic issue of whether a federal court has the power to issue such an injunction against a State.

Fourth, if a class action settlement covering Wisconsin's claims ever gets final judicial approval in the federal case, Wisconsin will be given the opportunity to opt out of that settlement, and it will almost certainly do so. Accordingly, Wisconsin's claim against TAP in this Court will proceed no matter what.

Fifth, even according to TAP's own argument, all the order in the federal case does is

issue a stay pending further proceedings. A stay order is no basis for *dismissing* this lawsuit against TAP.

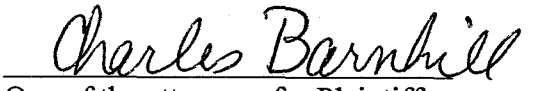
In short, TAP has provided this Court with no evidence that would allow it even to *stay* this lawsuit as against TAP, much less to dismiss TAP as a defendant.

CONCLUSION

Wisconsin respectfully requests that the Court deny the defendants' individual motions to dismiss.

Dated this 10th day of March, 2005.

Respectfully submitted,



One of the attorneys for Plaintiff

PEGGY A. LAUTENSCHLAGER
Attorney General (State Bar #1002188)

MICHAEL R. BAUER
Assistant Attorney General (State Bar #1003627)

CYNTHIA R. HIRSCH
Assistant Attorney General (State Bar #1012870)

FRANK D. REMINGTON
Assistant Attorney General (State Bar #1001131)

Wisconsin Department of Justice
PO Box 7857
Madison WI 53707-7857
(608) 266-0332 (MRB)
(608) 266-3861 (CRH)
(608) 266-3542 (FDR)

CHARLES BARNHILL
State Bar #1015932

WILLIAM P. DIXON
State Bar #1012532

ELIZABETH J. EBERLE
State Bar #1037016

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