

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

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**NOTICE OF MOTION AND MOTION FOR PROTECTIVE ORDER**

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**PLEASE TAKE NOTICE** that Defendants Johnson & Johnson, Janssen Pharmaceutica, Inc. (formerly Janssen Pharmaceutica Products, LP), Ortho-McNeil Pharmaceutical, Inc., Ortho Biotech Products, LP, and McNeil-PPC, Inc. (collectively, the “J&J Defendants”), will bring the following motion at a date and time to be determined by the Special Master:

**MOTION**

Pursuant to WIS. STATS. § 804.01(3)(a), the J&J Defendants, by counsel, respectfully move the Court for an order barring the State from proceeding with the § 804.05(2)(e) depositions of J&J Company representatives currently noticed for May 2, 2006.

**QUESTION PRESENTED**

This motion presents a question of fundamental importance to the sound and efficient management of discovery in this case, namely whether a defendant can be compelled to produce multiple witnesses on issues that are not in dispute, where the topics have already been

covered in other depositions that have been provided to the State, and where the State has failed to identify any reason why the previous deposition testimony does not fully address the State's legitimate discovery requirements. If Your Honor does not impose sensible limits on the State's right to take depositions in these circumstances, the cost and burden of discovery on the defendants will increase dramatically, even though the incremental benefit to the State will be minimal. This is especially true where, as here, there are less costly and equally effective discovery alternatives that would serve the State's needs as well or better than the requested depositions.

## **BACKGROUND**

### **A. The AWP Cases**

1. As Your Honor knows, this case is one of many relating to the pharmaceutical industry's alleged misuse of a reimbursement benchmark known as "average wholesale price" or "AWP." The State alleges that 37 pharmaceutical companies published "phony and inflated" AWP's for all of their drugs, resulting in overpayments by the State's Medicaid program and Wisconsin's citizens. Although discovery disputes are not the occasion to debate the merits of the parties' claims and defenses, an understanding of the broader legal landscape in which this case is being litigated will help to place the State's discovery requests in context and will serve to illustrate why the requests are unduly burdensome as to the J&J Defendants.

2. The first thing to understand about the AWP cases is that there are a lot of them. The largest, and the most procedurally advanced, is a multi-district, class-action litigation pending in Federal District Court in Boston, *In re Pharmaceutical Industry Average Wholesale*

*Price Litigation*, MDL 1456. That case involves the use of AWP by the federal Medicare program and by private insurance companies.

3. In addition to the federal case in Boston, a number of States have filed individual suits challenging AWP in the context of their state Medicaid programs. These cases typically fall into one of two groups. Some States, such as West Virginia, Connecticut, Florida, Texas, and New York, sued a small number of defendants for conduct pertaining to a limited number of drugs. (None of these States sued the J&J Defendants.) Other States, like Wisconsin, have sued virtually the entire pharmaceutical industry for conduct relating to nearly all of their drugs. Discovery in the industry-wide cases is just getting underway.

4. So far, the only AWP case that has gone to trial is the West Virginia case against Schering-Plough. That trial resulted in a defense verdict.

**B. AWP-Related Discovery of the J&J Defendants in the MDL**

5. Several of the defendants in this case, including the J&J Defendants, have been through extensive discovery in the MDL. The J&J Defendants, for example, produced hundreds of thousands of documents relating to 36 self-administered and physician-administered drugs. They produced, in addition, a mass of electronic data pertaining to millions of individual sales, chargeback and rebate transactions. A total of 28 witnesses were deposed. The cost incurred in responding to discovery in the MDL ran to several million dollars.

**C. The State's Initial Discovery Requests**

6. Early on in this case, the J&J Defendants offered to give the State full access to all of the discovery taken by the MDL plaintiffs. The State rejected this offer because it said it did not wish to be on the receiving end of a "document dump."

7. The State did, however, ask for and receive copies of all of the MDL deposition transcripts and exhibits. In addition, at the State's request, the J&J Defendants

produced information relating to the “average manufacturer prices” or “AMPs” that it reports to the federal government. AMP calculations are based on a statutory formula designed to estimate the price that wholesalers pay the manufacturer for drugs distributed to the retail pharmacy class of trade.

8. The State first served a deposition notice on the J&J Defendants on November 4, 2005. That Notice appears to have been prompted by an exchange of correspondence between the parties that occurred on November 2 and November 3. Copies of the State’s Deposition Notice and the two letters that preceded it are attached as Exhibits 1, 2, and 3.

9. The November 2 letter (Exhibit 2) was a letter from counsel for the J&J Defendants to counsel for the State. The letter sets forth objections to certain of the State’s discovery requests and asked the State to provide support for its allegation that the J&J Defendants “caused phony and inflated wholesale prices” to be published with respect to their drugs. Counsel for the J&J Defendants indicated in the letter that the J&J Defendants were not aware of any such evidence.

10. The November 2 letter prompted an immediate (and intemperate) reply. The State’s counsel wrote (Exhibit 3):

But this behavior [objecting to the State’s discovery requests] pales in comparison to the disingenuous position taken in your most recent letter. There you assert that your refusal to comply with our discovery requests is based at least in part on the fact that your client has no evidence that their published drug prices were and are phony and inflated. This is simply untrue and you know it. Your clients have extensive information (including AMPs) which show that the targeted drugs were never sold at the published Average Wholesale Price. Indeed, we all know that the published AWP of your clients’ drugs were not the averages of any price—they were not prices at all. In fact, in your motion to dismiss you defend your clients on the theory that Wisconsin should have known that they

were participating in deceptive behavior, not that you didn't engage in it. In such a context, your assertion that that [sic] your client lacks any evidence of phony and inflated prices for their drugs is truly unbelievable and it undermines your personal credibility.

**D. The Ensuing Discovery-Related Discussions**

11. Although dismayed by the personal nature of counsel's attack, the J&J Defendants nevertheless perceived that it should be possible to move the ball forward in a constructive manner by addressing directly the State's assertion that evidence that a company does not sell its drugs at AWP is evidence that the company is engaged in some sort of deception. Because AWP does not represent a selling price and is not intended to represent a selling price, it was obvious from the exchange of letters that the parties were drawing very different conclusions from the same, undisputed facts.<sup>1</sup>

12. Accordingly, on November 16, 2005, the J&J Defendants again wrote to the State's counsel. The letter described, in general terms, how the J&J Defendants priced their products to wholesalers and how those prices related to AWP. Among other things, the letter (Exhibit 5) explained that:

- The J&J Defendants sell their medicines to wholesalers at a published list price known as Wholesale Acquisition Cost or WAC, minus a small prompt pay discount;
- Depending on the publisher, the published AWP's for the J&J Defendants' medicines are 120% or 125% of WAC (or, alternatively, the WAC is 16 2/3% or 20% below AWP);
- The J&J Defendants do not know the average prices at which wholesalers sell their products to retail pharmacies, but that these figures could be calculated, if at all, from sales records maintained by the wholesalers;

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<sup>1</sup> The judge who presides over the MDL litigation retained an independent expert, Professor Ernst R. Berndt of MIT, to help her understand how pharmaceuticals are priced and distributed. His report includes a neutral description of AWP and its use as a reimbursement benchmark. If Your Honor is interested in reading more about AWP, we have provided a short excerpt from Dr. Berndt's report as Exhibit 4.

- It is common knowledge that wholesaler mark-ups on the pharmaceutical products sold to retail pharmacies are very thin due to intense price competition and economies of scale at the wholesaler level; and
- AWP is not the price normally paid to wholesalers by the retail class of trade, and is not used or understood to represent the price normally paid to wholesalers by the retail class of trade.

13. The November 16 letter asked plaintiff to consider whether, in light of this explanation, the requested depositions were really necessary. In subsequent telephone conversations counsel for the J&J Defendants indicated that the J&J Defendants were willing to stipulate to the accuracy of the facts outlined in the November 16 letter. The stipulation was offered in order to make clear to the State that, at least as far as the J&J Defendants were concerned, there was no reason to incur the burden and expense of in-person depositions on issues that were not disputed.

14. The State's counsel initially agreed to think about whether the State would be willing to forego depositions on these issues. He even prepared a draft stipulation which he said would be an acceptable alternative. Although the draft stipulation was not entirely accurate, counsel for the J&J Defendants undertook to revise the stipulation and told plaintiff's counsel that he was optimistic that the stipulation could be worded in a way that should be agreeable to both sides.

**E. The State's Revised Deposition Notice**

15. On March 24, 2006, before counsel for the J&J Defendants was able to revise the stipulation, the State served a Revised Notice of Deposition. Counsel for the State confirmed that the revised notice was served because the State had decided that it was no longer willing to consider a stipulation as an alternative to depositions. The State's revised deposition notice is attached as Exhibit 6.

16. The State's change of heart led the J&J Defendants to write another letter explaining why they continued to believe that the requested depositions were unnecessary and unduly burdensome. This second letter, dated April 13, 2006, provided the State with a detailed road map to the prior testimony on the issues specified in the revised deposition notice, including specific page citations to the depositions and exhibits that had already been provided. The April 13 letter is attached as Exhibit 7.

17. Following receipt of the April 13 letter, the State indicated that it was not willing to reconsider its position. Its reasons are set forth in the letter attached as Exhibit 8. In essence, the State (1) questions whether deposition testimony taken in another case would be admissible in Wisconsin (even though the J&J Defendants are willing to agree that it is admissible or, alternatively, to provide the same information by stipulation), (2) questions whether the testimony of individual witnesses would be "binding" on the J&J Defendants (even though several of the depositions were taken pursuant to Fed. R. Civ. Pro. 30(b)(6)), and (3) asserts that the State is entitled to take additional depositions so that the testimony is available in a "form easily understood by the jury" (even though the State does not argue that the existing testimony could not be understood by a jury).

18. This motion followed.<sup>2</sup>

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<sup>2</sup> The State demands a witness who could speak on behalf of "J&J" with respect to each subject. No such witness can be provided. Johnson & Johnson is a holding company. It does not make, market, or sell pharmaceuticals. Rather, it provides shared services (e.g., a law department) to various wholly-owned subsidiaries, only some of which are engaged in pharmaceutical sales. The persons most knowledgeable about pharmaceutical pricing, AWP, etc. work at the pharmaceutical operating companies, not at Johnson & Johnson.

## ARGUMENT

### **I. The Requested § 804.05(2)(e) Are Needlessly Duplicative and Unduly Burdensome.**

The J&J Defendants do not question the State's right to take the discovery it needs to develop and present its case. Indeed, as evidenced by the fact that documents and data have already been produced, and a vastly larger repository of documents has been offered and rejected, the J&J Defendants are committed to complete mutual disclosure of the relevant facts.

At the same time, the J&J Defendants, who have already spent millions of dollars responding to discovery in the MDL, should not have to provide duplicative deposition testimony when the State can avail itself of equally effective but less costly alternatives. Discovery is not so blunt an instrument that it can be had in any form, for any purpose, without regard to cost, convenience and necessity.

Striking the appropriate balance between the benefits and burdens of discovery is essential to the sound administration of justice. WIS. STATS. § 804.01(3)(a) thus permits the court to make any order that justice requires to "protect a party from discovery that would result in annoyance, embarrassment, oppression, or undue burden or expense." *Vincent & Vincent, Inc. v. Spacek*, 102 Wis. 2d 266, 271-72 (Ct. App. 1981). See Wis. Stat. § 804.01(3)(a)(1), (4); see also 8 Wis. Prac., Civil Discovery § 1.11 (the Court has "broad powers" to "regulate or prevent discovery" by issuing a protective order).

Discovery should be curtailed where it is duplicative and unnecessary. In *Cruz v. All Saints Healthcare Sys., Inc.*, for example, the Court of Appeals upheld the trial court's discretionary limit on class certification discovery because the record already contained "ample facts" to resolve the issue of class certification, making the discovery sought "unnecessary." 242 Wis. 2d 432, 446, 625 N.W.2d 344, 351-52 (Wis. Ct. App. 2001). Similarly, Wisconsin courts

may curtail discovery where the facts are already known. *See City of Neenah v. Alsteen*, 30 Wis. 2d 596, 604, 142 N.W.2d 232, 237 (Wis. 1966), citing *Am. Food Prod. Co. v. Am. M. Co.*, 151 Wis. 385, 399, 138 N.W. 1123 (Wis. 1912) and *Badger Brass Mfg. Co. v. Daly*, 137 Wis. 601, 609, 119 N.W. 328 (Wis. 1909) (deposition quashed where the “matter to be inquired into was obviously within the knowledge” of the parties).

The State’s request for depositions is unduly burdensome because it calls for testimony on topics where the answers are known and undisputed. Subjects 1 and 2, for example, call for witnesses who will provide testimony that the J&J Defendants have no evidence that wholesalers charge retail pharmacies AWP or more than AWP. (Exhibit 6 at Topics 1 and 2). This is a fact that the J&J Defendants do not dispute, and which the State admits it already knows. *See* Barnhill Letter, Exhibit 3 (“*we all know* that the published AWP’s of your clients’ drugs were not the averages of any price—they were not prices at all.”) (emphasis added). It is also a fact that is firmly documented in the MDL discovery. Moreover, it is something the J&J Defendants would be willing to stipulate is true. Requiring defendants to provide duplicative deposition witnesses on subjects established in prior depositions and known to the State would be pointless, inefficient, and burdensome.

The same is true of the other topics listed in the deposition notice. Subject No. 3 calls for witnesses who can testify about contacts with the price reporting services, First Data Bank and Redbook. This subject was also explored fully in the MDL discovery record (Exhibit 7 at 3):

**Subject No. 3:** This has been the subject of extensive testimony in the MDL. The relevant depositions and exhibits have already been produced to you. You might want to review the depositions Kurt Barry and William Parks (Janssen), Bob Spurr (Ortho McNeil Pharmaceuticals), Tom Hiriak and Elaine Kling (Ortho Biotech), and Rock Magnotta (McNeil Consumer). You might also take a

look at the exhibits marked during those depositions, particularly Barry Exhibits 10, 11, 12, 13, 14, 15, 16 and 17, Parks Exhibit 3, Kling Exhibits 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 16, and Magnotta Exhibits 4 and 5.

Subject No. 4 asks for depositions from witnesses who “communicated to First Data Bank or the Red Book that the published Average Wholesale Prices of their drugs were neither a price that was actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade.” The J&J Defendants cannot produce such a witness, because the AWP does not even purport to represent the price “actually paid by the retail class of trade.” Nevertheless, the J&J Defendants’ communications with the pricing services were fully explored in the MDL depositions (Exhibit 7 at 3):

**Subject No. 4.** I have not been able to identify a witness who would be able to testify on this subject because AWP is not, and does not purport to be, “a price that was actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade.” Rather, as established by the depositions we previously provided, the Johnson & Johnson defendants have historically submitted AWPs to publishers and wholesalers that were 120% of the list price. The publishing companies sometimes published the AWP figures that the Johnson & Johnson operating companies submitted, but they sometimes published different AWPs. *See, e.g.,* Deposition of Tom Hiriak at 205-06; Deposition of John Dempsey at 92; Deposition of Rock Magnotta at 91-93, 108-09; Deposition of Robert Spurr at 92-94; and Deposition of William Parks at 66-67, 72-76, 81-83.

Subject Nos. 5 and 6 relate to the AMP figures that the J&J Defendants report to the federal government, and which have already been produced to the State. In particular, the State wants witnesses who can testify about how AMPs are calculated and whether there is evidence that “actual average wholesale prices” are greater than AMP.

The State already has, and can readily compare, the J&J Defendants’ WAC and AMP figures. Although the term “actual average wholesale price” is not defined by the State, it appears to be the price the *wholesalers* charge their retail pharmacy customers. The wholesaler’s

price is determined by the wholesaler's mark-up, which is something the wholesaler determines. It is not an appropriate topic for a § 804.05(2)(e) witness because it is not something that a pharmaceutical company's employees could be expected to know any better than the State. As explained in counsel's letter (Exhibit 7 at 2):

The Johnson & Johnson companies have already produced to you AMP data reflecting the prices that the wholesalers pay for drugs distributed to the retail pharmacy class of trade, including relevant price concessions from the manufacturer. The prices that wholesalers in turn charge retail pharmacies is information maintained by the wholesalers, not by Johnson & Johnson's operating companies. Although there is anecdotal information that wholesaler margins are extremely thin (*see* Deposition of William Parks at 80-81), that information is as available to the State of Wisconsin as it is to Johnson & Johnson's operating companies.

The State must know that manufacturers cannot reasonably be expected to provide binding testimony about the prices charged by non-parties. In fact, after years of discovery in the MDL, counsel representing the MDL class plaintiffs admitted that they did not know the prices that the wholesalers charged their customers (in that instance, physicians):

Net acquisition cost is apparently what doctors ultimately pay to acquire the drug. We don't know what that is. It's completely irrelevant to our claims. Every J&J witness we asked, do you know what doctors pay to acquire your drug, the answer is no. We know what we sell to the wholesaler for. We have no idea what the wholesaler's mark-up is. To answer this we would need to know the information that J&J disclaims any knowledge of.

Tr. of Hr'g before Magistrate Judge Bowler (Nov. 9, 2005) at 14 (Exhibit 9).

## **II. The § 804.05(2)(e) Witnesses Cannot Be Made to Appear for Depositions in Madison Wisconsin.**

The State has insisted that the defendants' witnesses travel to Madison, Wisconsin because it is more convenient for the State's counsel. If the depositions are to proceed at all, they should take place where the witnesses work or at some other agreed-upon location. This issue has already been briefed and argued and will be decided in connection with the motion

filed last week by Merck & Company, Inc. Needless to say, the J&J Defendants will be guided by Your Honor's ruling on that motion.

**CONCLUSION**

The J&J Defendants respectfully request that their motion for a protective order be granted.

Dated: April 26, 2006

Respectfully submitted,

By: Donald K Schott

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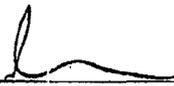
# **Exhibit 1**



3. What contacts Johnson & Johnson, or its subsidiaries, have had with First Data Bank or the Red Book about any of the targeted drugs.
4. Whether Johnson & Johnson, or any of its subsidiaries, ever communicated to either First Data Bank or the Red Book that the published Average Wholesale Prices of their drugs were neither a price that was actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade and, if so, when such communications took place and of what they consisted.
5. The Average Manufacturer's Price (AMP) reported to the federal government of each of the targeted drugs in each year since 1993.
6. Any evidence which shows that the actual average wholesale price at which any of the targeted drugs sold in any given year was greater than the AMP.

The designated deponents shall bring with them 1) all evidence or information showing that any of the targeted drugs was sold at a price equal to or greater than the published AWP from 1993 to the present, 2) for the same period all evidence or information showing that actual average wholesale prices of its targeted drugs were less than the published AWP, 3) for the same time period any evidence of communications between Johnson & Johnson and the Red Book about or concerning any of the targeted drugs, 4) for the same time period the reported AMPs of each targeted drug, and, 5) for the same time period any evidence defendant has showing that the actual average wholesale price of any of the targeted drugs was greater than the reported AMP.

Dated this 4<sup>th</sup> day of November, 2005.

  
\_\_\_\_\_  
One of Plaintiff's Attorneys

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- JANSSEN PHARMACEUTICAL PRODUCTS

Drug

DURAGESIC  
HISMANAL  
NIZORAL  
PROPULSID  
REMINYL  
RISPERDAL  
SPORANOX

- JOHNSON & JOHNSON.

Drug

CONCERTA  
DITROPAN  
ELMIRON  
MYCELEX

- MCNEIL PHARMACEUTICAL

Drug

HALDOL  
LEVAQUIN  
MOTRIN  
NICOTROL  
PANCREASE  
REGRANEX  
TOPAMAX  
TYLENOL  
ULTRACET  
ULTRAM

- ORTHO PHARMACEUTICAL CORPORATION

Drug

CYCLEN  
EVRA  
FLOXIN  
GRIFULVIN  
LEUSTATIN  
MICRONOR  
MONISTAT-D  
NOVUM  
ORTHO-CEPT  
PROCRIT  
RETIN-A  
SPECTAZOLE  
TERAZOL  
TRI-CYCLEN

# **Exhibit 2**

# Patterson Belknap Webb & Tyler LLP

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November 2, 2005

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**By Fax**

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**Re: State of Wisconsin v. Amgen, et al.**

Dear Chuck:

Thank you for your letter of November 1, 2005. I agree with you that we were unable to reach agreement on overall discovery issues. I want to reiterate, however, that my clients remain willing to produce the extensive materials identified in my prior letters, and that they are willing to do so without prejudice to the State's position that it is entitled to even more.

In addition, depending on the State's response to Defendants' First Set of Interrogatories and Document Requests, my clients may be willing to reconsider their position with respect to the production of sales data relating to drugs that were not the subject of the MDL proceedings. Those requests ask the State to identify its alleged "evidence that the manufacturers caused phony and inflated wholesale prices to be published with respect to each of the listed drugs" (the "listed drugs" are referred to in your letter as "targeted drugs.") My clients are not aware of any such evidence with respect to any targeted drugs manufactured by them, but if it turns out that the State has such evidence, we will take that evidence into account when formulating our response to the State's motion.

Sincerely yours,

Andrew D. Schau

cc: Don Schott

# **Exhibit 3**

MINER, BARNHILL & GALLAND, P.C.

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November 3, 2005

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Via Telefacsimile  
(212) 336-2222

Re: *State of Wisconsin v. Amgen Inc., et al.*  
Dane County Case Number 04-CV-1709

Dear Andy:

Your refusal to produce materials we have requested in connection with the drugs we identified for your client on the ground that a motion to dismiss is pending is unsupportable. The Court has endorsed no such stay of discovery. Moreover, your position seems completely hypocritical since you are now seeking discovery from us about all of our targeted drugs, including those for which you are refusing to produce information.

But this behavior pales in comparison to the disingenuous position you take in your most recent letter. There you assert that your refusal to comply with our discovery requests is based at least in part on the fact that your client has no evidence that their published drug prices were and are phony and inflated. This is simply untrue and you know it. Your clients have extensive pricing information (including AMPs) which shows that the targeted drugs were never sold at the published Average Wholesale Price. Indeed, we all now know that the published AWP's of your clients' drugs were not averages of any price—they were not prices at all. In fact, in your motion to dismiss you defend your clients on the theory that Wisconsin should have known that they were participating in this deceptive behavior, not that it didn't engage in it. In such a context

Andrew D. Schau  
Page Two  
November 3, 2005

your assertion that that your client lacks any evidence of phony and inflated prices for their drugs is truly unbelievable, and it undermines your personal credibility.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles E. Barnhill'. The signature is stylized with a large initial 'C' and a long horizontal stroke extending to the right.

Charles E. Barnhill

CB:jiz

Cc: Mr. Donald K. Schott

# **Exhibit 4**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY )  
AVERAGE WHOLESAL PRICE )  
LITIGATION )

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M.D.L. No. 1456  
Civil Action No. 01-12257-PBS

Judge Patti B. Saris

REPORT OF INDEPENDENT EXPERT  
PROFESSOR ERNST R. BERNDT  
TO JUDGE PATTI B. SARIS

FEBRUARY 9, 2005

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management firms.<sup>8</sup> Plaintiffs' expert Dr. Raymond S. Hartman simply calls the proposed class "large".<sup>9</sup>

13. In their December 17, 2004 amended motion for class certification, Plaintiffs have named end-payor classes as follows: (i) physician-administered drugs class (Medicare Part B co-pay and private system physician-administered drugs); (ii) self-administered and specialty pharmacy drugs class (third-party and co-payor class for self-administered drugs), further subdivided into (iia) brand name sub-class and (iib) generic sub-class; (iii) RICO class for self-administered and specialty drugs, further divided into (iiia) brand name sub-class and (iiib) generic sub-class. The proposed class period is January 1991 to the present.<sup>10</sup>

#### **B. The Role of AWP**

14. To knowledgeable industry observers, it has long been widely understood that in the US pharmaceutical industry the term "average wholesale price" (hereafter, "AWP") is a misnomer: it is not a measure of prices generally paid by wholesalers to manufacturers, it is not a measure of prices frequently paid by retail or mail order pharmacies to wholesalers, nor is it some average of these. I will document this below.

15. At least since the beginning of the widely publicized "Brand Name Drug Litigation" in 1994, it has been common knowledge among industry observers that brand pharmaceutical firms typically sell self-administered single-source drugs to wholesalers at a price known as "wholesale acquisition cost" ("WAC") that in most cases is 16.67% to 20% less than AWP; this

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<sup>8</sup> *Declaration of Steven J. Young In Opposition to the Plaintiff's Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, October 25, 2004, pp. 8-9.

<sup>9</sup> *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 16, 2004, p. 3.

<sup>10</sup> *Plaintiffs' Amended Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 17, 2004, pp. 3-4.

implies that AWP is typically 20% to 25% greater than WAC.<sup>11</sup> Moreover, using various rebates and chargeback policies, brand pharmaceutical manufacturers have offered a variety of discounts to health care providers and pharmaceutical benefit management (“PBM”) firms, frequently expressed as “AWP – x%” or “WAC ± y%”, in return for favorable placement of their drug on the client’s formulary, meeting market share or volume targets, and/or attaining other contractually specified goals.<sup>12</sup> In turn, providers and PBMs have contracted with pharmacy networks, reimbursing them for dispensing drugs, generally employing contractual terms such as “AWP – z%” plus a dispensing fee, and perhaps administrative fees.

16. If a contract involving branded single-source self-administered drugs were specified in terms of WAC rather than AWP, in most cases it has been straightforward to convert it to AWP terms, given the largely predictable relationships between AWP and WAC (although this AWP-WAC relationship is considerably more complex and variable with multisource brand and multisource generic drugs).<sup>13</sup> In this way, even though industry observers and academics have quipped that AWP stands for “Ain’t What’s Paid” rather than “Average Wholesale Price”,<sup>14</sup> it is nonetheless the case that AWP has served as a reference or focal point, an industry standard for baseline reimbursement, and as such a fictional benchmark price from which discounts are frequently specified, directly or indirectly. Hence, as Plaintiffs’ Expert Dr. Raymond Hartman has written, “AWP is interpreted by the industry as a measure of the underlying structure of drug

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<sup>11</sup> *In re Brand Name Prescription Drugs Antitrust Litigation*, Case No. 94 C 897; MDL No. 997, United States District Court for the Northern District of Illinois.

<sup>12</sup> Laurie P. Cohen and Elyse Tanouye, “Bitter Pill: Drug Makers Set to Pay \$600 Million to Settle Lawsuit by Pharmacies – Retailers Object to Practice of Granting Discounts To HMOs but Not Them – Eight Defendants to Fight On”, *Wall Street Journal*, 18 January 1996, p. A1.

<sup>13</sup> A branded drug can be either a patent-protected single source drug, an innovator branded drug that has lost patent protection and faces generic competition, or in some cases, a patent-protected drug sold under distinct brand names, or in even rarer cases, a “branded generic” that is a multisource drug promoted by its brand rather than chemical name. Multisource drugs include both brands that have lost patent protection and generic drugs.

<sup>14</sup> Although “AWP: Ain’t What’s Paid” was prominently displayed in the 1996 Barron’s article (Bill Alpert, “Hooked on Drugs: Why do insurers pay such outrageous prices for pharmaceuticals?”, *Barron’s*, June 10, 1996, 3 pp), as I note below, this association with AWP has an earlier history.

prices,”<sup>15</sup> and “The AWP, or its formulaic equivalent the WAC (wholesale acquisition cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs.”<sup>16</sup>

17. Given the widespread knowledge that AWP has long overstated actual transactions prices among manufacturers, providers, PBMs and retailers, as I understand it, in this litigation Plaintiffs are alleging that while payors understood that discounts off AWP were pervasive, certain manufacturers have covertly manipulated further the AWP and actual transactions cost structure of drug prices, resulting not just in an inflated AWP, but in an “artificially inflated”<sup>17</sup> or “grossly inflated”<sup>18</sup> AWP, which in turn allegedly damaged certain end-payer classes. These damages depend in large part on the “spread” between AWP and the actual average selling price (“ASP”) in the case of manufacturer contracts with PBMs, or between AWP and the actual average acquisition costs (“AAC”) in the case of sales by manufacturers to distributors or health care providers.<sup>19</sup> As examples, Plaintiffs call attention to recent guilty pleas and settlements involving physician-administered (not self-administered) drugs such as Lupron (an anti-cancer agent, marketed by Abbott Laboratories, Takeda Chemical Industries, Ltd., and TAP Pharmaceutical Products, Inc.) and Zoladex (a slightly different anti-cancer agent, marketed by AstraZeneca Pharmaceuticals LP)<sup>20</sup>. I note that these guilty pleas involved defendants’ actions

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<sup>15</sup> *Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification*, September 3, 2004, p. 1.

<sup>16</sup> *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff’s Motion for Class Certification*, December 16, 2004, p. 3.

<sup>17</sup> *Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification*, September 3, 2004, p. 6; *Plaintiffs’ Memorandum In Opposition to Defendants’ Motion to Strike the Hartman Declaration*, December 17, 2004, p. 10.

<sup>18</sup> *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff’s Motion for Class Certification*, December 16, 2004, p. 72.

<sup>19</sup> *Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification*, September 3, 2004, p. 6. As I note later, this is but one definition of “spread”.

<sup>20</sup> *Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification*, September 3, 2004, p. 6, fn. 18; also p. 8, and p. 13 fn. 32.

of providing free samples to physicians, and encouraging physicians to bill Medicare at the published AWP.<sup>21</sup>

18. In assessing whether the proposed end-payer classes were damaged, Plaintiffs' Expert Dr. Hartman proposes first to compute the spreads between AWP and ASP "for drugs unaffected by the scheme and fraud", and then use these as "yardsticks" in comparison with spreads observed "for the drugs subject to this litigation". In cases where he determines the latter spreads are larger than the former, Dr. Hartman proposes to employ his yardsticks along with mathematical and algebraic formulae "to determine the spread that would have been used for the affected drugs but-for the wrongful scheme", thereby determining "the overall class-wide injury and damage for each drug".<sup>22</sup>

19. Because there are numerous types of transactions among different parties in the drug distribution system (among manufacturers, wholesalers, pharmacies, pharmaceutical benefit managers ("PBMs), and third party payors (including health plans, insurers, and employers), there are many alternative concepts of "spreads". I will try to distinguish these as I proceed in this report. For example, at the Plaintiffs' tutorial before Judge Saris on December 6, 2004,

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<sup>21</sup> In the United States District Court for the District of Massachusetts, Eastern Division, *United States of America v. TAP Pharmaceutical Products, Inc., Criminal Action No. 01-CR-10354-WGY, Sentencing Memorandum of the United States*, the civil and criminal resolution was limited to TAP's violation of the Prescription Drug Marketing Act, for losses suffered by Medicare and Medicaid as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct, and for losses suffered by Medicaid for TAP's failure to provide "best price" for Lupron. There is no explicit charge of inflating or artificially inflating AWP, although TAP's ability to change AWP at any time is acknowledged. In United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS, *In Re: Lupron Marketing and Sales Practices Litigation, Memorandum and Order on Defendants' Motion to Dismiss Corrected Consolidated Amended Class Action Complaint and Second Amended Consolidated Complaint*, Judge Stearns cites Plaintiffs' allegation that defendants' (including TAP) conspired "to artificially inflate the price of the drug Lupron" (p. 1). The Judge later states that "...defendants trumpeted a lie by publishing the inflated AWP's, knowing (and intending) them to be used as instruments of fraud" (p. 18), and comments that "there is a difference between a sticker price and a sucker price" (fn. 19, p. 20). In the case of Zoladex, press releases on AstraZeneca's guilty plea to criminal charges of fraud in the marketing and pricing of Zoladex variously refer to "deliberately inflating" the reported AWP (see <http://www.ago.state.ma.us/sp.cfm?pageid=986&id=1050>, p. 1, accessed 12/31/04), and "improperly setting and reporting its price" (see <http://www.astrazeneca.com/pressrelease/500.aspx>, p. 1, accessed 12/31/04).

<sup>22</sup> *Plaintiffs' Memorandum In Opposition to Defendants' Motion to Strike the Hartman Declaration*, December 17, 2004, p. 3.

Professor Meredith Rosenthal discussed another concept and measure of “spread” that for a PBM referred instead to what the PBM charged the payor/insurer (e.g., AWP – f% + administrative fees) minus what the PBM reimbursed the pharmacy (e.g., AWP – g% + dispensing fee + administrative fee), in which case the PBM “spread” equaled  $g\% - f\% + \text{differential fees}$ .<sup>23</sup>

Professor Rosenthal also appears to assert that for the self-administered drug classes, each class member must have a contractual relationship with a PBM.<sup>24</sup>

### **III. THE ORIGINS, EVOLUTION AND PERSISTENCE OF AWP AND “SPREAD”**

#### **A. Brand Name/Single Source Self-Administered Drugs**

20. To understand today’s interactions among drug manufacturers, wholesalers, retailers and PBMs, it is informative to consider briefly the history of how AWP, and differences between AWP and WAC, came into being, along with the important role of information and communications technology in affecting distribution costs and industry structure. Unfortunately, much of this history is anecdotal and oral, known by the legions of economists, industry consultants and attorneys involved in the now legendary Brand Name Drug Litigation involving branded (typically patent-protected) self-administered medications (orals, topicals, inhalants, self-injectables and other miscellaneous products). Interestingly, in the context of this litigation a hint of this history is given in the deposition of AstraZeneca’s John R. Freeberry, on which I will comment further below.<sup>25</sup>

21. To the best of my knowledge, the first widely circulated written discussion of the AWP history is that by Professor E. M. (Mick) Kolassa, who in 1997 authored a textbook, *Elements of*

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<sup>23</sup> *Written Tutorial of Meredith Rosenthal*, Ph.D. presented before Judge Patti B. Saris, United States District Court for the District of Massachusetts, December 6, 2004, p. 16.

<sup>24</sup> *Written Tutorial of Meredith Rosenthal*, Ph.D., supra, p. 12.

<sup>25</sup> Deposition of John Richard Freeberry, May 20, 2004, pp. 168-172. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs’ Reply to AstraZeneca Pharmaceuticals LP’s Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

*Pharmaceutical Pricing*.<sup>26</sup> Substantial portions of the material in that text overlap, however, with paragraphs in an earlier 1994 peer-reviewed article,<sup>27</sup> as well as with presentational material prepared for previous marketing consulting/research seminars conducted by Professor Kolassa.<sup>28</sup>

Kolassa [1997] begins by defining AWP as follows:

“Neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times. Few, if any, wholesalers even consider AWP today when pricing their prescription products. It is, however, commonly used by retailers and others who dispense medications as the basis for many pricing decisions. Due to its availability from many sources, the AWP is often used as a surrogate for actual prices when studying prescription price trends”.<sup>29</sup>

22. In Kolassa [1994a], the original *raison d'être* for AWP and for the now infamous common 20%-25% “spreads” between wholesalers’ acquisition and retail pharmacy acquisition costs of branded self-administered drugs is recounted. Recall that during the 1980s, following the pioneering practices of WalMart and other “superbox” retailers, implementation of information and communications technological developments significantly impacted the rationalizing of wholesaler-retailer distribution logistics, the monitoring of transactions in real time, and the management of inventory, reducing costs and in the process leading to the demise of many small retail and wholesale firms. These phenomena also occurred in the context of pharmaceuticals.<sup>30</sup> Despite its length, the following quote from Kolassa [1994a] is illuminating:

“The AWP, the most common figure used for drug price comparisons, is a vestige of a drug distribution system that disappeared in the early 1980s. Prior to that

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<sup>26</sup> E. M. (Mick) Kolassa, *Elements of Pharmaceutical Pricing*, Binghamton, NY: The Pharmaceutical Products Press, 1997.

<sup>27</sup> Mick Kolassa, “Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents”, *Journal of Pain and Symptom Management*, 9(4), May 1994: pp. 235-243. Hereafter I denote this reference as Kolassa [1994a].

<sup>28</sup> See, for example, *Elements of Pharmaceutical Pricing: A two-day marketing research seminar*, Radisson Hotel & Suites, Fairfield, NJ, August 9-10, 1994. Hereafter I denote this reference as Kolassa [1994b].

<sup>29</sup> Kolassa [1997], *supra*, p. 30.

<sup>30</sup> For another discussion on the impacts of information and communications technology on wholesale-retail interactions in the pharmaceutical industry, see “Computers as Agents of Change” (pp. 61-65) and “Retailing Reorganized” (pp. 65-67) in John T. Fay, Jr., “The Wholesaler”, ch. 12 in Mickey C. Smith, ed., *Principles of Pharmaceutical Marketing*, Third Edition, Philadelphia: Lea & Febiger, 1983.

time, there were several hundred small, independent drug wholesalers, each operating regionally. Due to the inefficiencies of such a fragmented system, the operating costs were quite high. The average markup above cost by these wholesalers to their retail customers, primarily pharmacies, was 20% to 25%, depending on manufacturer. The manufacturer differences were due to the fact that, while most pharmaceutical manufacturers used a wholesaler-only method of distribution to the retail class of trade, a significant number of large firms had invested in their own distribution networks and preferred 'direct' sales over the use of wholesalers. By convention, wholesalers added 20% to the price of products from companies following a wholesaler-only policy while adding 25% to the prices of products from those companies who chose to 'compete' with the wholesalers. At that time, virtually all pharmaceutical companies sold products directly to hospitals that did not use wholesalers. As a result, less than one-half of the pharmaceutical products sold in the United States were handled by drug wholesalers in the early 1970s. {Footnote in Kolassa [1994a] omitted.}

In the late 1970s and early 1980s, several wholesale drug companies began to acquire smaller competitors. At that time, a few companies expanded significantly, many becoming national in scope. As a result, there are fewer than 90 separate wholesaler drug companies today, with more consolidations expected in the next few years. The expansion of major firms also concentrated competition. Prior to this consolidation, most wholesalers had little or no competition, so there was little pressure to reduce their markups. The consolidation in the industry resulted in major wholesale companies competing for the same business. The net effect was price competition.

This expansion of major wholesalers led to greater efficiencies as the wholesalers adopted more sophisticated inventory control systems, and to the expansion of services offered to retail and hospital customers. Large wholesalers then used their competitive advantages to gain and keep new customers. The utilization of wholesalers increased substantially during this period, resulting in the wholesalers' handling of over 80% of prescription product sales by 1987. {Footnote in Kolassa [1994a] not reproduced here.}

Additionally, during the 1980s, the prices charged by the manufacturers began to increase. This allowed the wholesalers to practice arbitrage, buying drugs in anticipation of price increases, then selling their inventory at the new, higher prices. These combined forces brought the average wholesale markup today to roughly 2.5%, significantly lower than the markup implied by the published AWP.

Price-reporting services, however, still rely upon the AWP as their primary figure, because many companies publish only that figure (usually called the "suggested price to pharmacy"). A recent move by several manufacturers, however, is to publish only their own list prices, refusing to offer the traditional AWP figure. This has been done, reportedly, because many name-brand drug makers feel the

AWP unfairly distorts their prices and results in competitive disadvantages. The AWP, although not the cost paid by retailers, still provides the basis for much retail pharmacy pricing, with retailers euphemistically referring to the difference between their actual cost and the AWP as 'earned discount'. This tradition is so ingrained that a retailer that sells a product at AWP, which is 12%-18% above their cost, refers to this price as a 'loss leader'.<sup>31</sup>

Kolassa summarizes this discussion by stating, "Within pharmacy circles, the definition of AWP, it is joked, is 'Ain't What's Paid.'"<sup>32</sup>

23. The evolution of the AWP – WAC "spread" for branded self-administered pharmaceuticals is therefore, as best I can tell, quite understandable, and apparently not the result of any sinister or nefarious conspiracies. Moreover, since AWP was publicly known, it served as a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically.

24. Why this "spread" practice has continued long after its underlying rationale has largely disappeared is a bit puzzling, but as I believe understandable and plausible. Given the AWP – WAC history, retail pharmacies plausibly continued to expect their acquisition costs to be 20-25% below AWP, and thus in their contracts with third party payors and PBMs, retailers generally expected to be reimbursed at 10-15% below AWP. In such a context, one can understand that a single manufacturer marketing a newly FDA approved drug would find it quite challenging if not impossible to successfully set an AWP that was only, say, 2-5% above the WAC, for with that small a differential, retailers would be unable to recover their acquisition costs, unless they renegotiated and rewrote contracts with PBMs and other third party payers (such contracts typically applied a uniform percent discount across all single source branded self-administered drugs, regardless of therapeutic class).<sup>33</sup>

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<sup>31</sup> Kolassa [1994], *supra*, pp. 236-237; much of this material is reproduced in Kolassa [1997], *supra*, pp. 33, 35-36.

<sup>32</sup> Kolassa [1994a], *supra*, p. 237.

<sup>33</sup> The percent figure typically varied, however, depending on whether the drug was a brand or generic.

25. An example may help to clarify this. Suppose that the AWP of Drugs X and Y is a common \$100, and that their WAC is a uniform \$80 (the AWP in both cases is 25% above the WAC). Suppose further that the pharmacy's acquisition cost for both drugs is equal to WAC, which is a reasonably decent approximation to actual retail pharmacy acquisition costs;<sup>34</sup> hence the pharmacy's actual acquisition cost ("AAC" for the moment) equals \$80. Finally, suppose that in its contract with a health plan or PBM, the pharmacy is reimbursed for all branded self-administered drugs at AWP – 15%.<sup>35</sup> This means that for each prescription of Drug X or Drug Y dispensed to a beneficiary of the health plan, the pharmacy is reimbursed at \$85 (with an AWP of \$100, AWP – 15% is  $\$100 - \$15 = \$85$ ). Notice that in this example, the pharmacy's gross margin on each prescription is \$5 (it is reimbursed \$85 by the health plan/PBM, and acquires the drug for \$80).

26. Now suppose that for whatever reason, the manufacturer of Drug X wants to bring AWP much closer into alignment with the WAC, and instead of setting an AWP spread of 25% over WAC, it seeks to reduce the premium to 10%. This reduces the AWP for Drug X from \$100 to \$88 (110% of the \$80 WAC price). Now, with reimbursement contracts between health plans/PBMs and retail pharmacies unchanged, the pharmacy will continue to be reimbursed for all branded self-administered drugs at AWP – 15%. Hence, the pharmacy would continue to be reimbursed at \$85 per prescription for Drug Y. While the pharmacy would also still be reimbursed for Drug X at 85% of AWP, now, however, the AWP will have fallen from \$100 to \$88, implying that reimbursement from the health plan/PBM would only be 85% of \$88, or \$74.80. With an unchanged acquisition cost of \$80 for both Drugs X and Y, the pharmacist

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<sup>34</sup> See, for example, Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*, December 2004, p. 8, fn. 12; Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates Inc., Cambridge, MA, August 30, 2004, p. 14.

<sup>35</sup> For simplicity, here I ignore dispensing fees and other administrative charges/fees.

would lose on each prescription for Drug X (receiving \$74.80 in reimbursement but having an \$80 acquisition cost, implying a \$5.20 loss on each Drug X prescription). The pharmacy would, however, continue to earn a \$5 gross margin on Drug Y. Clearly, the manufacturer of Drug X would find it difficult to sell its drug to the retail pharmacist, due to the lower AWP – WAC spread policy it implemented only for Drug X.

27. Recognizing this problem with retail pharmacies, the manufacturer of Drug X might try to arrange for unique treatment from health plans/PBMs contracting with pharmacies. Specifically, the manufacturer might attempt to have all contracts between all pharmacies and health plans/PBMs rewritten so that, unlike all other branded self-administered drugs reimbursed at AWP – 15%, Drug X would be reimbursed at AWP – 3.5%. With this new reimbursement formula, the pharmacies' gross margins for Drug X would continue to be about \$5 (or very slightly smaller at \$4.92), thereby making neutral or roughly equal the reimbursements received by the pharmacy for Drug X and Drug Y.<sup>36</sup> However, precisely because of the efficiency advantages of common contracting terms and common algorithmic formulas in processing pharmacy claims electronically, the health plans/PBMs and pharmacies would likely strongly resist such costly special treatment of Drug X. Even if the manufacturer were a very, very large manufacturer with a large portfolio of branded self-administered drugs, and even if it proposed reducing the spread on all its products, not just Drug X, it is very likely that the proposed policy change would be a failure commercially, and that pharmacies and health plans/PBMs would offer strong resistance.<sup>37</sup>

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<sup>36</sup> In this example, for an AWP of \$88, AWP – 3.5% is \$84.92. With an acquisition cost of \$80, the pharmacy gross margin would be \$4.92. A manufacturer to pharmacy pricing policy of AWP – 3.40909% would yield an almost perfectly neutral gross margin of \$5 for Drug X, identical to that for Drug Y.

<sup>37</sup> I am aware of course that Defendants' reducing the spread between AWP and actual acquisition costs is not the behavior alleged by Plaintiffs in this litigation.

28. In the current litigation, AstraZeneca deponent John R. Freeberry apparently refers to such an experience when in about 1994, the newly formed Astra Merck joint venture had to deal with two different legacies from its parent companies, one involving an AWP 20% greater than WAC, and the other a 25% differential. Astra Merck apparently sought to change the AWP – WAC differential from 25% to 20%, and may have even considered a more dramatic pricing policy change involving publication of an AWP that even more closely approximated average transaction price. According to Freeberry:

“...the reason we couldn’t really do that was because pharmacists are reimbursed on a set contract for all of their brands. That’s our understanding of it. So they’re reimbursed an AWP minus 10 percent, minus 15 percent.

So if we set our AWP at 2 percent, obviously they would lose money, and they wouldn’t use our products. So we have to be consistent with the industry standard in order for the – to be – competitively fair.”

Q: “When you’re referring to having changed the whole industry, are you referring to anyone other than the retailers and what you’ve just described with retailer contracts?”

A: “I’m referring to the whole reimbursement process for the pharmacists. All these contracts are based on AWP price to the retailers.”<sup>38</sup>

29. These observations suggest the very plausible hypothesis that even though the original rationale supporting the AWP – WAC or AWP – ASP differential for brand name/single source self-administered drugs had largely disappeared by the 1980s, there were no incentives for any one manufacturer to change the system pricing structure, and indeed, the incentives that did exist were perverse in that unilaterally publishing more accurate AWP prices would be unprofitable and therefore unsustainable for any one manufacturer.

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<sup>38</sup> Deposition of John Richard Freeberry, May 20, 2004, pp. 175-176 (quotation); this line of questioning begins earlier, on page 170. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs’ Reply to AstraZeneca Pharmaceuticals LP’s Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

30. Moreover, even if each company unilaterally decided to participate in a coordinated industry-wide agreement to change AWP/WAC pricing practices, such actions might invite antitrust scrutiny and challenge from the U.S. Department of Justice. Such antitrust concerns apparently occurred in the early 1990s when pharmaceutical manufacturers considered (and then rejected) the idea of mutually pledging to keep brand name drug prices from rising more rapidly than the Consumer Price Index.<sup>39</sup> In the current litigation, I note that in fact related antitrust allegations have been made by Plaintiffs involving participating defendants in the Together Rx Card program.<sup>40</sup>

31. In summary, for brand name/single source self-administered drugs, while the underlying rationale supporting a 20-25% spread between AWP and WAC has long disappeared, manufacturers and retailers appear to be locked in to this practice. In the jargon of economics and game theory, what we observe is a Nash equilibrium in which for all players AWP exceeds ASP and WAC. There is no incentive for any brand name manufacturer of self-administered single-source drugs to align its AWP to a level much closer to WAC.

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<sup>39</sup> Following Merck's 1990 announcement of a voluntary commitment to limit annual price increases to no more than growth in the overall Consumer Price Index ("CPI"), several other pharmaceutical firms followed suit. In 1993 the Pharmaceutical Manufacturers Association ("PMA") requested a business review by the U.S. Department of Justice of a program it proposed to implement, whereby member companies would commit to limiting annual price increases at rates not to exceed growth in the CPI, subject to independent audit. On October 1, 1993, Assistant U.S. Attorney General Anne Bingaman responded for the Department of Justice, opining that "the Department currently intends to bring suit to challenge the program if PMA and its members go forward with this proposal". Bingaman went on to write that "...the proposed program would violate the antitrust laws. An agreement among independent competitors that interferes with free and open price competition by restraining individual pricing decisions is a per se violation of the Sherman Act. The per se rule has been applied to agreements among competitors that fix or set the prices at which goods or services are sold as well as agreements that set price-related terms but not the specific price at which transactions occur." Online at <http://www.usdoj.gov/atr/public/busreview/0772.htm>, pp. 1,2.

<sup>40</sup>As I understand it, in the current litigation, the Nationwide End Payor Together Card Class Plaintiffs allege conspiracy and Sherman Act violations when defendants allegedly moved almost simultaneously to a common 25% spread between AWP and WAC for drugs covered by the Together Rx Card. See *Corrected Amended Master Consolidated Class Action Complain Modified Per the Court's Instruction at the November 21, 2003 Hearing with Amgen Amendments*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 5, 2003, Counts V through X, pp. 280-304.

32. An alternative potential source of change in bringing about more accurate public average prices could have been the federal government. While over the years the federal government has purchased a limited number of drugs in its Medicare Part B program, together with the states it currently pays for a much larger amount of drugs through the states' Medicaid programs. I will return to the federal government's role as possible agent of change in bringing published prices closer to actual acquisition prices in sub-section C below.

### **B. Generic/Multisource Self-Administered Drugs**

33. During the 1970s and 1980s when wholesaler-retailer interactions were revolutionizing electronic transactions, generic drugs played a relatively minor role, not only in numbers, but also in dollar sales proportions. While the share of prescriptions of self-administered drugs dispensed generically has increased substantially in the last two decades, their dollar share has remained relatively modest, typically in the range of 10%-20%.

34. According to a 1985 Federal Trade Commission study, in 1980 31% of prescriptions were written for single-source drugs, while 69% were written for multi-source drugs. However, among the 69% written for multi-source drugs, 55% had the brand name written on the prescription, while the remaining 14-15% specified the generic (not brand) name. Almost all prescriptions written with the brand name were dispensed as written (52% of the 55%), and only for a small portion (3% of the 55%) was a generic substituted for the brand.<sup>41</sup> The total proportion of prescriptions dispensed as generics was therefore about 18% (15% written as generic, plus 3% substituted with generic).

35. Since at that time the average retail prescription price of a generic was about 75% of that for a brand (\$6.22 vs. \$8.22), as a proportion of generic plus retail drug revenues, the generic

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<sup>41</sup> Alison Masson and Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws*, Staff Report of the Bureau of Economics, Federal Trade Commission, October 1985, p. 26, Figure 2-1. Washington DC: U. S. Government Printing Office.

# **Exhibit 5**

# Patterson Belknap Webb & Tyler LLP

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

November 16, 2005

Andrew D. Schau  
Partner  
(212) 336-2546  
adschau@pbwt.com

## By Fax & Mail

Charles Barnhill, Jr. Esq.  
Miner, Barnhill & Galland  
44 East Mifflin Street, Suite 803  
Madison, WI 53703

**Re: State of Wisconsin v. Amgen, Inc., et al.**

Dear Chuck:

I have your November 4 notice of deposition of Johnson & Johnson. We can produce a witness in response to your notice (although probably not on December 6, 2005), but I wonder if it is really necessary to do so in light of what I understand to be the purpose behind your notice. If it is necessary, I also have several questions about the type of information you want that witness to have. This letter explains my concerns and questions. Please call me after you have had a chance to consider it so that we can schedule a "meet and confer" discussion.

My impression is that the deposition notice is a direct result of the statement in my November 2, 2005 letter that my clients are not aware of any evidence that they "caused phony and inflated wholesale prices to be published with respect to each of the listed drugs." You responded with your November 3 letter calling this statement "truly unbelievable," and then with the November 4 notice of deposition. At the risk of repeating myself, let me explain again the basis for this statement.

The Johnson & Johnson operating companies typically sell their medicines to wholesalers at a published list price known as Wholesale Acquisition Cost or WAC. If the

wholesaler pays within 30 days, it receives a 2% prompt pay discount. In addition, when operating companies increase their prices, they sometimes offer the wholesaler a short term price adjustment designed to discourage the wholesaler from engaging in speculative buying. Thus, the wholesaler's net purchase price should be very close to WAC.

Historically, Johnson & Johnson's operating companies sent First Data Bank and the Red Book both the WAC price and a suggested AWP for each of their medicines. This same information was sent to the wholesalers. Consistent with long-standing industry norms, the suggested AWP's were 20% higher than the WAC prices. In 2002, without notice to my clients, First Data Bank increased the difference between WAC and AWP to 25% on several Johnson & Johnson company products.

Johnson & Johnson's operating companies do not track the wholesaler's prices to retailers, hospitals, physicians, and the like, although they obviously receive some feedback concerning some wholesaler prices. They also remit contracted rebates or charge backs on some medicines to selected end customers, such as the State of Wisconsin. (We are in the process of assembling sales, rebate and charge back data on each "targeted drug" – a massive undertaking because your client seeks substantially more information than did the plaintiffs in the MDL – and expect to produce that data to you within the next 60 days or so.)

Because wholesaler margins are typically quite thin, it is unlikely that retail pharmacies purchase medicines from wholesalers at prices equal to or greater than the then current AWP's published by First Data Bank or the Red Book. If what you are interested in doing is establishing that proposition, which is what seems to be the purpose of the requests in your deposition notice, then it seems to me that there is a way we can do that without the

formality of a deposition. If, on the other hand, you want specific information about prices paid by retail pharmacies, then it would make more sense to direct that discovery either to the retailers or the wholesalers. Either way, I don't think a deposition such as that contemplated by your notice is the most efficient approach.

Moreover, request no. 3 is extremely broad. What sorts of contacts between my clients and the publishers are you interested in exploring? As mentioned above, until recently Johnson & Johnson's operating companies sent to the publishers WAC prices and suggested AWP's that were 20% higher than WAC prices. Many different people at the different Johnson & Johnson operating companies were involved sending this information to the wholesalers and publishers, and it would be unrealistic and burdensome to make each of them available for deposition. What is more, several of these individuals were deposed in the MDL and your most recent document request no. 10 asked for a copy of those deposition transcripts. I have also offered to produce copies of the correspondence with the publishers.

With respect to request no. 4, my clients do not contend that AWP is the actual average of wholesaler prices. Nor do they contend that AWP is the price normally paid to wholesalers by the retail class of trade. I would be surprised if any Johnson & Johnson company employees ever told First Data Bank or Red Book that AWP is neither the actual average of wholesale prices nor the price normally paid to wholesalers by the retail class of trade, because we believe it is quite clear that First Data Bank and Red Book understood these facts. Moreover, if there were such a person, I wouldn't know how to go about identifying them. I can identify the people at the Johnson & Johnson operating companies in charge of communicating pricing

Charles Barnhill, Jr. Esq.  
November 16, 2005  
Page 4

information to the wholesalers and publishers, but they were deposed in the MDL and you've already asked for copies of their deposition transcripts in request no. 10.

I'm puzzled by request no. 5. As you know, I told you I would collect and produce the AMPs for each "targeted drug," and I am producing that information to you today under separate cover. I don't think the AMP figures are the subject of any dispute. What sort of AMP-related witness do you have in mind?

Finally, with respect to request no. 6, as I have explained, the Johnson & Johnson operating companies do not know the "actual average" prices that wholesalers charge for the targeted drugs, so there are no witnesses who could compare that actual average to the calculated AMPs.

Please consider the issues raised in this letter and then call me so that we can schedule a time to discuss them. I would like to discuss first whether, in light of the positions outlined above, you still believe that a deposition is necessary, and I would like Don Schott to participate in our discussion.

I look forward to hearing from you.

Sincerely yours,

Andrew D. Schau

cc: Donald K. Schott

# Exhibit 6



3. What contacts Johnson & Johnson, or its subsidiaries, have had with First Data Bank or the Red Book about any of the targeted drugs.
4. Whether Johnson & Johnson, or any of its subsidiaries, ever communicated to either First Data Bank or the Red Book that the published Average Wholesale Prices of their drugs were neither a price that was actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade and, if so, when such communications took place and of what they consisted.
5. The Average Manufacturer's Price (AMP) reported to the federal government of each of the targeted drugs in each year since 1993.
6. Any evidence which shows that the actual average wholesale price at which any of the targeted drugs sold in any given year was greater than the AMP.

The designated deponents shall bring with them 1) all evidence or information showing that any of the targeted drugs was sold at a price equal to or greater than the published AWP from 1993 to the present, 2) for the same period all evidence or information showing that actual average wholesale prices of its targeted drugs were less than the published AWP, 3) for the same time period any evidence of communications between Johnson & Johnson and the Red Book about or concerning any of the targeted drugs, 4) for the same time period the reported AMPs of each targeted drug, and, 5) for the same time period any evidence defendant has showing that the actual average wholesale price of any of the targeted drugs was greater than the reported AMP.

Dated this 24<sup>th</sup> day of March, 2006.

  
\_\_\_\_\_  
One of Plaintiff's Attorneys

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Attorneys for Plaintiff,  
State of Wisconsin

# **Exhibit 7**

# Patterson Belknap Webb & Tyler LLP

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April 13, 2006

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Charles Barnhill, Jr. Esq.  
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44 East Mifflin Street, Suite 803  
Madison, WI 53703

**Re: State of Wisconsin v. Amgen, Inc., et al.**

Dear Chuck:

I am writing to request a “meet and confer” regarding the State’s Revised Notice of Deposition of Defendant Johnson & Johnson. This letter outlines my clients’ substantive concerns.

The Revised Notice seeks a witness or witnesses to testify on six subjects:

1. The evidence or information, if any, about which it is aware, which shows that any of the drugs listed on the attached sheet (“targeted drugs”) were purchased by retail pharmacies at a price equal to or greater than the then current Average Wholesale Price (AWP) published by First Data Bank or the Red Book in any year from 1993 to the present.
2. The evidence or information about which it is aware which shows, or which defendant believes may tend to show, that the published AWP was higher than the price pharmacies were actually paying for any of the targeted drugs in each year from 1993 to the present.
3. What contacts Johnson & Johnson, or its subsidiaries, have had with First Data Bank or the Red Book about any of the targeted drugs.
4. Whether Johnson & Johnson, or any of its subsidiaries, ever communicated to First Data Bank or the Red Book that the published Average Wholesale Prices of their drugs were neither a price that was actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade and, if so, when such communications took place and of what they consisted.

5. The Average Manufacturer's Prices (AMP) reported to the federal government of each of the targeted drugs in each year since 1993.
6. Any evidence which shows the actual average wholesale price at which any of the targeted drugs sold in any given year was greater than the AMP.

**Subject No. 1:** I note at the outset that the Revised Notice did not include an attachment identifying the "targeted drugs," but I assume that this oversight is easily remedied. More fundamentally, I am perplexed by this request because it appears to relate to information outside of Johnson & Johnson's possession and control.

To reiterate what I have told you in the past, with the exception of a few direct purchasing chains, Johnson & Johnson's operating companies do not sell medicines directly to retail pharmacies. Rather, self-administered drugs are sold to wholesalers, and physician-administered drugs are sold to wholesalers and specialty distributors. The Johnson & Johnson companies have already produced to you AMP data reflecting the prices that the wholesalers pay for drugs distributed to the retail pharmacy class of trade, including relevant price concessions from the manufacturer. The prices that wholesalers in turn charge retail pharmacies is information maintained by the wholesales, not by Johnson & Johnson's operating companies. Although there is anecdotal information that wholesaler margins are extremely thin (*see* Deposition of William Parks at 80-81), that information is as available to the State of Wisconsin as it is to Johnson & Johnson's operating companies. Accordingly, I would like to discuss with you what specific, additional information you are seeking that would be an appropriate topic for a Rule 804.05(2)(e) witness.

**Subject No. 2:** I do not understand how this subject differs from the first subject. The published AWP's for the Johnson & Johnson company medicines are a matter of public

record. The prices that the wholesalers charge the retailers is information that can only be obtained from the wholesalers. Again, what specific information are you seeking that would be an appropriate topic for a Rule 804.05(2)(e) witness?

**Subject No. 3:** This has been the subject of extensive testimony in the MDL. The relevant depositions and exhibits have already been produced to you. You might want to review the depositions Kurt Barry and William Parks (Janssen), Bob Spurr (Ortho McNeil Pharmaceuticals), Tom Hiriak and Elaine Kling (Ortho Biotech), and Rock Magnotta (McNeil Consumer). You might also take a look at the exhibits marked during those depositions, particularly Barry Exhibits 10, 11, 12, 13, 14, 15, 16 and 17, Parks Exhibit 3, Kling Exhibits 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 16, and Magnotta Exhibits 4 and 5.

Please let me know whether there is any information you seek that is not established in the materials you already have.

**Subject No. 4.** I have not been able to identify a witness would be able to testify on this subject because AWP is not, and does not purport to be, “a price that was actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade.” Rather, as established by the depositions we previously provided, the Johnson & Johnson defendants have historically submitted AWP to publishers and wholesalers that were 120% of the list price. The publishing companies sometimes published the AWP figures that the Johnson & Johnson operating companies submitted, but they sometimes published different AWP. *See, e.g.,* Deposition of Tom Hiriak at 205-06; Deposition of John Dempsey at 92; Deposition of Rock Magnotta at 91-93, 108-09; Deposition of Robert Spurr at 92-94; and Deposition of William Parks at 66-67, 72-76, 81-83.

Charles Barnhill, Jr., Esq.  
April 13, 2006  
Page 4

**Subject No. 5.** We have already produced the AMP figures. Are you asking for a witness who can explain how AMP is calculated (there is a definition in the statute), or are you interested in something different?

**Subject No. 6.** AMP and AWP represent different things, and the State already has the AMP and AWP figures from which the comparison can be made. The term "actual average wholesale price," however, is not defined and is susceptible to multiple interpretations, depending, among other things, on the relevant class of trade. We should discuss precisely what you mean so that I can better understand what you are looking for.

This listing of topics for discussion is not meant to be exclusive. There are other open issues as well, such as the effect of the judge's ruling that the State's pleading is insufficient, her expected ruling on statute of limitations, etc. Please call me or Don Schott at your convenience so that we can schedule a time to discuss these issues.

Sincerely yours,

Andrew D. Schau

cc: Donald K. Schott, Esq.

# Exhibit 8

Dear Andy:

In response to your letter we are seeking sworn testimony in this case (not some other case) in a form easily understood by the jury which tells the jury the following, if true:

1. That Johnson & Johnson and its subsidiaries have no evidence whatsoever that the average wholesale prices it reports to medical compendiums are in fact accurate average wholesale prices for any of its drugs. If as a corporation Johnson & Johnson has no evidence on this score it should be easy to find a corporate designee to so state. Your assurances are not adequate from an evidentiary standpoint. Nor is it useful to point to testimony in other cases from which I might glean the answer. It is unclear how useful these other depositions will be at a trial in Wisconsin and, in any event, we are entitled to present our evidence to the jury in the form we think make the most sense, not the form the defendant likes best.
2. Item 2 asks for the converse of item 1. It seeks positive evidence that Johnson & Johnson knew that the AWP's it was reporting were actually higher than the price wholesalers were selling J&J drugs to retailers. In the depositions you sent me one witness testified to anecdotal information he possessed about the wholesaler mark up. That is not a sufficient response. We want the information possessed by the corporation testified to by a corporate designee.
3. We are seeking the corporate knowledge of all J&J contacts with First Data Bank or the Red Book. Again, evidence testified to by one or more individual witnesses is inadequate because it does not purport to be the knowledge of the corporation, because it comes in another case and therefore presents evidentiary problems, and because it comes in bits and pieces making it awkward to present to the jury. I would add that no one has testified with knowledge about the AWP verifications J&J apparently sent to the Red Book and to FDB.
4. Apparently J&J never told either the Red Book or FDB that its published wholesale prices were inaccurate until FDB raised the AWP on a few of the drugs in 2002. We want J&J to so testify, and we want a corporate representative to explain in more detail, and in a deposition usable in this case, the circumstances connected with the complaint J&J finally made.
5. I am asking for a witness to describe how J&J calculated its AMP's.
6. Since I assume that J&J has no evidence that actual average wholesale price its drugs were sold for was greater than the AMP prices it should not be difficult for J&J to produce a witness to this effect.

# **Exhibit 9**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

Docket No. 01-12257-PBS

COPY

CITIZENS FOR CONSUMER JUSTICE, ET AL.  
Plaintiffs

v.

ABBOTT LABORATORIES, et al  
Defendants

.....

TRANSCRIPT OF MOTION HEARING  
BEFORE THE HONORABLE MARIANNE B. BOWLER  
UNITED STATES MAGISTRATE JUDGE  
HELD ON NOVEMBER 9, 2005

APPEARANCES:

For the plaintiffs: Sean Matt, Esquire, Hagens, Berman, Sobol,  
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For Shering-Plough: John Montgomery, Esquire

For Pfizer and Pharmacia: Scott Stempel, Esquire

For Johnson & Johnson: Andrew Schau, Esquire, Adeel Mangi,  
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For Non-parties and Absent Class Members, Blue Cross Blue Shield  
of Vermont, et al: Thomas J. Poulin, Robins, Kaplan, Miller &  
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Court Reporter:

Proceedings recorded by digital sound recording, transcript  
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Wrentham, Massachusetts 02093  
(508) 384-2003

1 reimbursement cost.

2 THE COURT: Let's take it with - you've heard it,  
3 take it at that.

4 MR. MACORETTA: That's fine.

5 THE COURT: Next.

6 MR. MACORETTA: Admit that from 1998 to the present  
7 the rebates that Centocor has paid on Remicade have reduced the  
8 spread. Spread as defined by J&J is different than the way  
9 plaintiffs have always defined the spread. Spread here means  
10 the difference between the net acquisition cost, which is  
11 another term created by J&J and the net reimbursement cost.  
12 Net acquisition cost is apparently what doctors ultimately pay  
13 to acquire the drug. We don't know what that is. It's  
14 completely irrelevant to our claims. Every J&J witness we have  
15 asked, do you know what doctors pay to acquire your drug, the  
16 answer is no. We know what we sell it to the wholesalers for.  
17 We have no idea what the wholesalers mark-up is. To answer  
18 this we would need to know the information that J&J  
19 disclaims any knowledge of.

20 THE COURT: What's your response?

21 MR. SCHAU: I think again, this does not require them  
22 to crunch any numbers, but I will tell you that if they will  
23 say under oath that they have no idea what physicians pay for  
24 Remicade and that that lack of information has no implications  
25 for their case, I think that enhances my prospects for summary