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THE STATE OF WISCONSIN

Plaintiff,

CASE NO. 04-CV-1709

v.

AMGEN INC., et al.

Defendants.

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**DEFENDANT DEY, INC.'S RESPONSES AND OBJECTIONS  
TO PLAINTIFF'S SECOND SET OF CONSOLIDATED DISCOVERY  
REQUESTS TO ALL DEFENDANTS**

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Pursuant to Wis. Stat. §§ 804.01, 804.08, 804.09, and 804.11, Defendant Dey, Inc., by its undersigned counsel, asserts the following responses and objections to the Second Set of Consolidated Discovery Requests to All Defendants, dated July 10, 2008, ("Consolidated Discovery Requests") propounded by Plaintiff the State of Wisconsin ("Wisconsin," "Plaintiff," or the "State") as follows:

**GENERAL OBJECTIONS AND RESERVATION OF RIGHTS**

1. These responses and objections are made without waiving or intending to waive, but to the contrary intending to preserve and preserving: (a) any objections as to the competency, relevancy, materiality, privilege, or admissibility as evidence, for any purpose, of any documents or information produced in response to the Consolidated Discovery Requests; (b) the right to object on any ground to the use of documents or information produced in response to the Consolidated Discovery Requests at any hearing, trial or other point during this action; (c) the right to object on any ground at any time to a demand for further responses to the Consolidated Discovery Requests; or (d) the right at any time to revise, correct, add to, supplement, or clarify any of the responses or objections contained herein.

2. The documents, information, and responses supplied herein are for use in this action and for no other purpose.

3. No response or objection made herein, or lack thereof, is an admission by Dey as to the existence or non-existence of any documents or information.

4. Dey provides its responses subject to the Protective Order, entered on November 29, 2005 in this action.

5. Dey objects to the Consolidated Discovery Requests to the extent they seek to impose duties and obligations on Dey greater than, or inconsistent with, Dey's duties and obligations under the Wisconsin Rules of Civil Procedure and any applicable local rules. Dey will comply with its duties and obligations under the Wisconsin Rules of Civil Procedure and any applicable local rules.

6. Dey objects to the Consolidated Discovery Requests to the extent they seek information or documents not within Dey's knowledge, possession, custody or control or seek admissions concerning matters of which Dey has no knowledge.

7. Dey objects to the Consolidated Discovery Requests to the extent they are vague, ambiguous, unduly burdensome, overbroad, oppressive, duplicative, or not limited to the discovery of information which is relevant to the subject matter of this litigation or reasonably calculated to lead to the discovery of admissible evidence.

8. Dey objects to the Consolidated Discovery Requests to the extent that any of the Consolidated Discovery Requests seek documents, information, or admissions not related to sales in the State of Wisconsin on the grounds that such Consolidated Discovery Requests are overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of

admissible evidence, and fail to identify with sufficient particularity the documents or information sought.

9. Dey objects to the Consolidated Discovery Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent they seek documents, information, or admissions concerning pharmaceutical products not at issue in this action. Dey will provide documents and information relating only to pharmaceutical products attributed to Dey in the Stipulated Targeted Drug List (the “Dey Targeted Drugs”).

10. Dey objects to the Consolidated Discovery Requests as unduly burdensome to the extent that they purport to require Dey to create, compile, analyze, compute, and/or summarize voluminous data or information that Wisconsin has the ability to create, compile, analyze, compute, and/or summarize by reviewing the documents, information, or data that Dey has produced or will produce.

11. Dey objects to the Consolidated Discovery Requests to the extent they seek documents, information, or admissions concerning matters that are privileged or otherwise protected against discovery pursuant to the attorney-client privilege, the work product doctrine, the joint defense privilege, the consulting expert rule, the common interest doctrine, investigative privileges, or any other legally recognized privilege, immunity, or exemption from discovery. To the extent any such protected documents or information are inadvertently produced or disclosed in response to the Consolidated Discovery Requests, the production of such documents or information shall not constitute a waiver of Dey’s right to assert the applicability of any privilege or immunity to the documents, and any such documents shall be returned to Dey’s counsel immediately upon discovery thereof.

12. Dey objects to the disclosure, under any circumstance, of trade secret information where the probative value in this litigation is greatly exceeded by the potential harm to Dey if the information were to fall into the hands of its competitors, and further asserts each and every applicable privilege and rule governing confidentiality to the fullest extent provided by the law.

13. Dey objects to the Consolidated Discovery Requests to the extent that they seek documents, information, or admissions concerning matters that are publicly available or publicly known or more appropriately sought from third parties or other defendants to whom requests or interrogatories have been or may be directed.

14. Dey objects to the Consolidated Discovery Requests to the extent that they seek documents, information, or admissions concerning matters from outside of the statute of limitations applicable to Wisconsin's claims in this action, or beyond the time period relevant to this action. Dey objects to the Consolidated Discovery Requests as irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent that they seek documents, information, or admissions relating to a period of time after the filing of the Complaint on or around June 3, 2004.

15. Dey objects to the Consolidated Discovery Requests to the extent that they demand the production of proprietary documents or information of third parties.

16. Dey objects to any implications and to any explicit or implicit characterization of facts, events, circumstances, or issues in the Consolidated Discovery Requests. Any response by Dey to a particular Consolidated Discovery Request is not intended to indicate that Dey agrees with any implication or any explicit or implicit characterization of

facts, events, circumstances, or issues in the Consolidated Discovery Requests, or that such implications or characterizations are relevant to this action.

17. Dey objects to the Consolidated Discovery Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent they seek documents, information, or admissions concerning any discontinued product dated after the date of such product's discontinuation.

18. Dey objects to the Consolidated Discovery Requests to the extent they seek documents, information, or admissions relating to Dey's activities that are outside the scope of the allegations in the Second Amended Complaint.

19. Dey objects to the Consolidated Discovery Requests to the extent they seek documents, information, or admissions relating to Dey's activities other than those which concern Wisconsin, on the grounds that such documents are neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence.

20. Dey objects to the Consolidated Discovery Requests to the extent they purport to impose on Dey an obligation to search or produce email or other electronically stored data in any format on the grounds that such Consolidated Discovery Requests are overly broad, unduly burdensome, harassing, and not reasonably limited in scope.

21. Dey objects to the Consolidated Discovery Requests to the extent they seek documents, information, or admissions duplicative of what Dey has produced and provided or will produce and provide in response to Wisconsin's prior discovery requests.

22. Dey reserves the right to assert additional objections to these Consolidated Discovery Requests as appropriate and to amend or supplement these objections and responses in

accordance with the applicable rules and court orders and based on results of its continuing investigation.

### **OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS**

The General Objections and Reservations of Rights stated above apply to and are incorporated into Dey's objections to the definitions and instructions set forth below. Dey also objects to the definitions and instructions as follows:

1. Dey objects to the definition of "document" as set forth in Definition No. 1 to the extent that it seeks to impose discovery obligations that are broader than, or inconsistent with, Dey's obligations under the Wisconsin Rules of Civil Procedure and any applicable local rules. Dey will comply with the Wisconsin Rules of Civil Procedure and any applicable local rules. Dey further objects to this definition to the extent it requires or seeks to require Dey to search for information that was not generated in the form of written or printed records, or to create or re-create printouts from electronic data compilations, on the grounds that such a requirement would be unduly burdensome. Dey further objects to this definition to the extent it requires or seeks to require Dey to: (a) produce documents or data in a particular form or format; (b) convert documents or data into a particular or different file format; (c) produce data, fields, records, or reports about produced documents or data; (d) produce documents or data on any particular media; (e) search for and/or produce any documents or data on back-up tapes; (f) produce any proprietary software, data, programs, or databases; or (g) violate any licensing agreement or copyright laws.

2. Dey objects to the definition of "identify" as set forth in Definition No. 2 to the extent it purports to seek the production of documents or information not within the knowledge, possession, custody, or control of Dey, its agents, or its employees, or that are more

appropriately sought from third parties to whom requests have been or may be directed. Dey further objects to the definition as unduly burdensome. Any Dey employees that are identified should be contacted through Dey's outside counsel Kelley Drye & Warren LLP.

3. Dey objects to the definitions of "you," "your," and "your company" as set forth in Definition No. 4 on the grounds that they are vague, ambiguous, overly broad, and unduly burdensome because, *inter alia*, they contain terms that are themselves vague, ambiguous, or undefined, including but not limited to "affiliated company," "joint venture," and "any other person or entity acting on behalf of defendant". Dey further objects to these definitions as overly broad to the extent they purport to include persons or entities that have no authorization to act on behalf of Dey and over whom Dey has no control. Dey further objects to these definitions as overly broad and unduly burdensome to the extent that they purport to include persons or entities that are not parties to this action and whose conduct is in no way relevant to the claims in this action. Dey further objects to the definition of "your company" as unduly burdensome and irrelevant on the grounds that the phrase "your company" does not appear in any of the Consolidated Discovery Requests.

4. Dey objects to the Instructions to the extent they seek to impose obligations on Dey that are greater than, or inconsistent with, Dey's obligations under the Wisconsin Rules of Civil Procedure and any applicable local rules.

5. Dey objects to Instruction No. 1 for Interrogatories the extent that it requires Dey to provide any information or documents within the knowledge, possession, custody or control of Dey's "attorneys" when such information or documents are protected by the attorney-client privilege, the work-product doctrine, or any other applicable privilege, rule, or

doctrine. Dey further objects to this Instruction because the phrase “subject to reasonable inquiry by you” is vague, ambiguous and overbroad.

6. Dey objects to Instruction No. 2 for All Discovery Requests as unduly burdensome.

**SPECIFIC RESPONSES AND OBJECTIONS TO  
THE CONSOLIDATED DISCOVERY REQUESTS**

Dey expressly incorporates all of the above-stated General Objections and Reservation of Rights, and the Objections to Definitions and Instructions into each and every response and objection to the Consolidated Discovery Requests set forth below. Any specific objection provided below is made in addition to these Objections and Reserved Rights and a failure to reiterate an Objection or Reserved Right below shall not constitute a waiver of that or any other objection.

**CONSOLIDATED DISCOVERY REQUEST NO. 7**

**REQUEST FOR ADMISSION NO. 7:**

At no time has the State of Wisconsin and you agreed on the meaning or definition of average wholesale price (“AWP”).

**DEY’S RESPONSE:**

Dey objects to Request for Admission No. 7 on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms and phrases that are themselves vague, ambiguous, or undefined, including, but not limited to, “agreed,” “meaning,” and “definition.”

Subject to and without waiving the foregoing general and specific objections, Dey denies the matters set forth in Request for Admission No. 7.

**INTERROGATORY NO. 7:**

If your response to request for admission no. 7 is anything other than an unqualified admission, state all bases for your response, including the following:

- (a) identify the definition of AWP that you contend the State of Wisconsin and you agreed on;
- (b) identify the date when you contend that the State of Wisconsin and you first agreed on the definition of AWP provided in response to subpart (a) of this interrogatory;
- (c) state whether you contend that the State of Wisconsin and you agree on the definition of AWP provided in your response to subpart (a) of this interrogatory as of the date that you answer this second set of consolidated discovery requests to all defendants;
- (d) if your answer to subpart (c) is “no,” identify the last date when you contend the State of Wisconsin and you agreed on the definition of AWP provided in response to subpart (a) of this interrogatory;
- (e) state whether you contend that the State of Wisconsin and you together developed the definition of AWP provided in response to subpart (a) of this interrogatory;
- (f) if your answer to subpart (e) is “yes,” describe in detail the manner in which the State of Wisconsin and you together developed the definition of AWP provided in response to subpart (a) of this interrogatory, including (1) the identity of each person involved in the development of the definition; (2) the role of each such person; (3) the dates of each such person's participation in the development of the definition; and (4) the dates and substance of each communication between the State of Wisconsin and you regarding the development of the definition of AWP;
- (g) identify all documents supporting your response to request for admission no. 7;
- (h) identify all documents supporting your answer to interrogatory no. 7, including all subparts; and
- (i) identify all documents supporting any contention you provide in your answer to interrogatory no. 7, including all subparts.

DEY'S RESPONSE AND OBJECTIONS:

Dey hereby adopts and incorporates its specific objections to Request for Admission No. 7 into its response to Interrogatory No. 7.

Subject to and without waiving the foregoing general objections, Dey responds as

follows:

On January 1, 1991, Dey entered into a rebate agreement (the “Rebate Agreement”) with the Secretary of the Department of Health and Human Services, who entered into the agreement on behalf of states with Medicaid programs, including Wisconsin. *See* 42 U.S.C. § 1396r-8(a)(1). The Rebate Agreement requires Dey to pay rebates to the states based on the Average Manufacturer Price (“AMP”) and, where applicable, Best Price for its products. *See* 42 U.S.C. § 1396r-8(b)(1)(A). Dey has paid rebates to the States and the federal government, further lowering the costs of drugs to the Medicaid program. The Rebate Agreement requires Dey to provide to CMS, on a quarterly basis, the AMP and, where applicable, Best Price for its products that are reimbursed by Medicaid. *See* 42 U.S.C. § 1396r-8(b)(3).

The Rebate Agreement sets forth the following definition of AMP:

(a) “Average Manufacturer Price (AMP)” means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(Rebate Agreement, § I(a).)

The Rebate Agreement also sets forth the following definition of Best Price:

(d) “Best Price” means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best Price includes prices to wholesalers, retailers, non profit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the Best Price. The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under section 1927 of the Act). It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundles Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(Rebate Agreement, § I(d).)

The terms of the Rebate Agreement require the payment of quarterly rebates to each of the State Medicaid programs based on these reported prices and the quantity of each product for which the State paid Medicaid reimbursements. (Rebate Agreement, § II(b).)

Notably, Wisconsin does not allege that Dey failed to report, or reported inaccurately, AMP or Best Price information to CMS. There is also no allegation in the Complaint that Dey ever failed to make the rebate payments to Wisconsin called for under the terms of the Rebate Agreements.

Section III(b) of the Rebate Agreement gives the Secretary of DHHS the power to survey Dey and the wholesalers who purchase Dey’s drugs to verify that the AMPs Dey reports are accurate.

Section IV of each Rebate Agreement is a penalty provision that provides for

penalties in the event Dey “refuses requests for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information.” (Rebate Agreement, § IV(a).) Section V provides a mechanism for resolution of disputes in connection with rebate amounts arising under the Agreement.

CMS has calculated unit rebate amounts (“URAs”) based upon the formula set forth in federal statute and the AMPs and Best Prices reported by the drug manufacturers to the Medicaid program. *See* 42 U.S.C. § 1396r-8(c). For instance, rebates for non-innovator, multiple source (*i.e.* generic) drugs are equal to 11% of AMP. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B). (Prior to January 1, 1994, the rebate percentage was 10%. *See id.*) CMS provides the URAs, which constitute AMP information, to the State Medicaid programs, including Wisconsin’s. Thus, Wisconsin Medicaid officials have the necessary information to determine the AMP for each of Dey’s generic products by performing a simple arithmetic calculation, *i.e.*, dividing the URA by 11%, the applicable rebate percentage for non-innovator, multiple source drugs. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B).

Deirdre Duzor, the CMS Director of the Pharmacy Division for the Medicaid program, testified:

Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?

\* \* \*

A: Yes. The AMPs have been fairly transparent for generic drugs.

Duzor Tr. 679; 12-17.

The administrators in charge of running the Medicaid program have testified that States have had access to AMPs. *See* Vladeck Tr. 461:12-15; 463:19-464:06; Scully Tr. 627:13-20. Bruce Vladeck, the Administrator of HCFA from May 1993 to September 1997 testified:

Q: So as far as you know, people within HCFA shared AMP data with state Medicaid agencies?

A: That was my understanding.

\* \* \*

Q: So it was entirely possible -- it was entirely possible for the heads of a state Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to what they were reimbursing for those drugs. That was entirely possible. Right?

A: It's -- I don't know any reason why it wouldn't be possible.

Vladeck Tr. 461:12-15; 463:19-464:06.

Thomas Scully, the Administrator of CMS from May 2001 to December 2003

testified:

Q: Did you ever tell any state that they should calculate their reimbursement methodology for Medicaid taking into account AMP data?

A: No.

Q: Why not?

A: States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.

Scully Tr. 627:13-20.

Regardless of what Wisconsin did or could have done with Dey's AMPs, CMS had the ability to compare Dey's AMPs to Dey AWP and WACs. CMS approved Wisconsin's reimbursement rate for Wisconsin's Medicaid program, which used AWP as one of several bases to calculate reimbursement amounts, and set reimbursement rates under the Medicare Part B program based on AWP, with full knowledge of Dey's AMPs and the "spreads" between AMPs and AWP and WACs.

Dey has never reported false AWP. AWP is not defined by any federal statutes

or regulations and Wisconsin has never set forth a definition of AWP in statute or regulation or otherwise prescribed the manner in which drug manufacturers should set, calculate, or report AWPs.

Dey's general practice was as follows: When Dey introduced a new generic drug product to the market, it set the AWP for its drug at a certain percentage below the AWP for the therapeutically-equivalent branded product. Early on in Dey's business, Ed Edelstein of First Data Bank advised Dey that, for purposes of acceptance by the reporting services of Dey's product as a generic, the AWP for that product should be a minimum of 10% below the innovator product's AWP, and historically, Dey has observed this principle. Generally, it is Dey's practice to set AWPs for its generic drugs before they are first sold and not to subsequently change that AWP. Dey understands that this is consistent with industry practice. There are some instances to the contrary depending on the market and/or other forces. Dey's AWPs for its brand name drugs at issue in this action have been set and revised as Dey's WACs have increased. Dey understands that this practice is also consistent with industry practice.

Dey further states that, as numerous documents produced in this action demonstrate, Wisconsin has known since well before the time period relevant to this action that AWPs reported by drug manufacturers, including Dey, were not an actual average of the prices charged by drug wholesalers to their customers. The following are examples of such documents:

- A 1975 memorandum from the Director of the Legislative Fiscal Bureau ("LFB") to the Joint Committee on Finance, states that "the policy of the Department of Health and Social Services has been to reimburse at the listed wholesale price plus \$2 dispensing fee. Many observers believe that this method of reimbursement is not economical since it fails to take into account state variations from the national wholesale price list or discounts obtained through bulk purchasing." (Memorandum from Dale Cattanaach to the Joint Committee on Finance, *Health and Social Services—Medical Assistance Cost Controls and Sum Sufficient Reestimate* at 4 (Apr. 25, 1975))
- In 1976, the Governor's Task Force on Medicaid Pharmacy Reimbursement (the "Task

Force”) concluded “that the Blue Book prices overstate actual drug costs.” The Task Force recommended that Wisconsin reimburse Medicaid providers at actual acquisition costs, defined as “invoice cost minus bulk purchasing discounts plus billed warehouse costs.” (1976 Task Force Report at 3, 5.)

- In a memo from November of 1989, a Wisconsin Medicaid official suggested revising Wisconsin’s reimbursement methodology to AWP-10% because of an August 1989 transmittal from the Health Care Financing Administration which stated that: “...absent valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers.” (Memorandum from Mike Boushon to Peggy Bartels and Dr. Dally, *Alternatives to Current Drug Reimbursement Method* at 1 (Nov. 24, 1989) (WI-Prod-AWP-097939 to 942).)
- In a 1995 study, the Wisconsin Department of Agriculture, Trade and Consumer Protection described AWP as follows:

The AWP is set by the manufacturer and provides a starting point for many of the price negotiations which are outlined later in this section.

...

The AWP is the manufacturer’s suggested selling price for wholesalers to use. The “Actual Acquisition Cost” is the true cost that retailers pay. This amount may, and does, differ significantly from AWP. The wholesaler is often granted discounts from the AWP from the manufacturer.

- (Wisconsin Department of Agriculture, Trade and Consumer Protection, *Wholesale Pricing of Prescription Drugs in Wisconsin* (July 28, 1995), at 18, 21 (WI-Prod-AWP-106223 to 297)
- A Budget Issue Paper prepared by the Wisconsin DHFS in June of 1998 states that AWP “represents more than cost[,]” and that “Wisconsin MA’s current drug payment methodology over-compensates pharmacy providers for their cost of drugs.” DHFS 1999-2001 Biennial Budget Issue Paper, *Cost of Drugs* at 1 (June 2, 1998) (WI-Prod-AWP-095303-306).
- An LFB paper dated June 1, 1999 states that “AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to the ‘sticker price’ of a car. It does not reflect the actual cost of acquiring the drug.” (LFB, Joint Committee on Finance, *Drug Reimbursement*, Paper #479 at 3 (June 1, 1999) (attached as Ex. 32) (WI-Prod-AWP-106010-18).)
- A 2002 study commissioned by Wisconsin to investigate pharmacy reimbursement concluded that AWP exceeded actual acquisition costs by 17.52 to 17.58% for brand

name drugs, and 74.44 to 76.16% for generics. (David Kreling, *Pharmacy Cost of Dispensing/Acquisition Cost Study Final Report* (“Kreling Report”) at ii (Mar. 6, 2002) (PSW\_00010245-67).)

- In a 2004 letter responding to a private attorney’s solicitation to participate in an AWP litigation, a Wisconsin DHFS official noted that Wisconsin had been aware of the disparity between AWP and actual acquisition costs for some time:

The issue you present is one of which we have been aware for several years. In 1997, and again in 2001, Wisconsin was one of the eight states that the Department of Health and Human Services’ Office of the Inspector General included in its survey of Medicaid Coverage of Prescription Drugs. That survey indicated that pharmacists could obtain brand name prescription drugs at 21.84 percent below the average wholesale price, while Medicaid reimbursement for those drugs averaged around 10-12 percent below the average wholesale price.

- (Letter from Mark B. Moody to Gary F. Franke (Mar. 17, 2004) (WI-Prod-AWP-126686).)

In addition to the documents listed above, Wisconsin has received directives and/or reports from the federal government that AWP does not reflect the cost to providers for Dey’s drugs. Government reports and studies confirm that Wisconsin knew AWPs were only benchmark prices that did not reflect the providers’ actual acquisition costs. For example, in 1984, the HHS-OIG issued a report alerting every state Medicaid agency that “[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price.” That AWP is a benchmark price has been recognized in numerous other public reports, including the following:

- In 1977, HCFA told the States that “[i]n order to set estimated acquisition costs which come close to AAC [actual acquisition costs], some states, for example, begin with AWP prices but apply a percentage markdown to determine acquisition costs.” HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, *Medicaid - Formula for Determining EAC for Drugs*, reprinted in *Medicare and Medicaid Guide* (CCH) ¶ 28,714.
- In 1984, the HHS-OIG reported that “AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order

discounts, . . . rebates, or free goods that do not appear on the pharmacist's invoices," and recommended that state agencies be precluded from using an undiscounted AWP. The report found pharmacy drug purchases were made at prices averaging approximately 15.93% below AWP, with some at 42% below AWP. *Medicaid Action Transmittal No. 84-12* at 3, 6.

- In 1989, the HHS-OIG reported: "[w]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs. When AWP is used, we believe it should be discounted." *OIG Rep. Concerning Medicaid and Medicare Reimbursement for Drugs* at 7.
- In 1996 and 1997, the HHS-OIG publicly issued thirteen audit reports finding that AWP's significantly exceed pharmacies' actual acquisition costs.
- Between 1996 and 2004, the HHS-OIG published at least eight reports that specifically discussed spreads between pharmacists acquisition costs and published AWP's for albuterol products. In 2002 and 2003, the HHS-OIG issued similar reports discussing similar spreads for ipratropium bromide products.

In May 2000, the Wisconsin Medicaid program received average wholesale market pricing information for about 400 national drug codes compiled by the U.S. Department of Justice ("DOJ"), without reliance on published AWP's (the "DOJ Prices"). All of the States that participated in the Medicaid program, including Wisconsin, were told actual acquisition costs may be even lower than the DOJ Prices, "because purchasers often receive further discounts, below the advertised wholesale catalog price . . . ." Program Memorandum Intermediaries/Carriers, Transmittal AB-00-86 (September 8, 2000).

Moreover, Dey has explained to Medicaid officials exactly what Dey's AWP's represent. Starting in at least 1999, Dey informed Wisconsin Medicaid officials:

As you know, the AWP listed here does not represent the actual price which will be or has been charged for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. Dey believes this to be clearly understood by state and federal Medicaid regulators.

(Letter from Robert F. Mozak to State Medicaid Administrator, August 10, 1999, WI-Prod-AWP-128276.) Despite this disclosure, Wisconsin never objected to the manner in which Dey

set its AWP prior to this lawsuit. Indeed, as far as Dey knows, Wisconsin has never even attempted to contact Dey to discuss the manner in which it sets its AWP.

Dey further states that, throughout the relevant time period, Wisconsin calculated its reimbursement payments for drugs dispensed to Medicaid beneficiaries based on a methodology that included a percentage discount off of AWP as one of its options, despite knowing that AWP did not represent an actual average of providers' actual acquisition costs. From at least the late-1970s until June 1990, Wisconsin has reimbursed based on the lower of (1) EAC, which Wisconsin defined as the Direct Price charged by certain manufacturers, an undiscounted AWP, or MAC plus a reasonable dispensing fee; or (2) "usual and customary charge." (See State Plan Amendment No. 79-0032 (Sept 21, 1979) (WI-Prod-AWP-022148); State Plan Amendment No. 90-0006 (Apr. 17, 1990) (WI-Prod-AWP-011366).) In July 1990, Wisconsin Medicaid changed its definition of EAC from an undiscounted AWP to AWP-10%. (Vavra Tr. at 394:5-21.) In July 2001, Wisconsin modified the reduction off of AWP in its reimbursement methodology to AWP-11.25%. (Vavra Tr. at 97:6-13; State Plan Amendment No. 01-0009 (July 1, 2001) (WI-Prod-AWP-027602).) In 2003, Wisconsin again modified the reduction off of AWP in its reimbursement methodology to AWP-12%, and, in 2004, it changed it to AWP-13%, and has not changed it since. (Vavra Tr. at 436:2-13, 452:12-15.) Indeed, even today, after the commencement of this lawsuit, Wisconsin continues to use AWP as one of the possible bases to calculate reimbursement.

The existence of a "spread" between reimbursement rates based on AWP and the prices at which Dey's drugs were purchased by providers did not violate the law, was not misleading, and did not cause Medicare or Medicaid to make excessive reimbursement payments. Medicare and Medicaid actively decided to use a reimbursement methodology with a

built-in “spread” between a provider’s acquisition costs and reimbursement amounts to serve their own needs, including ensuring that beneficiaries of the programs had adequate access to care.

Participation by providers in the Medicaid and Medicare programs is voluntary. To ensure that beneficiaries have adequate access to medical care, the Wisconsin Medicaid program utilizes a reimbursement methodology that includes, as one of its bases, a percentage discount off of AWP to provide an economic incentive for providers’ participation. Likewise, prior to 2005, the Medicare Part B program used a reimbursement methodology that included, as one of its bases, a percentage discount off of the median AWP to provide an economic incentive for providers’ participation. The Medicaid and Medicare programs knew that their reimbursement methodology for the ingredient portion did not approximate providers’ costs to acquire the drugs, but did not change their reimbursement methodologies because, among other reasons, they had to ensure that a sufficient number of providers enrolled to ensure access to care for their beneficiaries. Additionally, federal law requires that states’ Medicaid payments “are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” 42 U.S.C. § 1396a(a)(30)(A).

The Medicaid and Medicare programs have used AWP as a benchmark price as a way of ensuring access to care for beneficiaries because the “spread” the programs built in has been intended to cover providers’ costs and ensure providers receive a profit on the transactions. Indeed, Wisconsin recognizes that Medicaid reimbursement must provide pharmacists with a reasonable profit margin. In 2006, the Governor of Wisconsin established a commission to study cost-saving alternatives to reducing pharmaceutical reimbursement rates. One of the goals of the

commission was “to balance the interests of various stakeholders,” including pharmacists’ interest “to be provided with sufficient reimbursement to cover their costs of doing business, i.e., the cost of the drug (ingredient cost), and the costs of dispensing and some profit margin.” (Governor’s Commission on Pharmacy Reimbursement -- Final Report (“2006 Governor’s Commission Report”) at 7 (Mar. 30, 2006) (emphasis added).)

Additionally, dispensing fees do not cover dispensing costs incurred by providers, much less provide a profit. The dispensing fee component of Wisconsin’s reimbursement methodology has long been well below Wisconsin’s own estimates of pharmacists’ dispensing costs. For instance:

- In 1990, extrapolating from a study performed in 1979, Wisconsin estimated that the average cost of dispensing, in 1990, was \$5.28 per prescription. (*Projecting a 1990 Cost of Dispensing a Prescription Drug*, (1990) (WI-Prod-AWP-097969-971).) However, Wisconsin did not raise its dispensing fee to \$5.28; rather, it only raised the fee to \$4.69. (Memorandum from Christine Nye to Mark Gajewski (May 1, 1990).)
- In 2000, Wisconsin commissioned Dr. David Kreling to determine the average cost of dispensing prescriptions. Dr. Kreling concluded that, in 2000, the average dispensing costs was \$6.60. (Kreling Report at 2.) Yet, during this time, Wisconsin’s dispensing fee was \$4.38. (*See State Plan Amendment No. 01-0009*, (July 1, 2001) (WI-Prod-AWP-027605).)
- In 2002, Dr. Kreling projected the average dispensing cost to be between \$7.03 and \$7.43 per prescription. (2002 Kreling Report at 2.) During this time, Wisconsin retained its \$4.38 dispensing fee.
- In 2006, the commission convened by the Governor to explore alternative cost-reduction measures found that the average dispensing costs was \$9.50. (2006 Governor’s Commission Report at 7.) Yet Wisconsin’s dispensing fee remained at \$4.38.

Thus, Wisconsin relies on the spread between pharmacists’ acquisition costs and the reimbursement calculations based on AWP to cover pharmacists’ costs and provide them with a reasonable profit:

- In 1988, the Bureau of Health Care Financing (“BHCF”), the bureau responsible at the time for administering Medicaid, stated that: “It is generally accepted that

[Wisconsin Medicaid's] stated professional fee is lower than actual pharmacy overhead costs, but this discrepancy had previously been nullified by the difference between [Wisconsin Medicaid's] payment for the drug and the actual new drug cost to the pharmacy. (A lower net cost can be due to 'volume' or early-pay discounts offered by wholesalers.)” (Memorandum from Christine Nye to Roberta Kostrow at 3 (Nov. 22, 1988).)

- In 1989, BHCF “acknowledge[d] that AWP is inflated, but argue[d] that total payments are not excessive because dispensing fees are artificially low and off-set the over allowance.” (Memorandum from Christine Nye to George MacKenzie at 2 (June 26, 1989).)
- In 2001, the Legislative Fiscal Bureau noted that “[t]he margin between the acquisition cost and the reimbursement rate, together with the dispensing fees, represents the pharmacies' total reimbursement for service costs.” (Legislative Fiscal Bureau, *Reimbursement Rates for Prescription Drugs (DHFS-Medical Assistance)* Paper #474 at 4 (June 4, 2001).)
- In 2003, the Legislative Fiscal Bureau warned that a proposed cut in reimbursement from AWP-11.25% to AWP-15% would reduce a pharmacist’s margin to a “\$2.22 margin on AWP,” which “may not cover all of a pharmacy’s costs to dispense a prescription.” (Legislative Fiscal Bureau, *Reimbursement Rates for Prescription Drugs (DHFS-Health Care Financing-Payments, Services and Eligibility)* Paper #389 at 5 (May 21, 2003).)

As a result, the Medicare and Medicaid programs used, and the Wisconsin Medicaid program continue to use, a reimbursement methodology that includes, as one of its bases, a percentage discount off of AWP to compensate for this shortfall in dispensing fees and to ensure that providers earn a profit on Medicaid and Medicare transactions. Meanwhile, when the federal government switched Medicare reimbursement to a system based on Average Sales Price (“ASP”), it drastically increased dispensing fees.

Through its reimbursement methodology that includes, as one of its bases, a percentage discount off of AWP, Wisconsin knowingly provided larger “spreads” or margins for generic drugs than for brand-name drugs in order to provide an incentive for pharmacies to dispense lower-cost generic drugs. Generic drugs are typically less costly than brand-name drugs. For example, in 1996, the HHS-OIG found that providers’ acquisition costs, on average,

were 18.3% below AWP for brand-name drugs and 42.5% for generic drugs.

Even though reimbursement for a generic drug may give a provider a larger “spread” than reimbursement for a brand-name drug, its total reimbursement payment for the generic drug will still be lower than that for a brand-name drug, thereby saving Wisconsin money. As “spreads” for generic drugs increase, Wisconsin benefits because the larger spreads increase incentives for providers to dispense generic drugs. Moreover, contrary to Plaintiff’s claims, Dey does not benefit from increased spreads. First, drug manufacturers, like Dey, do not receive the money which comes from the spread. The so-called spread in the reimbursement payments goes to the providers. Second, if the spread for a particular generic Dey drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower. At the same time, Dey’s costs are increasing and its margins are declining.

Wisconsin and Dey have therefore shared an understanding that AWP exceeded providers’ acquisition costs, as evidenced by (a) the Rebate Agreement, (b) Wisconsin’s understanding, consistent with Dey’s understanding, that AWP did not represent an average of actual wholesale prices for Dey’s drugs, (c) Wisconsin’s failure to implement a different definition of AWP, either through statute, regulation, or by agreement; and (d) Wisconsin’s continued use of AWP throughout the relevant time period to achieve certain policy goals within the Wisconsin Medicaid program.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 7:

Produce all documents identified in your Response to Interrogatory No. 7.

DEY’S RESPONSE AND OBJECTIONS:

Dey hereby adopts and incorporates its objections and response to Request for

Admission No. 7 and Interrogatory No. 7 into its response to Request for Production of Documents No. 7. Dey further objects to Request for Production of Documents No. 7 to the extent that it demands the production of documents that Dey has produced or will produce in response to Wisconsin's prior interrogatories and requests for production, or that are otherwise already within Wisconsin's possession, custody, or control.

Subject to and without waiving the foregoing general and specific objections, Dey directs Wisconsin to the documents noted in Dey's response to Interrogatory No. 7.

### CONSOLIDATED DISCOVERY REQUEST NO. 8

#### REQUEST FOR ADMISSION NO. 8:

At no time has the State of Wisconsin and you agreed on the meaning or definition of wholesale acquisition cost ("WAC").

#### DEY'S RESPONSE AND OBJECTIONS:

Dey objects to Request for Admission No. 8 on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms and phrases that are themselves vague, ambiguous, or undefined, including, but not limited to, "agreed," "meaning," and "definition."

Subject to and without waiving the foregoing objections, Dey denies the matters set forth in Request for Admission No. 8.

#### INTERROGATORY NO. 8:

If your response to Request for Admission No. 8 is anything other than an unqualified admission, state all bases for your response, including the following:

- (a) identify the definition of WAC that you contend the State of Wisconsin and you agreed on;
- (b) identify the date when you contend that the State of Wisconsin and you first agreed on the definition of WAC provided in response to subpart (a) of this interrogatory
- (c) state whether you contend that the State of Wisconsin and you

agree on the definition of WAC provided in your response to subpart (a) of this interrogatory as of the date that you answer this second set of consolidated discovery requests to all defendants;

(d) if your answer to subpart (c) is “no,” identify the last date when you contend the State of Wisconsin and you agreed on the definition of WAC provided in response to subpart (a) of this interrogatory;

(e) state whether you contend that the State of Wisconsin and you together developed the definition of WAC provided in response to subpart (a) of this interrogatory;

(f) if your answer to subpart (e) is “yes,” describe in detail the manner in which the State of Wisconsin and you together developed the definition of WAC provided in response to subpart (a) of this interrogatory, including (1) the identity of each person involved in the development of the definition; (2) the role of each such person; (3) the dates of each such person's participation in the development of the definition; and (4) the dates and substance of each communication between the State of Wisconsin and you regarding the development of the definition of WAC;

(g) identify all documents supporting your response to request for admission no. 8;

(h) identify all documents supporting your answer to interrogatory no. 8, including all subparts;

(i) identify all documents supporting any contention you provide in your answer to interrogatory no. 8, including all subparts.

DEY'S RESPONSE AND OBJECTIONS:

Dey hereby adopts and incorporates its specific objections to Request for Admission No. 8 into its response to Interrogatory No. 8.

Subject to and without waiving the foregoing objections, Dey responds as follows:

Dey adopts and incorporates herein the portions of its response to Interrogatory No. 7 that discuss the Rebate Agreement.

Dey states that WAC is not defined anywhere in Wisconsin's statutes or

regulations and Wisconsin has never provided or directed Dey to any definition of WAC. Dey's WAC is the invoice price that Dey charges wholesalers. When each of Dey's generic drugs was launched, Dey set a WAC at a percentage below the AWP for the drug. It has been Dey's general practice to reduce its WACs for its generic drugs on a periodic basis as prices for the drug have eroded in the marketplace due to generic competition.

Dey has explained to Medicaid officials, including officials in Wisconsin's Medicaid program, exactly what Dey's WACs represent. Starting in at least 2000, Dey informed Medicaid officials:

As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the actual invoice price charged by a pharmaceutical manufacturer to its drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid.

(Letter from Robert Mozak to various state Medicaid officials, including Roma Rowlands, July 18, 2000, DEY-WI-0121379-385, 380.) Despite this disclosure, Wisconsin never objected to the manner in which Dey set its WACs prior to this lawsuit. Indeed, as far as Dey knows, Wisconsin has never even attempted to contact Dey to discuss the manner in which it sets its WACs.

This is consistent with Wisconsin's own understanding that WAC represented an undiscounted price to a wholesaler that did not include rebates, chargebacks, and other reductions in price. In a 1995 study, the Wisconsin Department of Agriculture, Trade and Consumer Protection described WAC as follows:

In general, wholesalers purchase from manufacturers at the Wholesale Acquisition Cost (WAC). Rebates or discounts from WAC, may be granted, such as those based on volume purchasing.

...

Often the Wholesale Acquisition Cost (WAC) will be above the contractual price [from the wholesaler to its customer], indicating that the wholesaler is taking a loss. However, the wholesaler does usually recover the difference between the contractual price and the WAC from the manufacturer through a process commonly referred to as a charge back. For each product sold at a contractual price, the wholesaler must file that transaction with the manufacturer to obtain a refund of the difference between WAC and the contract price.

(Wisconsin Department of Agriculture, Trade and Consumer Protection, Wholesale Pricing of Prescription Drugs in Wisconsin (July 28, 1995), at 18, 21(WI-Prod-AWP-106223 to 297).

James Vavra, another of Wisconsin's designated witnesses, confirmed that this was consistent with his, and consequently Wisconsin's, understanding of WAC. (Vavra Tr. at 133-34.)

Likewise, the federal government has advised states, including Wisconsin, that WAC is not equal to providers' acquisition cost and that WAC does not include discounts and price reductions that may affect the price to wholesalers. *See, e.g.*, GAO Report, "Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom" (January 1994), at p. 19, n.16. Indeed, in the federal Medicare Modernization Act of 2003 (Pub. L. 108-173), Congress defined WAC to exclude "prompt pay or other discounts, rebates or reductions in price." *Id.* at Sec. 1847A (c)(6)(B).

Wisconsin and Dey therefore have shared an understanding that WAC was an invoice price to wholesalers that did not include discounts, rebates or other reductions in price, as evidenced by (a) the Rebate Agreement, (b) Wisconsin's understanding, consistent with Dey's understanding, that WAC was an invoice price to wholesalers that did not include discounts, rebates and other price reductions, (c) the definition of WAC set forth in federal statute, and (d)

Wisconsin's failure to implement a different definition of WAC.

REQUEST FOR PRODUCTION OF DOCUMENTS No. 8:

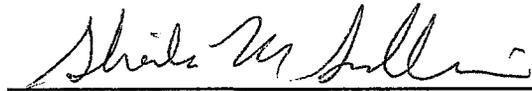
Produce all documents identified in your Response to Interrogatory No. 8.

DEY'S RESPONSE AND OBJECTIONS:

Dey hereby adopts and incorporates its objections and responses to Request for Admission No. 8 and Interrogatory No. 8. into its response to Request for Production of Documents No. 8. Dey further objects to Request for Production of Documents No. 8 to the extent that it demands the production of documents that Dey has produced or will produce in response to Wisconsin's prior interrogatories and requests for production, or that are otherwise already within Wisconsin's possession, custody, or control.

Subject to and without waiving the foregoing general and specific objections, Dey directs Wisconsin to the documents noted in Dey's response to Interrogatory No. 8.

Dated: August 11, 2008.



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**CALIFORNIA JURAT WITH AFFIANT STATEMENT**

- See Attached Document (Notary to cross out lines 1-6 below)
- See Statement Below (Lines 1-5 to be completed only by document signer[s], *not* Notary)

1 \_\_\_\_\_  
 2 \_\_\_\_\_  
 3 \_\_\_\_\_  
 4 \_\_\_\_\_  
 5 \_\_\_\_\_  
 6 \_\_\_\_\_

Signature of Document Signer No. 1                      Signature of Document Signer No. 2 (if any)

State of California  
 County of Napa

Subscribed and sworn to (or affirmed) before me on this

9th day of August, 2008, by  
Date                      Month                      Year

(1) Samela Marks  
Name of Signer

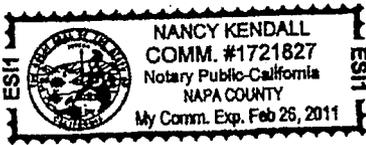
proved to me on the basis of satisfactory evidence to be the person who appeared before me (.) (✓)

(and

(2) none  
Name of Signer

proved to me on the basis of satisfactory evidence to be the person who appeared before me.)

Signature Nancy Kendall  
Signature of Notary Public



Place Notary Seal Above

**OPTIONAL**

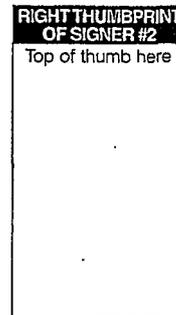
*Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.*

**Further Description of Any Attached Document**

Title or Type of Document: WI Verification

Document Date: \_\_\_\_\_ Number of Pages: 32

Signer(s) Other Than Named Above: none



VERIFICATION AS TO RESPONSES TO INTERROGATORIES

I, PAMELA MARRS, having first been duly sworn, hereby state that I am the Senior Vice-President and Chief Financial Officer of Dey, Inc. I have read the foregoing Responses and Objections to Plaintiff's Second Set of Consolidated Discovery Requests to All Defendants and verify that the information contained in responses to the interrogatories therein is true and correct to my best knowledge, information and belief.

DEY, INC.

By: *Pamela Marr*  
Pamela Marrs

Title: Senior Vice-President and Chief Financial Officer

~~Sworn to and subscribed before me  
this \_\_\_\_\_ day of August, 2008~~

~~*see ATTACHED*~~

~~\_\_\_\_\_  
Notary Public~~