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Via LexisNexis File and Serve

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Charles J. Barnhill, Jr.
Miner, Barnhill & Galland, PC
44 E Mifflin St #803
Madison, WI 53703

Re: *State of Wisconsin v. Abbott Laboratories, et al.*
Case No. 04-CV-1709

Dear Chuck:

Enclosed please find Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.'s Responses and Objections to Plaintiff's First Set of Consolidated Discovery Requests to All Defendants. The signed Verification will be served under separate cover as soon as we receive it.

Sincerely yours,



Lissa R. Koop

Enclosure

cc: LNFS Service List

THE STATE OF WISCONSIN

Plaintiff,

CASE NO. 04-1709

v.

ABBOTT LABORATORIES, et al.

Defendants.

**DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S
RESPONSES AND OBJECTIONS TO PLAINTIFF'S FIRST SET OF
CONSOLIDATED DISCOVERY REQUESTS TO ALL DEFENDANTS**

Pursuant to Wis. Stat. §§ 804.01, 804.08, 804.09, and 804.11, Defendants Mylan Inc. (formerly known as "Mylan Laboratories Inc.") and Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") (Mylan Inc. and Mylan Pharmaceuticals are referred to collectively herein as "Mylan"), by their undersigned counsel, assert the following responses and objections to the First Set of Consolidated Discovery Requests to All Defendants, dated May 15, 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 Mylan as to the existence or non-existence of any documents or information.

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

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

6. Mylan objects to the Consolidated Discovery Requests to the extent they seek information or documents not within Mylan's knowledge, possession, custody or control or seek admissions concerning matters of which Mylan has no knowledge. Mylan Inc. is a holding company and does not itself manufacture, market or sell drugs.

7. Mylan 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. Mylan 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. Mylan 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. Mylan will provide documents and information relating only to pharmaceutical products attributed to Mylan in the Stipulated Targeted Drug List (the “Mylan Targeted Drugs”).

10. Mylan objects to the Consolidated Discovery Requests as unduly burdensome to the extent that they purport to require Mylan 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 Mylan has produced or will produce.

11. Mylan 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 Mylan’s right to assert the applicability of any

privilege or immunity to the documents, and any documents shall be returned to Mylan's counsel immediately upon discovery thereof.

12. Mylan objects to the Consolidated Discovery Requests to the extent that they seek documents, information, or admissions concerning or containing trade secrets, or proprietary, commercially sensitive or other confidential information.

13. Mylan 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 Mylan 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.

14. Mylan objects to the Consolidated Discovery Requests to the extent that they seek documents, information, or admissions concerning matters, that are: (a) not within the knowledge, possession, custody, or control of Mylan, its agents, or its employees, (b) publicly available or publicly known; or (c) more appropriately sought from third parties or other defendants to whom requests or interrogatories have been or may be directed.

15. Mylan 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. Mylan 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.

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

17. Mylan 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 Mylan to a particular request or interrogatory is not intended to indicate that Mylan 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.

18. Mylan 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.

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

20. Mylan objects to the Consolidated Discovery Requests to the extent they seek documents, information, or admissions relating to Mylan'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.

21. Mylan objects to the Consolidated Discovery Requests to the extent they purport to impose on Mylan 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.

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

23. Mylan 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 Mylan's objections to the definitions and instructions set forth below. Mylan also objects to the definitions and instructions as follows:

1. Mylan 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, Mylan's obligations under the Wisconsin Rules of Civil Procedure and any applicable local rules. Mylan will comply with the Wisconsin Rules of Civil Procedure and any applicable local rules. Mylan further objects to this definition to the extent it requires or seeks to require Mylan 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 request would be unduly burdensome. Mylan further objects to this definition to the extent it requires or seeks to require Mylan 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. Mylan 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 Mylan, its agents, or its employees, or that are more appropriately sought from third parties to whom requests have been or may be directed. Mylan further objects to the definition as unduly burdensome.

3. Mylan objects to the definition of “incentive” as set forth in Definition No. 3 on the grounds that it is vague, ambiguous, overly broad, and unduly burdensome because, *inter alia*, it contains terms that are themselves vague, ambiguous, or undefined, including but not limited to, “anything of value,” “provided,” “customer,” “reward,” “lowering the cost of a pharmaceutical to the customer in any way, regardless of the time it was provided...and regardless of its name,” “payments or proposed payments in cash or in kind,” “chargebacks,” “credits,” “discounts,” “return to practice discounts,” “prompt-pay discounts,” “volume discounts,” “on-invoice discounts,” “off-invoice discounts,” “rebates,” “market-share rebates,” “access rebates,” “bundled-drug rebates,” “free goods or samples,” “administrative fees or administrative fee reimbursements,” “marketing fees,” “stocking fees,” “conversion fees,” “patient education fees,” “off-invoice pricing,” “educational or other grants,” “research funding,” “clinical trials,” “honoraria,” “speaker’s fees or payments,” “patient education fees,” and “consulting fees.”

4. Mylan 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*, it contains 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”. Mylan further objects to this definition as overly broad to the extent it purports to include persons or entities that have no authorization to act on behalf of Mylan and over whom Mylan has no control. Mylan further objects to this definition as overly broad and unduly burdensome to the extent that it purports 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. Mylan further objects to this definition as unduly burdensome and irrelevant on the grounds that the phrase “your company” does not appear in any of the Consolidated Discovery Requests.

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

6. Mylan objects to Instruction No. 1 for Interrogatories the extent that it requires Mylan to provide any information or documents within the knowledge, possession, custody or control of Mylan’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. Mylan further objects to this Instruction because the phrase “subject to reasonable inquiry by you” is vague, ambiguous and overbroad.

7. Mylan objects to Instruction No. 2 for All Discovery Requests as unduly burdensome.

SPECIFIC RESPONSES AND OBJECTIONS TO THE CONSOLIDATED DISCOVERY REQUESTS

Mylan 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. 1

REQUEST FOR ADMISSION NO. 1:

At no time has the State of Wisconsin, its Department of Health & Family Services, or any employee thereof, explicitly approved your practice of reporting to First DataBank average wholesale prices (“AWPs”) for your drugs that were not the true average prices charged by wholesalers to their customers for your drugs.

MYLAN’S RESPONSE AND OBJECTIONS:

Mylan objects to Request for Admission No. 1 on the grounds that it is vague and ambiguous, *inter alia*, because it contains terms and phrases that are themselves vague, ambiguous, or undefined, including, but not limited to, “your practice,” “reporting,” “average wholesale prices (‘AWPs’)” and “true average prices.” Mylan further objects to this request as unduly burdensome to the extent that it seeks admissions concerning matters that are not within Mylan’s knowledge, are already within Wisconsin’s knowledge, or are more appropriately sought from third-parties, as Mylan is not aware of the “true average prices charged by wholesalers.” Mylan further objects to this request on the grounds that it improperly assumes facts not in evidence. Mylan further objects to this request to the extent that it improperly implies that the AWP’s Mylan Pharmaceuticals provided to First DataBank were false. Mylan further objects to this request to the extent that it improperly implies that Mylan was obligated to seek approval from Wisconsin concerning Mylan Pharmaceuticals’ determination and reporting of AWP’s, or that Wisconsin had adopted statutes, regulations, or guidelines governing, or in any way controlled or sought to control, the manner in which Mylan Pharmaceuticals or any other

drug manufacturer determined and reported AWP's. Mylan further objects to this request as overly broad and unduly burdensome to the extent it seeks admissions concerning unspecified actions and/or statements taken and/or made by unspecified individuals during an unspecified period of time.

Subject to and without waiving the foregoing general and specific objections, Mylan denies the matters set forth in Request for Admission No. 1.

INTERROGATORY NO. 1:

If your response to Request for Admission No. 1 is anything other than an unqualified admission, state all bases for your response, including the following:

- (a) identify whether the approval was made verbally or in writing;
- (b) identify the person(s) who approved the practice;
- (c) identify the date(s) on which the approval was made;
- (d) state whether the approval was communicated to you;
- (e) if the approval was communicated to you, state whether the communication was made verbally or in writing;
- (f) if the approval was communicated to you, identify the date of such communication(s);
- (g) if the approval was communicated to you, identify the person(s) who made the communication(s);
- (h) if the approval was communicated to you, identify the person(s) who received the communication(s);
- (i) identify all documents relating to the approval of the practice;
- (j) identify all documents relating to the communication of the approval to you.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan hereby adopts and incorporates its specific objections to Request for Admission No. 1 into its response to Interrogatory No. 1. Mylan further objects to this

interrogatory as unduly burdensome to the extent that it seeks information that is: (a) not within Mylan's knowledge, possession, custody, or control; (b) already within Wisconsin's knowledge, possession, custody, or control; or (c) more appropriately sought from third parties.

Subject to and without waiving the foregoing general and specific objections, Mylan responds as follows:

Mylan states that it has never reported false AWP. AWP is not defined by any federal or Wisconsin statutes or regulations. The AWP that Mylan Pharmaceuticals sets when it launches a generic drug is established by reference to the corresponding brand name therapeutically equivalent product. It is Mylan Pharmaceuticals' practice to set an AWP for a generic drug before the drug is ever sold, at a percentage amount below the AWP of the corresponding brand name drug. Mylan Pharmaceuticals' practice of setting AWP for its generic products at a percentage amount below the AWP of the corresponding brand name AWP is consistent with industry practice. Due to changes in market and competitive conditions, Mylan Pharmaceuticals may, from time to time, change the AWP for its generic drugs.

Mylan 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 AWP reported by drug manufacturers, including Mylan Pharmaceuticals, 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 Cattanach 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 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 Administration¹ 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

¹ The Health Care Financing Administration or HCFA is now known as the Centers for Medicare and Medicaid Services. The Health Care Financing Administration and the Centers for Medicare and Medicaid Services collectively referred to hereinafter as “CMS”.

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 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 Mylan Pharmaceuticals’ drugs. For example, Medicaid Action Transmittal No. 84012 explained to the State and other state governments that “states can save money under Medicaid by paying for drugs at rates paid by pharmacies, rather than paying the average wholesale price as is often the custom.” The Federal Department of Health & Human Services Office of the Inspector General (“HHS-OIG”) also issued reports addressing the relation between AWP and providers’ actual acquisition costs. *See, e.g., OIG Report Concerning Medicaid and Medicare Reimbursement for Drugs* (Oct. 1989), reprinted in *Medicare and Medicaid Guide* (CCH) § 38,215 at 1 (1990) (“[I]n August 1989, the Health Care Financing Administration (HCFA)

issued a revision to the State Medicaid Manual pointing out the preponderance of evidence demonstrating that AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent. The Manual issuance provides that, absent valid documentation to the contrary, it will not be acceptable under Medicaid for a state to make reimbursements using AWP without a significant discount.”).

In addition, many other government reports and studies confirm that participating Medicaid states, including 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 AWPs significantly exceed pharmacies’ actual acquisition costs.

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 (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).

Mylan further states that, in addition to Wisconsin’s general knowledge concerning the nature of AWP, Wisconsin has known that providers can obtain Mylan’s drugs at prices significantly below AWP. In a 1998 e-mail to the Director of the Bureau of Health Care Program Integrity for the Wisconsin Division of Health Care Financing (“Wisconsin DHCF”), a consultant who was later employed by Wisconsin DHCF stated: “since AWP (i.e., ain’t what’s paid) prices rarely reflect the market, we should continue to have a MAC price. The most recent Mylan prices from Dohman Drug Wholesaler shows Mylan lorazepam selling price at a small fraction of the AWP.” (E-mail from Ted Collins to Alan White Re: Generic Supplies (Feb. 24, 1998) (WI-Prod-AWP-090070 to 71).) Despite knowing that providers could purchase Mylan Pharmaceuticals’ products at prices significantly below their AWP, Wisconsin has never objected to the manner in which Mylan Pharmaceuticals set its AWP prior to this lawsuit. Indeed, Mylan has never represented to Wisconsin that Mylan Pharmaceuticals’ AWP represented an actual average of prices and, as far as Mylan knows, Wisconsin has never attempted to contact Mylan Pharmaceuticals to discuss the manner in which it sets its AWP.

Mylan further states that, throughout the relevant time period, Wisconsin calculated its reimbursement payments for drugs dispensed to Medicaid beneficiaries on AWP,

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 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 Mylan Pharmaceuticals' 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 an AWP-based reimbursement methodology to provide an economic incentive for providers' participation. Likewise, prior to 2005, the Medicare Part B program used an AWP-based reimbursement methodology 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, it had to ensure that a sufficient number of providers enrolled to ensure access to care for Medicaid 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 Wisconsin Medicaid program has never limited reimbursement payments to a provider's acquisition cost for a product by its use of AWP. Consistent with federal regulations and subject to approval by the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers the Medicaid program, Wisconsin has the right to establish its reimbursement methodology for prescription drugs. Wisconsin could have established a reimbursement system based on a relatively small discount from AWP to provide the greatest reimbursement, as some States have done, or one based upon providers' acquisition costs, as has been done elsewhere. Wisconsin's use of a discounted AWP in its reimbursement methodology was the result of political negotiations between the Medicaid agency and Medicaid providers and represents Wisconsin's effort to balance the political goals of the Medicaid program. Similarly, the federal government's use of AWP in reimbursement under the Medicare Part B program prior to 2005 and later its decision to discontinue using AWP for most drugs after 2005 also is

the result of political negotiations between the federal government and Medicare providers and represents the federal government's effort to balance the political goals of the Medicare program. CMS approved the Medicaid and Medicare reimbursement methodologies with full knowledge of the built-in "spread."

The Medicaid and Medicare programs have used AWP as 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).)

Reimbursement for prescription drugs is intended to cover the ingredient cost of the drug, the costs incurred by a provider in dispensing the product, and a reasonable profit to the provider. Generally, 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, an AWP-based reimbursement methodology to compensate for this shortfall in dispensing fees and to ensure that providers earn a profit on Medicaid transactions. Meanwhile, when the federal government switched Medicare reimbursement from an AWP-based system to a system based on Average Sales Price (“ASP”), it drastically increased dispensing fees.

Through its AWP-based reimbursement methodology, 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, was 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, Mylan does not benefit from increased spreads. Drug manufacturers, like Mylan Pharmaceuticals, do not receive the money which comes from the spread. The so-called spread in the reimbursement payments goes to the providers.

Mylan further states that Mylan Pharmaceuticals’ payment of rebates pursuant to 42 U.S.C. § 1396r-8, *et seq.* and the rebate agreement entered into between Mylan Pharmaceuticals and the Secretary of HHS which provides for such payment of rebates (the

“Rebate Agreement”) precludes all liability and damages against Mylan. Section 4401 of the Omnibus Budget Reconciliation Act of 1990, 42 U.S.C. § 1396r-8 (the “Medicaid Rebate Act”), created the requirement that drug manufacturers enter into rebate agreements and pay rebates to the Medicaid program in order to have their drugs eligible for reimbursement under the Medicaid program. The Rebate Agreement was entered into by Mylan Pharmaceuticals and HHS, who entered into the agreement on behalf of the federal government and States with approved Medicaid programs, including Wisconsin. The Rebate Agreement defines Mylan Pharmaceuticals’ obligations to the federal government and Wisconsin concerning price reporting under the Wisconsin Medicaid program. Since Mylan Pharmaceuticals and Wisconsin are parties to an agreement which concerns and delineates the scope of Mylan Pharmaceuticals obligations to report prices, which do not include the obligation to report AWP, the Rebate Agreement precludes liability based on the reporting of AWP.

Pursuant to the Rebate Agreement, Mylan Pharmaceuticals was obligated to report, and did report, AMPs and, where applicable, Best Price, not AWPs, on a quarterly basis throughout the relevant time period to CMS. *See* Rebate Agreement, *see also* 42 U.S.C. § 1396r-8(b)(3). The Rebate Agreement defines AMP as “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” after all “cash discounts allowed and all other price reductions...which reduce the actual price” are taken into account. *See* Rebate Agreement at § I(a).

CMS, in turn, uses the AMPs it receives from Mylan Pharmaceuticals to calculate Unit Rebate Amounts (“URAs”) for Mylan Pharmaceuticals’ products, which are then submitted to Wisconsin and are used as the basis for the rebate amounts Wisconsin invoices Mylan Pharmaceuticals. Wisconsin invoiced Mylan Pharmaceuticals on a quarterly basis for Medicaid

rebates by multiplying the URA for each drug by the number of units dispensed of that drug to Medicaid beneficiaries under the Wisconsin Medicaid program. In response to these invoices, Mylan Pharmaceuticals has paid rebates to Wisconsin and the federal government, thereby lowering the cost of drugs to the Wisconsin Medicaid program.

The URAs are calculated from AMPs for the Mylan Subject Drugs based on the simple mathematical formula for multi-source, or generic, drugs set forth in federal statute, *i.e.*, 11% of AMP. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B). Thus, Wisconsin Medicaid officials have the necessary information to determine the AMP for each of Mylan Pharmaceuticals' generic products by performing a simple arithmetic calculation, *i.e.*, dividing the URA by 11%. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B). Indeed, 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; *see also* 1991 HCFA Transmittal sent to Wisconsin Medicaid (describing how URAs and rebate amounts are calculated from AMPs).

Additionally, even though the drug manufacturer reported the AMP information to CMS, CMS was permitted to disclose this information to Wisconsin. In a proposed rule in 1995, HCFA (n/k/a CMS) stated: "We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by 'the Secretary or a State agency (or contractor therewith).' By including States

within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute.” 60 Fed. Reg. 48442, 48475 (1995). Indeed, prior to the implementation of the Medicaid Rebate Act, the State Medicaid Directors met with representatives of CMS to discuss the Act and to give input to CMS. During this meeting, the State Medicaid Directors discussed the States’ need to know AMP “to establish a pharmacist reimbursement baseline.” The meeting minutes state that “HCFA will definitely share AMP information and actual rebate amount by NDC.”

The Administrators in charge of running the Medicaid program have testified that States have had access to AMPs. 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. at 627:13-20.

Wisconsin set reimbursement rates under its Medicaid program with access to Mylan Pharmaceuticals' AMP information and the "spreads" between the AWP and AMPs. CMS approved Wisconsin's reimbursement rate for the Wisconsin Medicaid program and set reimbursement rates under the Medicare Part B program with full knowledge of Mylan Pharmaceuticals' AMPs and the "spreads" between the AWP and AMPs.

Wisconsin approved the practice of drug manufacturers' reporting to First DataBank AWP that exceeded the actual averages of prices charged by wholesalers to their customers because the reimbursement methodology it set, along with its other policy decisions made in connection with determining appropriate reimbursement rates, described above, reflect and rely upon knowledge of and purposeful utilization of this precise fact. Indeed, Wisconsin has known that published AWP were not an actual averages of providers' acquisition costs for the drugs and that AWP minus the applicable percentage in its reimbursement methodology exceeded providers' acquisition costs. Moreover, Wisconsin did not instruct Mylan to set or report AWP in any particular manner.

Additionally, CMS explicitly approved of Wisconsin's use of an AWP-based reimbursement methodology with knowledge of the spread between the reimbursement amount and providers' acquisition costs. The Medicaid program is jointly funded by the States and the federal government, and the federal government has funded at least 50% of all expenditures of the State Medicaid programs. In order to obtain federal funds, Wisconsin was required to submit

its prescription drug reimbursement methodology to CMS for approval. CMS approved Wisconsin's reimbursement methodology with knowledge: (1) of Mylan Pharmaceuticals' AMP as compared to Mylan Pharmaceuticals' AWP; (2) that the reimbursement methodology included a spread between actual acquisition cost and reimbursement amount; and (3) that Medicaid programs in other states were reimbursing at lower amounts, including any state that reimbursed at actual acquisition cost. In other words, CMS effectively approved of and ratified the spread Wisconsin incorporated into its reimbursement methodology.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 1:

Produce all documents identified in your Response to Interrogatory No. 1.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan hereby adopts and incorporates its specific objections to Request for Admission No. 1 and Interrogatory No. 1. into its response to Request for Production of Documents No. 1. Mylan further objects to Request for Production of Documents No. 1 to the extent that it demands the production of documents that Mylan 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, Mylan directs Wisconsin to the documents noted in Mylan's response to Interrogatory No. 1.

CONSOLIDATED DISCOVERY REQUEST NO. 2

REQUEST FOR ADMISSION NO. 2:

At no time has the State of Wisconsin, its Department of Health & Family Services, or any employee thereof, explicitly approved your practice of reporting to First DataBank suggested wholesale prices ("SWPs") for your drugs that were not the true average prices charged by wholesalers to their customers for your drugs.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan objects to Request for Admission No. 2 on the grounds that it is vague and ambiguous, *inter alia*, because it contains terms and phrases that are themselves vague, ambiguous, undefined, and/or interpreted differently by the parties, including, but not limited to, “your practice,” “reporting,” “suggested wholesale prices (‘SWPs’)” and “true average prices.” Mylan further objects to this request as unduly burdensome to the extent that it seeks admissions concerning matters that are not within Mylan’s knowledge, are already within Wisconsin’s knowledge, or are more appropriately sought from third-parties. Mylan further objects to this request on the grounds that it improperly assumes facts not in evidence. Mylan further objects to this request to the extent that it improperly implies that the prices Mylan Pharmaceuticals provided to First DataBank were false. Mylan further objects to this request to the extent that it improperly implies that Mylan was obligated to seek approval from Wisconsin concerning Mylan Pharmaceuticals’ determination of the prices it provided to First DataBank, or that Wisconsin had adopted statutes, regulations, or guidelines governing, or in any way controlled or sought to control, the manner in which Mylan Pharmaceuticals or any other drug manufacturer determined such prices. Mylan further objects to this request as overly broad and unduly burdensome to the extent it seeks admissions concerning unspecified actions and/or statements taken and/or made by unspecified individuals during an unspecified period of time.

Subject to and without waiving the foregoing general and specific objections, Mylan denies the matters set forth in Request for Admission No. 2.

INTERROGATORY NO. 2:

If your response to Request for Admission No. 2 is anything other than an unqualified admission, state all bases for your response, including the following:

- (a) identify whether the approval was made verbally or in writing;

- (b) identify the person(s) who approved the practice;
- (c) identify the date(s) on which the approval was made;
- (d) state whether the approval was communicated to you;
- (e) if the approval was communicated to you, state whether the communication was made verbally or in writing;
- (f) if the approval was communicated to you, identify the date of such communication(s);
- (g) if the approval was communicated to you, identify the person(s) who made the communication(s);
- (h) if the approval was communicated to you, identify the person(s) who received the communication(s);
- (i) identify all documents relating to the approval of the practice;
- (j) identify all documents relating to the communication of the approval to you.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its objections and response to Request for Admission No. 2.

Subject to and without waiving the foregoing general and specific objections, Mylan states that, throughout the relevant time period, Mylan did not report a "suggested wholesale price" or "SWP" for its drugs to First DataBank. Request for Admission No. 2 is therefore a hypothetical without factual basis.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 2:

Produce all documents identified in your Response to Interrogatory No. 2.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its objections and response to Request for Admission No. 2.

CONSOLIDATED DISCOVERY REQUEST NO. 3

REQUEST FOR ADMISSION NO. 3:

At no time has the State of Wisconsin, its Department of Health & Family Services, or any employee thereof, explicitly approved your practice of reporting to First DataBank wholesale acquisition costs (“WACs”) for your drugs that were not the true average prices, net of discounts, rebates, chargebacks, and incentives, paid by wholesalers to you for your drugs.

MYLAN’S RESPONSE AND OBJECTIONS:

Mylan objects to Request for Admission No. 3 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, “reporting,” “wholesale acquisition costs (‘WACs’),” “true average prices,” “net,” “discounts,” “rebates,” and “chargebacks.” Mylan further objects to this request as unduly burdensome to the extent that it seeks admissions concerning matters that are not within Mylan’s knowledge, are already within Wisconsin’s knowledge, or are more appropriately sought from third-parties. Mylan further objects to this request on the grounds that it improperly assumes facts not in evidence. Mylan further objects to this request to the extent that it improperly implies that the WACs reported by Mylan Pharmaceuticals were in any way false. Mylan further objects to this request to the extent that it improperly implies that Mylan was obligated to seek approval from Wisconsin concerning Mylan Pharmaceuticals’ practice of determining and reporting WACs, or that Wisconsin had adopted statutes, regulations, or guidelines governing, or in any way controlled or sought to control, the manner in which Mylan Pharmaceuticals or any other drug manufacturer determined and reported WACs. Mylan further objects to this request as overly broad and unduly burdensome to the extent it seeks admissions concerning unspecified actions and/or statements taken and/or made by unspecified individuals during an unspecified period of time.

Subject to and without waiving the foregoing general and specific objections, Mylan denies the matters set forth in Request for Admission No. 3.

INTERROGATORY NO. 3:

If your response to Request for Admission No. 3 is anything other than an unqualified admission, state all bases for your response, including the following:

- (a) identify whether the approval was made verbally or in writing;
- (b) identify the person(s) who approved the practice;
- (c) identify the date(s) on which the approval was made;
- (d) state whether the approval was communicated to you;
- (e) if the approval was communicated to you, state whether the communication was made verbally or in writing;
- (f) if the approval was communicated to you, identify the date of such communication(s);
- (g) if the approval was communicated to you, identify the person(s) who made the communication(s);
- (h) if the approval was communicated to you, identify the person(s) who received the communication(s);
- (i) identify all documents relating to the approval of the practice;
- (j) identify all documents relating to the communication of the approval to you.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan hereby adopts and incorporates its specific objections to Request for Admission No. 3 into its response to Interrogatory No. 3. Mylan further objects to this interrogatory as unduly burdensome to the extent that it seeks information that is: (a) not within Mylan's knowledge, possession, custody, or control; (b) already within Wisconsin's knowledge, possession, custody, or control; or (c) more appropriately sought from third-parties.

Subject to and without waiving the foregoing general and specific objections,

responds as follows:

Mylan states that WAC is not defined anywhere in Wisconsin's statutes or regulations and Wisconsin has never provided or directed Mylan to any definition of WAC. Mylan Pharmaceuticals' WAC is the price that Mylan Pharmaceuticals invoices to wholesalers for its products. Mylan Pharmaceuticals sets the WAC at an amount below the AWP for the drug. Due to changes in market and competitive conditions, Mylan Pharmaceuticals may, from time to time, change the WAC for its generic products.

Mylan further states that Wisconsin has never understood WAC to represent an actual average of the prices, net of discounts, rebates, chargebacks, and incentives, paid by wholesalers to drug manufacturers. Carrie Gray – the witness designated by Wisconsin to testify about Wisconsin's efforts to define, calculate, determine, investigate, understand or interpret AWP or WAC – testified that she was not aware of any drug manufacturer ever representing to Wisconsin that WAC was an actual average of wholesale acquisition cost. Gray Dep. at 122:18-22.

Rather, during the relevant time period, Wisconsin was aware that WAC is not equal to wholesalers' acquisition costs "net of discounts, rebates, chargebacks, and incentives, paid by wholesalers". The federal government has advised States, including Wisconsin, 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).

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 incentives a wholesaler might receive. 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.)

Mylan further incorporates its response to Interrogatory No. 1 herein and states that Wisconsin has had access to Mylan Pharmaceuticals' AMPs and has had the ability to compare those AMPs with Mylan Pharmaceuticals' WACs.

Wisconsin approved of the manner in which Mylan Pharmaceuticals and other drug manufacturers set their WACs at all times relevant to this action as evidenced by: (a) Wisconsin's knowledge that WAC did not represent an average of prices, net of all discounts, rebates, and chargebacks, paid by wholesalers to manufacturers; (b) Wisconsin's access to and knowledge of Mylan Pharmaceuticals' AMPs; and (c) Wisconsin's decision throughout the relevant time period to not define WAC in statute or regulation or otherwise direct Mylan

Pharmaceuticals to set or report its WACs in any particular manner.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 3:

Produce all documents identified in your Response to Interrogatory No. 3.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan hereby adopts and incorporates its specific objections to Request for Admission No. 3 and Interrogatory No. 3. into its response to Request for Production of Documents No. 3. Mylan further objects to Request for Production of Documents No. 3 to the extent that it demands the production of documents that Mylan 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, Mylan directs Wisconsin to the documents noted in Mylan's response to Interrogatory No. 3.

CONSOLIDATED DISCOVERY REQUEST NO. 4

REQUEST FOR ADMISSION NO. 4:

The average wholesale prices ("AWPs") that you reported to First DataBank for your drugs were not the true average prices charged by wholesalers to their customers for your drugs. Rather, the AWPs that you reported to First DataBank for your drugs were more than the true average prices charged by wholesalers to their customers for your drugs.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan objects to Request for Admission No. 4 on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms and phrases that are themselves vague, ambiguous, and/or undefined, including, but not limited to, "reported," "average wholesale prices ("AWPs")" and "true average prices." Mylan further objects to this request on the grounds that it is premised on a definition of "average wholesale price" or "AWP" that is inconsistent

with the common understanding of that term as it was used throughout the relevant time period, and therefore is not susceptible to a meaningful response. Mylan further objects to this request as unduly burdensome to the extent that it requires Mylan to analyze voluminous transactional data over an unspecified period of time between wholesalers and their customers, which data: (a) is not within Mylan's possession, custody, or control; (b) is more appropriately sought from the wholesalers themselves; and (c) Wisconsin has the ability to analyze itself. Mylan further objects to this request on the grounds that it is improperly compound. Mylan further objects to this request to the extent that it improperly implies that the AWP's Mylan Pharmaceuticals provided to First DataBank were false.

Subject to and without waiving the foregoing general and specific objections, Mylan denies the matters set forth in this Request to the extent that the Request states that the AWP's that Mylan provided to First DataBank were not Mylan's true AWP's. Mylan further states that it is without knowledge or information sufficient to admit or deny the remaining matters set forth in Request for Admission No. 4 because Mylan does not have any knowledge of and, upon reasonable inquiry, cannot readily obtain the average prices at which wholesalers have sold Mylan's drugs to their customers during the relevant time period.

INTERROGATORY NO. 4:

If your response to Request for Admission No. 4 is anything other than an unqualified admission, state all bases for your response and identify all documents that support or relate to your response.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its objections to Request for Admission No. 4.

Subject to and without waiving the foregoing general and specific objections, Mylan states that the AWP's Mylan Pharmaceuticals provided to First DataBank were consistent with the common understanding of that term by the parties, including Wisconsin, throughout the

relevant time period and incorporates herein its response to Interrogatory No. 1. Mylan further states that it does not have any knowledge of and, upon reasonable inquiry, cannot readily obtain the average prices at which wholesalers have sold Mylan Pharmaceuticals' drugs to their customers during the relevant time period.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 4:

Produce all documents identified in your Response to Interrogatory No. 4.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its objections and responses to Request for Admission No. 4 and Interrogatory No. 4.

CONSOLIDATED DISCOVERY REQUEST NO. 5

REQUEST FOR ADMISSION NO. 5:

The suggested wholesale prices ("SWPs") that you reported to First DataBank for your drugs were not the true average prices charged by wholesalers to their customers for your drugs. Rather, the SWPs that you reported to First DataBank for your drugs were more than the true average prices charged by wholesalers to their customers for your drugs.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan objects to Request for Admission No. 5 on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms and phrases that are themselves vague, ambiguous, undefined, and/or interpreted differently by the parties, including, but not limited to, "reported," "suggested wholesale prices ('SWPs')" and "true average prices." Mylan further objects to this request as unduly burdensome to the extent that it requires Mylan to analyze voluminous transactional over an unspecified period of time between wholesalers and their customers, which data: (a) is not within Mylan's possession, custody, or control; (b) is more appropriately sought from the wholesalers themselves; and (c) Wisconsin has the ability to

analyze itself. Mylan further objects to this request on the grounds that it is improperly compound. Mylan further objects to this request on the grounds that it assumes facts not in evidence. Mylan further objects to this request to the extent that it improperly implies that the prices Mylan Pharmaceuticals provided to First DataBank were in any way false.

Subject to and without waiving the foregoing general and specific objections, Mylan denies the matters set forth in Request For Admission No. 5.

INTERROGATORY NO. 5:

If your response to Request for Admission No. 5 is anything other than an unqualified admission, state all bases for your response and identify all documents that support or relate to your response.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its objections to Request for Admission No. 5.

Subject to and without waiving the foregoing general and specific objections, Mylan states that, throughout the relevant time period, Mylan did not report a "suggested wholesale price" or "SWP" for its drugs to First DataBank. Request for Admission No. 5 is therefore a hypothetical without factual basis.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 5:

Produce all documents identified in your Response to Interrogatory No. 5.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its responses and objections to Request for Admission No. 5 and Interrogatory No. 5.

CONSOLIDATED DISCOVERY REQUEST NO. 6

REQUEST FOR ADMISSION NO. 6:

The wholesale acquisition costs ("WACs") that you reported to First DataBank for your drugs were not the true average prices, net

of discounts, rebates, chargebacks, and incentives, paid by wholesalers to you for your drugs. Rather, the WACs that you reported to First DataBank for your drugs were more than the true average prices, net of discounts, rebates, chargebacks, and incentives, paid by wholesalers to you for your drugs.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan objects to Request for Admission No. 6 on the grounds that it is vague and ambiguous because, *inter alia*, it contains terms and phrases that are themselves vague, ambiguous, undefined, and/or interpreted differently by the parties, including, but not limited to, "reported," "wholesale acquisition costs ('WACs')" and "true average prices." Mylan further objects to this request on the grounds that it is premised on a definition of "wholesale acquisition cost" or "WAC" that is inconsistent with the definition of that term set forth in federal statute and the common understanding of that term as it was used throughout the relevant time period, and therefore is not susceptible to a meaningful response. Mylan further objects to this request as unduly burdensome on the grounds that it requires Mylan to analyze voluminous transactional data over an unspecified period of time between Mylan and its wholesaler customers, which data Mylan has produced or will produce to Wisconsin and which Wisconsin itself has the ability to analyze. Mylan further objects to this request on the grounds that it is improperly compound. Mylan further objects to this request to the extent that it improperly implies that the WACs Mylan provided to First DataBank were false.

Subject to and without waiving the foregoing general and specific objections, Mylan denies the matters set forth in this Request to the extent that the Request states that the WACs that Mylan provided to First DataBank were not Mylan's true WACs. Mylan further states that it does not know, and cannot readily determine without undue burden, the average prices, net of all discounts, rebates, chargebacks, and other price reductions paid by wholesalers to Mylan Pharmaceuticals for its products. Mylan refers Wisconsin to the correspondence

between Mylan Pharmaceuticals and First DataBank in Mylan's prior document productions, and the transactional data Mylan will produce to Wisconsin, and states that the burden of comparing the information is substantially the same for Wisconsin as it would be for Mylan.

INTERROGATORY NO. 6:

If your response to Request for Admission No. 6 is anything other than an unqualified admission, state all bases for your response and identify all documents that support or relate to your response.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its objections to Request for Admission No. 6.

Subject to and without waiving the foregoing general and specific objections, Mylan states that the WACs Mylan Pharmaceuticals reported during the relevant time period were consistent with the definition of "wholesale acquisition cost" set forth in 42 U.S.C. § 1395w-3a(c)(6)(B), which provides, "[t]he term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price..." Mylan further states that this definition was consistent with Wisconsin's understanding of WAC throughout the relevant time period and incorporates herein its response to Interrogatory No. 3. Mylan further states that it does not know, and cannot readily determine without undue burden, the average prices, net of all discounts, rebates, chargebacks, and other price reductions paid by wholesalers to Mylan Pharmaceuticals for its products. Mylan refers Wisconsin to the correspondence between Mylan Pharmaceuticals and First DataBank in Mylan's prior document productions, and the transactional data Mylan will produce to Wisconsin, and states that the burden of comparing the information is substantially the same for Wisconsin as it would be for Mylan.

REQUEST FOR PRODUCTION OF DOCUMENTS NO. 6:

Produce all documents identified in your Response to Interrogatory
No. 6.

MYLAN'S RESPONSE AND OBJECTIONS:

Mylan incorporates herein its response and objections to Request for Admission

No. 6.

Dated: June 30, 2008



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Mylan Laboratories Inc., and Mylan
Pharmaceuticals Inc*

VERIFICATION AS TO RESPONSES TO INTERROGATORIES

Brian S. Roman, being duly sworn, states that he is the Vice President and General Counsel of Mylan Pharmaceuticals Inc., that he has read Mylan Inc. and Mylan Pharmaceuticals Inc.'s Responses and Objections to Plaintiff's First Set of Consolidated Discovery Requests to All Defendants, and that the information contained in the responses to interrogatories therein is true to his own knowledge and belief.

By: _____
Brian S. Roman
Vice President and General Counsel
Mylan Pharmaceuticals Inc.

SUBSCRIBED AND SWORN TO
Before me this __th day of June, 2008

Notary Public

STATE OF WISCONSIN

CIRCUIT COURT
BRANCH 9

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

Case No. 04-CV-1709
Unclassified Civil: 30703

v.

ABBOTT LABORATORIES, et al.,

Defendants.

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.'s Responses and Objections to Plaintiff's First Set of Consolidated Discovery Requests to All Defendants to be served on counsel of record by transmission to LNFS pursuant to order dated December 20, 2005.

Dated this 30th day of June, 2008.



Teresa L. Anders