

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF WISCONSIN**

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THE STATE OF WISCONSIN

Plaintiff,

v.

CASE NO. 05 C 408 C

Honorable Barbara B. Crabb,

ABBOTT LABORATORIES, INC., ET AL.

Defendants.

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**NOVARTIS PHARMACEUTICALS CORPORATION'S  
RESPONSES AND OBJECTIONS TO PLAINTIFF'S FIRST SET  
OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO ALL DEFENDANTS**

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Pursuant to Rules 26, 33 and 34 of the Federal Rules of Civil Procedure, Defendant Novartis Pharmaceuticals Corporation ("Novartis"), by its undersigned counsel, responds as follows to Plaintiff's First Set of Requests for Production of Documents to All Defendants served on or about January 27, 2005 (the "Requests"):

**GENERAL OBJECTIONS**

Novartis expressly incorporates all of the General Objections set forth below into each Response to the Requests. Any specific objections provided below are made in addition to these General Objections and a failure to reiterate a General Objection below does not constitute a waiver or limitation of that or any other objection. To the extent that Novartis states that it will produce documents responsive to any Request, such statement is made subject to, and without waiver or limitation of, all specific objections stated in response to such Request and all General Objections set forth below.

A. By responding to these Requests, Novartis does not waive or intend to waive: (i) any objections as to the competency, relevancy, materiality, or admissibility as evidence, for any purpose, of any documents or information produced in response to these Requests; (ii) the right to object on any ground to the use of the documents or information produced in response to these Requests at any hearing or trial; (iii) the right to object on any ground at any time to a demand for further responses to these Requests; or (iv) the right at any time to revise, correct, add to, supplement, or clarify any of the responses contained herein.

B. By responding to these Requests, Novartis does not waive or intend to waive any privilege, for any purpose, of any documents or information produced in response to these Requests, and, in particular, Novartis objects to each Request to the extent that it purports to seek information protected by the attorney-client privilege, work-product doctrine, common-interest doctrine, joint-defense privilege, or any other applicable privileges or protections. Novartis will produce a timely privilege log in accordance with the applicable rules and Court orders.

C. By responding that it will produce documents in response to a particular Request, Novartis does not assert that it has responsive materials or that such materials exist, only that it will conduct a reasonable search and make available responsive, nonprivileged documents. No objection, or lack thereof, is an admission by Novartis as to the existence or non-existence of any documents. Where Novartis already has identified specific documents responsive to a particular Request and states that it will produce responsive documents “including” certain specifically identified documents, “including” means “including but not limited to.”

D. These responses are based on Novartis’ investigation to date of those sources within its control where it reasonably believes responsive documents or information may

exist. Novartis reserves the right to amend or supplement these responses in accordance with the applicable rules and Court orders with additional information, documents, or objections that may become available or come to Novartis' attention, and to rely upon such information, documents, or objections in any hearing, trial or other proceeding in this litigation..

E. Novartis objects to Plaintiff's "Definitions," "Rules of Construction" and "Instructions" to the extent that they purport to expand upon or alter Novartis' obligations under the Federal Rules of Civil Procedure.

F. Novartis objects to collecting and producing the broad range of information Plaintiff seeks before Plaintiff has identified in its Complaint which Novartis pharmaceutical products it claims to have overpaid for and how and what it overpaid for such products. Although Plaintiff has offered to narrow the definition of "Targeted Drug" currently found in the Document Request, Novartis has advised Plaintiff that as part of its first round of production, it will produce sales data, including sales data resident in the (i) Integrated Managed Healthcare Contracting System and (ii) Distribution System, for the period January 1, 1997 through June 12, 2002, for the following Novartis drugs which are named in the Amended Master Consolidated Class Action Complaint filed in the action styled *In Re: Pharmaceutical Industry Average Wholesale Price Litigation* (D. Mass.), MDL No. 1456 (hereinafter, the "AMCC Complaint"): (1) Clozaril; (2) Comtan; (3) Estraderm; (4) Exelon; (5) Femara; (6) Lamisil; (7) Lescol; (8) Lotensin; (9) Lotrel; (10) Miacalcin; (11) Parlodel; (12) Ritalin; (13) Starlix; (14) Tegretol; (15) Tegretol-XR; and (16) Trileptal (hereinafter, the "Novartis AMCC Drugs"). Novartis has also advised Plaintiff that it is Novartis' hope and expectation that Plaintiff will be able to narrow other outstanding Interrogatories based on what it learns from the data and information concerning the Novartis AMCC Drugs and that such data and information

will demonstrate that many of Plaintiff's claims do not warrant or justify Plaintiff's exceedingly broad and burdensome Document Requests.

G. Novartis objects to these Requests to the extent that they seek information not contained in documents that currently exist at Novartis and purport to require Novartis to create, compile or develop new documents.

H. Novartis objects to collecting and producing the broad range of information Plaintiff seeks prior to producing sales transaction or other summary data that will demonstrate that many of Plaintiff's claims do not warrant or justify Plaintiff's exceedingly broad and burdensome Requests. Novartis has advised Plaintiff that it will produce such sales transaction or other summary data first, in the hope and expectation that Plaintiff will be able to narrow other outstanding Requests based on what they learn from such discovery.

I. Novartis objects to these Requests to the extent that they seek production of documents or information not in Novartis' custody or control, publicly available documents or information, documents or information equally available to Plaintiff or documents or information more appropriately sought from third parties to whom subpoenas or requests could be or have been directed.

J. Given the confidential and proprietary nature of the documents requested, Novartis' production of documents is pursuant to the Qualified Protective Order limiting the scope of disclosure, review and dissemination of documents previously entered by Judge Moria Kreuger, Dane Count Circuit Court, on May 11, 2005. Novartis will begin its production of non-privileged responsive documents on or about July 25, 2005, and will continue to provide documents or data thereafter on a rolling basis in as expeditious and efficient a manner as possible as it completes its review and processing of such documents and data.

K. The documents and information produced in response to these Requests are for use in this litigation and for no other purpose.

**A. OBJECTIONS TO DEFINITIONS**

1. The term “average manufacturer price” or “AMP” means the price you report or otherwise disseminate as the average manufacturer price for any pharmaceutical (see definition below) that you report for purposes of the Medicaid program, pursuant to 42 U.S.C. §1396r-8.

**OBJECTION:** Novartis incorporates by reference its objection to the definition of the term “Pharmaceutical,” and objects to the definition of “Average Manufacturer Price” and “AMP” as set forth in Definition No. 1 on the grounds that it is vague and ambiguous with respect to the language “the price you report or otherwise disseminate as the average manufacturer price for any Pharmaceutical that you report.” Novartis further objects to this definition to the extent that it purports to set an accurate or legally significant definition of the term “AMP” or “average manufacturer price.”

2. The term “Chargeback” means any payment, credit or other adjustment you have provided to a purchaser of a drug to compensate for any difference between the purchaser’s acquisition cost and the price at which the Pharmaceutical was sold to another purchaser at a contract price.

**OBJECTION:** Novartis incorporates by reference its objection to the definition of the term “Pharmaceutical,” and objects to the definition of “Chargeback” as set forth in Definition No. 2 on the grounds that it is vague and ambiguous with respect to the language “payment, credit or other adjustment you have provided to a purchaser of a drug to compensate for any difference between the purchaser’s acquisition cost and the price at which the Pharmaceutical was sold to another purchaser at a contract price.”

3. The term “Defined Period of Time” means from January 1, 1993 to the present and Documents relating to such period even though created before that period.

**OBJECTION:** Novartis incorporates by reference its objection to the definition of the term “Document,” and objects to the definition of “Defined Period of Time” as set forth in Definition No. 3 on the grounds that it is overly broad and unduly burdensome, and vague and ambiguous with respect to the language “Documents relating to such period.” Novartis further objects to this definition to the extent it seeks information outside of the limitations periods applicable to the claims in the Complaint, or beyond the time period relevant to this litigation, 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. Novartis’ production of any documents outside of the limitations periods applicable to the claims in the Complaint in this action does not constitute a waiver by Novartis of this objection. In addition, Novartis objects to the definition of “Defined Period of Time” to the extent that it purports to require that Novartis search for and produce documents generated or assembled either prior to January 1, 1997, which was the date Novartis was created by operation of merger following approval by the Federal Trade Commission on December 17, 1996, or after June 12, 2003, the date on which the AMCC Complaint was filed in MDL No. 1456, on the ground that such documents are neither relevant to the subject matter of this action, nor reasonably calculated to lead to the discovery of admissible evidence. Novartis further objects to Definition No. 3, and to each Request that purports to require Novartis to produce “all” documents described by such Request, as unduly burdensome, cumulative, duplicative and vexatious on its face. Novartis will search for and produce documents sufficient to provide the information or data sought by specific Requests, and where appropriate (*i.e.*, where non-identical documents provide additional relevant information), Novartis will produce all non-identical documents.

4. The term “Document” means any writing or recording of any kind, including, without limitation, agendas, agreements, analyses, announcements, audits, booklets, books, brochures, calendars, charts, contracts, correspondence, electronic mail (e-mail),

facsimiles (faxes), film, graphs, letters, memos, maps, minutes (particularly Board of Directors and/or Executive Committee meeting minutes), notes, notices, photographs, reports, schedules, summaries, tables, telegrams, and videotapes in any medium, whether written, graphic, pictorial, photographic, electronic, phonographic, mechanical, taped, saved on computer disk, hard drives, tape drives, or otherwise, and every non-identical copy. Different versions of the same document, such as different copies of a written record bearing different handwritten notations, are different documents within the meaning of the term as used. In case originals or original non-identical copies are not available, "Document" includes copies of originals or copies of non-identical copies as the case may be.

**OBJECTION:** Novartis objects to the definition of "Document" as set forth in Definition No. 4 to the extent that it seeks to impose discovery obligations that are broader than, or inconsistent with, Novartis' obligations under the Federal Rules of Civil Procedure. Novartis further objects to this definition to the extent it requires or seeks to require Novartis to: (i) produce documents or data in a particular form or format; (ii) convert documents or data into a particular or different file format; (iii) produce data, fields, records, or reports about produced documents or data; (iv) produce documents or data on any particular media; (v) search for and/or produce any documents or data on back-up tapes; (vi) produce any proprietary software, data, programs, or databases; or (vii) violate any licensing agreement, copyright laws, or proprietary rights of any third party.

5. The term "Incentive" means anything of value provided to a customer or other party to induce that customer to purchase, promote, prescribe, dispense or administer a pharmaceutical (see definition below) or course of treatment; to reward a customer or other party for purchasing, promoting, prescribing, dispensing or administering a pharmaceutical or course of treatment; or which had, will have, or is intended to have, the effect of lowering the cost of a pharmaceutical to the customer in any way, regardless of the time the "incentive" was provided (for example, at the time of invoicing, shipment, or payment, or monthly, quarterly, annually, or at any other time or on any other basis) and regardless of its name. As used in this definition, the term "customer or other party" includes, but is not limited to, a drug wholesaler, physician, clinic, store chain, pharmacy, pharmaceutical benefit manager, hospital, federal or state government agency, health maintenance organization, or other managed care organization. The term "incentive" therefore includes, but is not limited to, payments or proposed payments in cash or in kind; chargebacks (see definition above); credits, discounts such as return-to-practice discounts, prompt-pay discounts, volume discounts, on-invoice discounts, or off-invoice discounts; rebates such as market-share rebates, access rebates, or bundled-drug rebates; free goods or samples; credits, administrative fees or administrative fee reimbursements; marketing fees; stocking fees; conversion fees; patient education fees; off-invoice pricing; educational or other grants; research funding; payments for participation in clinical trials; honoraria; speaker's fees or payments; patient education fees; or consulting fees.

**OBJECTION:** Novartis incorporates by reference its objection to the definition of the term “Chargeback,” and objects to the definition of “Incentive” as set forth in Definition No. 5 on the grounds that it is overly broad and unduly burdensome, and vague and ambiguous with respect to the language “anything of value,” “provided,” “customer,” “reward a customer or other party for promoting, prescribing, dispensing or administering a Pharmaceutical or course of treatment; or which had, will have, or is intended to have, the effect of lowering the cost of a Pharmaceutical to the customer in any way, regardless of the time the ‘Incentive’ was provided . . . and regardless of its name,” “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,” “patient education fees” and “consulting fees.” Novartis further objects to this definition to the extent it seeks information from beyond the time period relevant to this litigation.

6. The term “national sales data” means data sufficient to identify for each sales transaction involving each targeted drug (see definition below) the following information:

- a. transaction date;
- b. transaction type;
- c. your product number;
- d. product description;
- e. package description;
- f. NDC;
- g. NDC unit quantity;
- h. NDC unit invoice price;

- i. NDC unit WAC (assigned by you);
- j. contract price;
- k. invoice price;
- l. customer name, identification number, address and class of trade;
- m. all paid or distributed incentives (see definition above);
- n. all accrued Incentives calculated at any time, identifying the amount of the accrual, its nature or type, the date of the accrual, and other information sufficient to identify as particularly as possible each sales transaction giving rise to the accrual.

**OBJECTION:** Novartis incorporates by reference its objections to the definitions of the terms “Targeted Drugs” and “Incentives,” and objects to the definition of “National Sales Data” in Definition No. 6 on the grounds that it is overly broad and unduly burdensome, and vague and ambiguous with respect to the language “data sufficient to identify for each sales transaction,” “transaction type,” “your product number,” “product description,” “package description,” “WAC,” “NDC,” “NDC Unit Quantity,” “NDC unit invoice price,” “you,” “contract price,” “invoice price,” “identification number,” “paid or distributed Incentives,” “accrued Incentives,” “calculated at any time” and “other information sufficient to identify as particularly as possible each sales transaction giving rise to the accrual.” In addition, Novartis further objects to this definition to the extent that it (i) refers to information not relevant to the State’s claims, which are limited to Wisconsin, (ii) seeks information from beyond the time period relevant in this litigation, or (iii) seeks information about drugs not named in the Complaint, on the grounds that such information is neither relevant to the subject matter of the pending action nor reasonably calculated to lead to the discovery of admissible evidence.

7. The term “Pharmaceutical” means any drug or other product, whether sold by you, or any other manufacturer, which requires a physician’s or other prescriber’s prescription, including, but not limited to, biological products such as hemophilia factors and intravenous solutions.

**OBJECTION:** Novartis objects to the definition of “Pharmaceutical” in Definition No. 7 on the grounds that it is overly broad, unduly burdensome and vague and ambiguous with respect to the language “any drug,” “administered,” “other product,” “you,” “prescription,” and “biological products.” In addition, Novartis objects to this Definition to the extent that it (i) refers to information not relevant to the State’s claims, which are limited to Wisconsin, (ii) seeks information from beyond the time period relevant in this litigation, or (iii) seeks information about drugs not named in the Complaint, on the grounds that such information is neither relevant to the subject matter of the pending action nor reasonably calculated to lead to the discovery of admissible evidence.

8. The term “Targeted Drugs” means those drugs manufactured by you which have total utilization under the Medicaid and Medicare Part B program exceeding \$10,000.00 during the Defined Period of Time in the state of Wisconsin.

**OBJECTION:** Novartis incorporates by reference its objection to the definitions of the terms “Defined Period of Time” and “Pharmaceutical,” and objects to the definition of “Targeted Drugs” as set forth in Definition No. 9 on the grounds that it is overly broad and unduly burdensome and vague and ambiguous with respect to the language “you” and “total utilization.” In addition, Novartis objects to this Definition to the extent that it (i) refers to information not relevant to the State’s claims, which are limited to Wisconsin, (ii) seeks information from beyond the time period relevant in this litigation, or (iii) seeks information about drugs not named in the Complaint, on the grounds that such information is neither relevant to the subject matter of the pending action nor reasonably calculated to lead to the discovery of admissible evidence.

**B. OBJECTIONS TO INSTRUCTION**

\*Documents are to be produced in electronic format with all documentation required to identify files and fields by name, content and format, and explanations for all coded data. Acceptable electronic format for documents which in their native form are organized as

word processing documents, or printed documents other than tabular reports (documents comprised principally of text, or of a combination of text and graphics) is searchable Adobe Acrobat portable document format (.pdf). Acceptable electronic format for documents which in their native form are organized as spreadsheets is Microsoft Excel format (.xls). Acceptable electronic format for documents which in their native form are comprised principally of tabular data, or tabular reports with fixed column widths or field lengths is fixed-field ASCII text (.txt). Acceptable electronic format for documents which in their native form are comprised principally of electronic data in one or more data tables, files, or other data entries, is delimited ASCII text (.csv).

**OBJECTION:** Novartis objects to this Instruction to the extent that it seeks to impose on Novartis the obligation to produce electronic materials in specified formats. Novartis further objects to this instruction to the extent that it seeks to impose any obligation in conflict with or beyond those imposed by applicable Wisconsin law. Novartis states that it will comply with this Instruction to the extent mandated by the rules of applicable Wisconsin law.

**SPECIFIC RESPONSES AND OBJECTIONS TO  
REQUEST FOR PRODUCTION OF DOCUMENTS**

**REQUEST NO. 1:** All National Sales Data for each Targeted Drug during the Defined Period of Time.\*

**RESPONSE TO REQUEST NO. 1:** In addition to the foregoing General Objections, Novartis objects to Request No. 1 on the grounds that it is overly broad and unduly burdensome. Subject to and without waiving this objection and the foregoing General Objections, Novartis will produce sales data, including sales data resident in the (i) Integrated Managed Healthcare Contracting System and (ii) Distribution System, for the period January 1, 1997 through June 12, 2002 for the following Novartis AMCC Drugs):

1. Clozaril
2. Comtan
3. Estraderm
4. Exelon
5. Femara
6. Lamisil
7. Lescol
8. Lotensin

9. Lotrel
10. Miacalcin
11. Parlodel
12. Ritalin
13. Starlix
14. Tegretol
15. Tegretol-XR
16. Trileptal

**REQUEST NO. 2:** All Documents containing AMPs as reported or calculated by you for the Targeted Drugs or a spread sheet or database showing all reported and calculated AMPs for each Targeted Drug over the Defined Period of Time which lists when such AMPs were reported or calculated, and the quarter to which each AMP applies.\*

**RESPONSE TO REQUEST NO. 2:** In addition to the foregoing General Objections, Novartis objects to Request No. 2 on the grounds that it is overly broad and unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Novartis further objects to this request on the grounds that it is vague and ambiguous with respect to the language “all,” “reported or calculated,” “you,” “spreadsheet” and “database.” Subject to this and the foregoing General Objections, Novartis will produce non-privileged responsive documents, including Broadcast faxes, quarterly average manufacturer price calculation reports, and sales data resident in the Integrated Managed Healthcare Contracting System, which includes potentially responsive data, for the period of the First Quarter of 1997 through the Fourth Quarter of 2003 for the Novartis AMCC Drugs.

**REQUEST NO. 3:** All Documents created by you, or in your possession, that discuss or comment on the difference (or Spread) between any Average Wholesale Price or Wholesale Acquisition Cost and the list or actual sales price (to any purchaser) of any defendants’ Pharmaceuticals or any Pharmaceuticals sold by other manufacturers. Documents which merely list the AWP or WAC price and the list or actual sales price without further calculation of the difference, or without other comment or discussion of or about the spread between such prices are not sought by this request.

**RESPONSE TO REQUEST NO. 3:** In addition to the foregoing General Objections, Novartis objects to Request No. 3 on the grounds that it is overly broad and unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Novartis further objects to

this request on the grounds that it is vague and ambiguous with respect to the language “all,” “created,” “you,” “in your possession,” and “Pharmaceuticals sold by other Pharmaceutical manufacturers.” Subject to and without waiving this and the foregoing General Objections, Novartis will produce non-privileged documents created during the period January 1, 1997 through June 12, 2003 that discuss or comment on a difference (or spread) between any average wholesale price or wholesale acquisition cost and the list or actual sales price (to any purchaser) for the Novartis AMCC Drugs or any pharmaceutical products sold by other manufacturers.

**REQUEST NO. 4:** All Documents containing an average sales price or composite price identified by you in response to Interrogatory No. 1 of Plaintiff’s First Set of Interrogatories to All Defendants.\*

**RESPONSE TO REQUEST NO. 4:** In addition to the foregoing General Objections, Novartis objects to Request No. 4 on the grounds that it is overly broad and unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Novartis further objects to this Request on the grounds that it is vague and ambiguous with respect to the language “all,” “average sales price,” and “composite price.” Subject to and without waiving this and the foregoing General Objections, Novartis has no documents which are responsive to Request No. 4.

**REQUEST NO. 5:** All Documents sent to or received from First DataBank, Redbook and Medi-span regarding the price of any Targeted Drug.

**RESPONSE TO REQUEST NO. 5:** In addition to the foregoing General Objections, Novartis objects to Request No. 5 on the grounds that it is overly broad and unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Novartis further objects to this request on the grounds that it is vague and ambiguous with respect to the language “all,” “received,” “regarding” and “price.” Subject to and without waiving this and the foregoing General Objections, Novartis will produce non-privileged documents created during the period

January 1, 1997 through June 12, 2003 which were sent to or received from First DataBank, Redbook and Medi-span concerning the price of the Novartis AMCC Drugs and other Novartis pharmaceutical products.

**REQUEST NO. 6:** All Documents in your possession prepared by IMS Health regarding a Targeted Drug or the competitor of a Targeted Drug regarding pricing, sales or market share.

**RESPONSE TO REQUEST NO. 6:** In addition to the foregoing General Objections,

Novartis objects to Request No. 6 on the grounds that it is overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence in that it is not limited to pricing, price reporting, average wholesale price, the relationship between average wholesale price and wholesale acquisition cost, or any other issue in this litigation, and to the extent that it seeks information that Novartis is prohibited by its contract with IMS Health from disclosing. Subject to and without waiving these and the foregoing General Objections, Novartis will produce non-privileged, non-restricted documents in its possession which were prepared by IMS Health during the period January 1, 1997 through June 12, 2003 which concern the average wholesale price for the Novartis AMCC Drugs.

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Dated: July 15, 2005

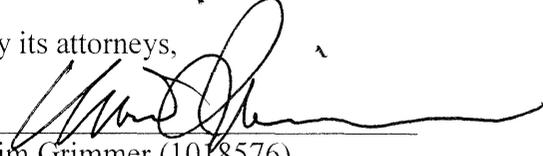
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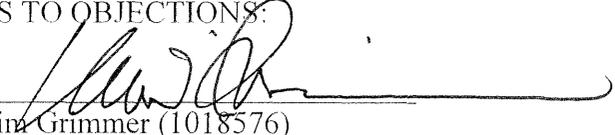
Respectfully submitted,

Novartis Pharmaceuticals Corporation

By its attorneys,

  
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AS TO OBJECTIONS:

  
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