#### UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

## In the Matter of

# MERCK & CO., INC., a corporation, and MERCK-MEDCO MANAGED CARE, L.L.C., a limited liability company.

## File No. 951 0097

## AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of the acquisition of Merck-Medco Managed Care, L.L.C. ("Medco") by Merck & Co., Inc. ("Merck"), and it now appearing that Merck and Medco, hereinafter sometimes referred to as proposed respondents, are willing to enter into an agreement containing an order to remedy the alleged lessening of competition resulting from such acquisition, and providing for other relief:

**IT IS HEREBY AGREED** by and between proposed respondents, by their duly authorized officers and their attorney, and counsel for the Commission that:

- 1. Proposed respondent Merck is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at One Merck Drive, Whitehouse Station, New Jersey.
- 2. Proposed respondent Medco is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Summit Avenue, Montvale, New Jersey.
- 3. Proposed respondents admit all the jurisdictional facts set forth in the draft of complaint here attached.
- 4. Proposed respondents waive:
  - a. Any further procedural steps;
  - b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
  - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
  - d. Any claim under the Equal Access to Justice Act.
- 5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.
- 6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft of complaint here attached, or that the facts as alleged in the draft complaint, other than jurisdictional facts, are true.
- 7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to the

proposed respondents, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the order shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondents' addresses as stated in this agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

8. Proposed respondents have read the proposed complaint and order contemplated hereby. Proposed respondents understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

## **ORDER**

I

## IT IS ORDERED that the following definitions shall apply herein:

- A. "Merck" means Merck & Co., Inc., its directors, officers, employees, agents, representatives, predecessors, successors and assigns; its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures controlled by Merck & Co., Inc., other than Medco or any other supplier of PBM Services owned or controlled by Merck; and the respective directors, officers, employees, agents, representatives, successors and assigns of each.
- B. "Medco" means Merck-Medco Managed Care, L.L.C., its managers, directors, officers, employees, agents, representatives, predecessors, successors and assigns; its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures controlled by Medco other than Merck; all other suppliers of PBM Services owned or controlled by Merck; and the respective directors, officers, employees, agents, representatives, successors and assigns of each.
- C. "Respondents" means both Merck and Medco.
- D. "Commission" means the Federal Trade Commission.
- E. "Formulary" means a listing, by therapeutic category, of branded and generic ambulatory drug products that are approved for use by the U.S. Food & Drug Administration ("FDA"), which listing is made available to pharmacies, physicians, third-party payors, or other persons involved in the healthcare industry, to guide in the prescribing or dispensing of pharmaceuticals. An "Open Formulary" is a formulary that allows the inclusion of any ambulatory prescription drug product approved by the FDA for use in the United States, which the P&T Committee (defined below) determines is appropriate for inclusion in such formulary. For purposes of this Order, an Open Formulary may provide truthful information stating or indicating the benefits of drugs on the formulary.
- F. "Pharmacy Benefit Management Services" or "PBM Services" means services provided by a pharmacy benefits manager, such as formulary services, negotiation of rebates or discounts from pharmaceutical manufacturers, prescription claims processing, and drug utilization review.
- G. "Formulary Services" means the provision, development, establishment, management or maintenance of a formulary by a pharmacy benefits manager. For purposes of this Order, "management" of a formulary includes the negotiation and administration of rebate or discount agreements with pharmaceutical manufacturers for drugs included on a formulary.
- H. "Merck Non-Public Information" means information not in the public domain that is

provided to Merck by a supplier of PBM Services in connection with the supply of PBM Services and that directly or indirectly discloses actual, relative or proposed prices, discounts, rebates, other trade terms (including, but not limited to, returned goods arrangements, delivery arrangements, performance levels and guarantees) or similar terms or conditions of sale of such supplier of PBM Services.

- I. "Medco Non-Public Information" means information not in the public domain that is provided to Medco by a manufacturer of prescription drug products in connection with the supply of prescription drug products and that directly or indirectly discloses actual, relative or proposed prices, discounts, rebates, other trade terms (including, but not limited to, returned goods arrangements, delivery arrangements, and payment terms or schedules) or similar terms or conditions of sale of such manufacturer of prescription drug products.
- J. "Auditors" means 1) those employees of Merck whose primary responsibility is systematically inspecting, substantiating, and reporting on: the reliability and integrity of Merck's information; its compliance with laws and regulations; the safeguarding of its assets; the economical and efficient use of its resources; and the accomplishment of its established objectives and goals; and who regularly work in the organizational subdivision of Merck with company-wide responsibility for performing these functions, and 2) employees of independent firms retained by Merck to perform one or more of these functions.
- K. "Pharmacy and Therapeutics Committee" or "P&T Committee" means a group of healthcare professionals, such as doctors, pharmacists, and pharmacologists, appointed for the purpose of evaluating prescription drug products for inclusion on a formulary.

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## IT IS ORDERED that:

- A. Within sixty (60) days from the date this Order becomes final, Merck shall cause Medco to, and Medco shall, maintain, disclose the availability of, and make available an Open Formulary. Such Open Formulary shall provide information concerning the relative costs of drugs listed on such formulary and such information shall be truthful and accurate. As of the date this Order becomes final, the Medco "Universal Formulary," a copy of which is attached hereto as Appendix A, shall be deemed an Open Formulary that complies with this Paragraph II.A.
- B. Within thirty (30) days from the date this Order becomes final, Merck shall cause Medco to, and Medco shall, appoint or reappoint an independent P&T Committee with the authority and responsibility to maintain an Open Formulary as required by Paragraph II.A above. Such P&T Committee shall make all decisions concerning the inclusion of drugs on such Open Formulary, the exclusion of drugs from such Open Formulary, and the clinical and therapeutic advice and evaluation appearing in such Open Formulary, and shall operate according to the following provisions:
  - 1. Such P&T Committee shall consist of at least seven (7) members, all of whom shall be physicians, pharmacists, pharmacologists, or other healthcare professionals.
  - 2. A majority of the P&T Committee shall consist of persons who are not employees, officers, directors, or agents of, and who have no financial interest in: (a) Merck, (b) Medco, or (c) any other person who has an ownership interest in Merck or Medco; provided, however, that Medco may pay P&T Committee members reasonable and customary consulting fees and/or honoraria for their services. Any person who meets the criteria set forth in this subparagraph shall be deemed an "independent" member of the P&T Committee.
  - 3. Each independent member of the P&T Committee shall have one vote on each decision of the P&T Committee.
  - 4. All members of the P&T Committee who are employees, officers, directors, or

agents of, or who have a financial interest in, Merck, Medco, or any other person who has an ownership interest in Merck or Medco, shall not be entitled to vote on decisions of the P&T Committee.

- 5. All independent members of the P&T Committee shall be appointed for two-year terms, except that the initial terms for approximately one-half of the independent members may be for fewer than two years if necessary to ensure that approximately one-half of the independent members' terms expire each year. At the expiration of their terms, or upon the occurrence of a vacancy, members may be reappointed, or new members may be appointed, by a majority of the then-appointed independent members of the P&T Committee.
- 6. No independent member of the P&T Committee may be removed except for cause by vote of a majority of the independent members of the P&T Committee.
- 7. In performing its responsibilities in maintaining the Open Formulary, the P&T Committee shall utilize only criteria relating to safety, efficacy, FDA approved indications, side effects, contraindications, pharmacokinetics, patient compliance, physician follow-up requirements, effect on emergency room visits and hospitalizations, laboratory tests, cost, and similar objective factors. Such P&T Committee shall give no preference to the products of Merck, or of any other person with an ownership interest in Medco, except on the basis of such objective criteria.
- 8. Merck shall cause Medco to, and Medco shall, cover the reasonable costs and expenses of the P&T Committee, and Merck shall cause Medco to, and Medco shall, indemnify the P&T Committee against any losses or claims of any kind that might arise out of its performance of functions under this Order, except to the extent that such losses or claims result from misfeasance, gross negligence, willful or wanton acts, or bad faith.
- 9. Medco shall maintain written records, for five (5) years from the date thereof, sufficient to show the basis and rationale for all P&T Committee decisions relating to the exclusion of any products from the Open Formulary required by Paragraph II.A.
- C. Merck shall cause Medco to, and Medco shall, accept all discounts, rebates or other concessions offered solely in connection with the Open Formulary by any manufacturer, seller or distributor of pharmaceutical products included by the P&T Committee on the Open Formulary, and Merck shall cause Medco to, and Medco shall, ensure that all such discounts, rebates, or concessions are truthfully and accurately reflected in the information concerning the relative costs of drugs listed on such Open Formulary.
- D. Nothing in this Order shall preclude Medco from offering any formulary other than the Open Formulary to any customer.
- E. Merck shall cause Medco to, and Medco shall, provide a copy of this Order to each member of the P&T Committee on or before the date of each such person's appointment to such P&T Committee or on or before the date this Order becomes final.

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#### IT IS FURTHER ORDERED that:

- A. Merck shall not provide, disclose, or otherwise make available to Medco any Merck Non-Public Information; and
- B. Medco shall not provide, disclose, or otherwise make available to Merck any Medco Non-Public Information; PROVIDED, HOWEVER:
  - 1. For the purpose of obtaining legal advice, Medco may provide Medco Non-Public Information to lawyers for Merck, on condition that such lawyers for Merck shall not disclose such Medco Non-Public Information to any other person at Merck not

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expressly permitted to receive the information under this Section III.B. and shall not use such information for any purpose other than providing legal advice;

- 2. For the purpose of obtaining legal advice, Merck may provide Merck Non-Public Information to lawyers for Medco, on condition that such lawyers for Medco shall not disclose such Merck Non-Public Information to any other person at Medco not expressly permitted to receive the information under this Section III.B. and shall not use such information for any purpose other than providing legal advice; and
- 3. Medco may disclose to Merck auditors Medco Non-Public Information to the extent necessary to enable Merck auditors to perform their auditing duties in the ordinary course of business, on condition that such auditors shall not use such Non-Public Information for any other purpose and shall not disclose such Non-Public Information to any other person at Merck not expressly permitted to receive the information under this Section III.B.

IV

IT IS FURTHER ORDERED that Merck shall retain all documents and shall cause Medco to separately retain all documents, and Medco shall retain all documents, that relate to (A) the exclusion of any prescription drug product from the Open Formulary required by Paragraph II.A above, (B) any preference or ranking accorded to any prescription drug product on the Open Formulary required by Paragraph II.A above, or (C) statements or indications of discounts, rebates, or other concessions, as described in Paragraph II.C above, for a period of five (5) years from the date such document is created or received.

V

**IT IS FURTHER ORDERED** that Merck and Medco shall disclose the availability of the Open Formulary as follows:

A. Merck shall cause Medco to, and Medco shall, disclose the availability of the Open Formulary to all persons who currently have an agreement with Medco concerning PBM Services or concerning the inclusion of pharmaceuticals on a formulary, by providing to each such person a written communication containing the following statement not later than ten (10) days after initiation of contact between Medco and such person regarding renewal or extension of such person's existing agreement with Medco:

Medco maintains an Open Formulary that allows, subject to the determination of an independent Pharmacy and Therapeutics Committee, the inclusion of any ambulatory prescription drug product approved by the FDA for use in the United States. This Open Formulary will be provided to you upon request.

B. For a period of five (5) years from the date this Order becomes final, Merck shall cause Medco to, and Medco shall, provide in writing the statement set forth in Paragraph V.A above to each prospective customer of Medco at the time of Medco's response to such prospective customer's request for proposal, or at the time of Medco's initial written formulary proposal to such prospective customer, whichever occurs first.

VI

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

VII

# IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date this Order becomes final, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they have complied and are complying with Paragraph II.B of this Order.
- B. Within sixty (60) days after the date this Order becomes final, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they have complied and are complying with Paragraph II.A of this Order.
- C. One (1) year from the date this Order becomes final, annually thereafter on the anniversary of the date this Order becomes final until the Order terminates, and at other times as the Commission may require, Respondents shall file verified written reports with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.
- D. Respondents shall include in their compliance reports a copy of the Open Formulary required by Paragraph II.A above, and all written communications, internal memoranda, and reports and recommendations concerning compliance with the Order.

#### VIII

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents relating to any matters contained in this Order; and
- B. Upon five days' notice to Respondents and without restraint or interference from them, to interview officers, directors, or employees of Respondents in the presence of counsel.

#### IX

**IT IS FURTHER ORDERED** that this Order shall terminate seven (7) years from the date this Order becomes final.

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Signed this day of	_, 19
FOR MERCK & CO., INC., A CORPORATION	FOR THE BUREAU OF COMPETITION FEDERAL TRADE COMMISSION
Raymond V. Gilmartin	Karen E. Berg
Chairman, President and CEO	Attorney
Merck & Co., Inc.	
	APPROVED:
FOR MERCK-MEDCO MANAGED CARE,	
L.L.C., A LIMITED LIABILITY COMPANY	Veronica Kayne
	Deputy Assistant Director
Per G.H. Lofberg	
President	Michael D. McNeely
Merck-Medco Managed Care, L.L.C.	Assistant Director
Counsel for Merck and Medco	Willard K. Tom
Michael N. Sohn, Esq.	Acting Deputy Director

Arnold & Porter

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William J. Baer Director

Bureau of Competition