

1 EXPEDITE
2 No Hearing Set
3 Hearing is Set
4 Date:
5 Time:

6
7 STATE OF WASHINGTON
8 THURSTON COUNTY SUPERIOR COURT

9 In Re:
10 MERCK & CO., Inc., SCHERING-
11 PLOUGH Corporation, MSP
12 SINGAPORE Company, LLC regarding
the drugs (Vytorin and Zetia),
Respondents.

NO.
ASSURANCE OF
DISCONTINUANCE

13 **ASSURANCE OF DISCONTINUANCE**

14 This Assurance of Discontinuance (“AOD”) is entered into by the Attorneys General of
15 Arizona, Arkansas, California, Colorado, Delaware, the District of Columbia, Florida, Hawaii,
16 Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi,
17 Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North
18 Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas,
19 Vermont, Washington, West Virginia, and Wisconsin, acting pursuant to their respective State
20 Consumer Protection Laws, and Schering-Plough Corporation, Merck & Co., Inc., and MSP
21 Singapore Company, LLC.

22 **PREAMBLE**

23 **WHEREAS**, the Multistate Working Group has initiated an investigation of the
24 Companies with respect to the Covered Conduct;

25 **WHEREAS**, the Companies deny that they have engaged in any wrongful or unlawful
26 conduct;

1 7. "Joint Venture(s)" shall mean any entity in which Merck or Schering maintains a direct
2 and/or indirect ownership interest of 50% or less on the date this Agreement is signed.

3 8. "Merck" shall mean Merck & Co., Inc., and its United States-based affiliates,
4 subsidiaries, predecessors, successors, and assigns, but shall not include any Joint
5 Ventures (as that term is defined in the prior subparagraph) except for MSP.

6 9. "MSP" shall mean MSP Singapore Company, LLC.

7 10. "Multistate Executive Committee" shall mean the Attorneys General and their staffs
8 representing Arizona, California, the District of Columbia, Florida, Illinois, New
9 Jersey, Ohio, Oregon, Pennsylvania, South Carolina, and Texas.

10 11. "Multistate Working Group" ("MSWG") shall mean the Attorneys General and their
11 staffs representing Arizona, Arkansas, California, Colorado, Delaware, the District of
12 Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine,
13 Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New
14 Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania,
15 South Carolina, South Dakota, Tennessee, Texas, Vermont, West Virginia,
16 Washington, and Wisconsin.

17 12. "Parties" shall mean the Companies and the Individual States.

18 13. "Product" shall mean any prescription drug or biological product manufactured,
19 distributed, sold, marketed, or promoted in the United States in any way.

20 14. "Schering" shall mean Schering-Plough Corporation and its United States-based
21 affiliates, subsidiaries, predecessors, successors, and assigns, but shall not include any
22 Joint Ventures (as that term is defined in the prior subparagraph) except for MSP.

23 15. "Signatory Attorney(s) General" shall mean the Attorney General, or his or her
24 designee, of each state in the Multistate Working Group.

1 16. "State Consumer Protection Laws" shall mean the consumer protection laws under
2 which the Signatory Attorneys General have conducted their investigation.¹

3 17. "Vytorin®" shall mean ezetimibe/simvastatin.

4 18. "Zetia®" shall mean ezetimibe or any product that contains ezetimibe other than
5 Vytorin®.

6 **ASSURANCES**

7
8 19. The Companies agree that each of them shall, with respect to the products Vytorin®
9 and Zetia®, be bound by the provisions contained in Paragraphs 5.1 through 5.3 of the
10 Consent Decree attached hereto as Exhibit A (hereinafter "Exhibit A").

11
12 ¹ ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – Arkansas
13 Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200
14 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*;
15 DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF
16 COLUMBIA, *Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida*
17 *Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.001-501.164, 501.207;
18 HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*;
19 IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and*
20 *Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA – *Iowa Consumer Fraud Act*, Iowa Code
21 Section 714.16; KENTUCKY – *Kentucky Consumer Protection Act*, KRS Ch. 367.110, *et seq.*; LOUISIANA –
22 *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, *et seq.*; MAINE – *Unfair Trade*
23 *Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4;
24 MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MISSISSIPPI – *Mississippi*
25 *Consumer Protection Act*, Miss. Code Ann. § 75-24-1 *et seq.* (1972 as amended); MISSOURI – *Missouri*
26 *Merchandising Practices Act*, Mo. Rev. Stat. §§ 407 *et seq.*; MONTANA – Montana Code Annotated 30-14-101
et seq.; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*; NEVADA – Deceptive
Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY – *New Jersey Consumer Fraud*
Act, NJSA 56:8-1 *et seq.*; NEW MEXICO – NMSA 1978, § 57-12-1 *et seq.*; NORTH CAROLINA – North
Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1,1, *et seq.*; NORTH DAKOTA – *Unlawful*
Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*,
R.C. 1345.01, *et seq.*; OREGON – *Oregon Unlawful Trade Practices Act*, ORS 646.605 *et seq.*;
PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*;
SOUTH CAROLINA – *South Carolina Unfair Trade Practices Act*, sections 39-5-10 *et seq.*; SOUTH DAKOTA
– *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE –
Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade*
Practices-Consumer Protection Act, Tex. Bus. & Com. Code 17.47, *et seq.*; VERMONT – *Consumer Fraud Act*,
9 V.S.A. §§ 2451 *et seq.*; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86
et seq.; WEST VIRGINIA – *West Virginia Consumer Credit and Protection Act*, W. Va. Code § 46A-1101 *et*
seq.; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

1 20. The Companies agree that each of them shall, with respect to the products Vytorin®
2 and Zetia®, be bound by the provisions contained in Paragraph 5.7 of Exhibit A. The
3 Companies' obligations with respect to the provisions contained in Paragraph 5.7 of
4 Exhibit A shall remain in effect for six years following the Effective Date. With respect
5 to the provisions contained in Paragraph 5.7 of Exhibit A, the Companies shall abide by
6 any such written recommendation when such submission is made within six years of
7 the Effective Date.

8 21. The Companies agree that each of them shall, with respect to the products Vytorin®
9 and Zetia®, be bound by the provisions contained in Paragraphs 5.9 through 5.12 of
10 Exhibit A. The Companies' obligations with respect to the provisions contained in
11 Paragraph 5.12 of Exhibit A shall remain in effect for eight years following the
12 Effective Date. The Companies' obligations with respect to the provisions contained in
13 Paragraph 5.12(b) of Exhibit A shall only apply to speakers' contracts entered into,
14 amended to extend the contract period, or renewed after the Effective Date.

15 22. The Companies agree that each of them shall, with respect to the products Vytorin®
16 and Zetia®, be bound by the provisions contained in Paragraphs 5.14 and 5.16 through
17 5.18 of Exhibit A. The provisions contained in subparagraph 5.14(d)(ii) of Exhibit A
18 shall also apply to consulting relationships with Schering-Plough Research Institute.
19 The Companies' obligations with respect to the provisions contained in Paragraph 5.14
20 of Exhibit A shall remain in effect for six years following the Effective Date.

21 23. Nothing in this AOD shall require the Companies to:
22 a. take an action that is prohibited by the FDCA or any regulation promulgated
23 thereunder, or by FDA; or
24 b. fail to take an action that is required by the FDCA or any regulation promulgated
25 thereunder, or by FDA. Any written or oral promotional claim subject to this AOD
26 which is the same, or materially the same, as the language required or agreed to by

1 the Director of DDMAC or the Director of the Center for Drug Evaluation or their
2 authorized designees in writing shall not constitute a violation of this-AOD.

3 24. All obligations undertaken by the Companies in this AOD shall apply prospectively,
4 except, to the extent permitted by the National Library of Medicine, the Companies
5 shall submit, as soon as practicable, clinical trial results to the clinical trial registry and
6 results data bank created by the FDA Amendments Act for all “applicable clinical
7 trials” (as that term is defined by the Act) of Vytorin® and/or Zetia® that were initiated
8 after July 1, 2005.

9 25. The Companies shall be bound by the provisions of paragraphs 19 through 24 of this
10 AOD beginning 120 days after the Effective Date.

11 **GENERAL PROVISIONS**

12 26. Release of Claims: By its execution of this AOD, each Individual State releases the
13 Companies and all of their past and present subsidiaries, affiliates, predecessors and
14 successors (collectively, the “Released Parties”) from all civil claims, causes of action,
15 damages, restitution, fines, costs, and penalties on behalf of the Individual State under
16 the consumer protection statutes listed in footnote 1 of this AOD arising from the
17 Covered Conduct that is the subject of this AOD.

18 27. Claims Reserved: Notwithstanding any term of the AOD, specifically reserved and
19 excluded from the Release in Paragraph 26 as to any entity or person, including
20 Released Parties, are any and all of the following:

21 a. Any criminal liability that any person or entity, including Released Parties, has or
22 may have to any State;

23 b. Any civil or administrative liability that any person or entity, including Released
24 Parties, has or may have to any State under any statute, regulation or rule not
25 expressly covered by the release in Paragraph 26 above, including but not limited to
26 any and all of the following claims:

- i. State or federal antitrust violations;
 - ii. Reporting practices, including “best price,” “average wholesale price,” or “wholesale acquisition cost”;
 - iii. Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State’s Medicaid program; and
 - iv. State false claims violations.
- c. Any liability under the State Consumer Protection Laws which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said State, and which have not been specifically enumerated as included herein.

28. Mutual Understanding: The Parties mutually recognize the following:

- a. The Companies are entering into this AOD solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or any other matter of fact or law, or of any liability or wrongdoing, all of which the Companies expressly deny. The Companies do not admit any violation of the State Consumer Protection Laws set forth in footnote 1, and do not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the AOD under those laws. No part of this AOD, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by the Companies.
- b. This AOD shall not be construed or used as a waiver or limitation of any defense otherwise available to the Companies in any action, or of the Companies’ right to defend themselves from, or make any arguments in, any private individual or class claims or suits relating to the subject matter or terms of this AOD. This AOD is made without trial or adjudication of any issue of fact or law or finding of liability

1 of any kind.

2 c. It is the intent of the Parties that this AOD not be admissible in other cases or
3 binding on the Companies in any respect other than in connection with the
4 enforcement of this AOD.

5 d. No part of this AOD shall create a private cause of action or confer any right to any
6 third party for violation of any federal or state statute except that a State may file an
7 action to enforce the terms of this AOD.

8 29. Reimbursement for Investigative Costs: Within ten business days of the Effective Date
9 of this AOD, the Companies shall pay a total amount of \$5,400,000.00 to the Signatory
10 Attorneys General. A portion of this amount designated by the Multistate Executive
11 Committee in the sole discretion of that Committee shall be paid by the Companies
12 directly to each Signatory Attorney General. Said payments shall be made in
13 reimbursement of the Multistate Working Group's attorneys' fees and other costs of
14 investigation and shall be put to use as permitted by state law at the sole discretion of
15 each Signatory Attorney General.

16 30. Compliance: For purposes of resolving disputes with respect to compliance with this
17 AOD:

18 a. Should any of the Signatory Attorneys General have a reasonable basis to believe
19 that the Companies have engaged in a practice that violates a provision of this AOD
20 subsequent to the Effective Date of this AOD, then such Attorney General shall
21 notify the Companies in writing of the specific objection, identify with particularity
22 the provisions of this AOD that the practice appears to violate, and give the
23 Companies thirty (30) days to respond to the notification; provided, however, that a
24 Signatory Attorney General may take any action where the Signatory Attorney
25 General concludes that, because of the specific practice, a threat to the health or
26 safety of the public requires immediate action.

1 b. Upon receipt of written notice, the Companies shall provide a good-faith written
2 response to the Attorney General notification, containing either a statement
3 explaining why the Companies believe they are in compliance with the AOD, or a
4 detailed explanation of how the alleged violation occurred and a statement
5 explaining how the Companies intend to cure the alleged breach.

6 c. Upon giving the Companies thirty (30) days to respond to the notification described
7 above, the Signatory Attorney General shall also be permitted reasonable access to
8 relevant, non-privileged, non-work product records and documents in the
9 possession, custody, or control of the Companies that relate to the Companies'
10 compliance with each provision of this AOD as to which cause that is legally
11 sufficient in the State has been shown. If the Signatory Attorney General makes or
12 requests copies of any documents during the course of that inspection, the Signatory
13 Attorney General will provide a list of those documents to the Companies. Nothing
14 in this paragraph shall be interpreted to limit the State's Civil Investigative Demand
15 ("CID") or subpoena authority, to the extent such authority exists under applicable
16 state law, and the Companies reserve all rights with respect to a CID or subpoena
17 issued pursuant to such authority.

18 d. The State may assert any claim that the Companies have violated this AOD in a
19 separate civil action to enforce this AOD, or to seek any other relief afforded by
20 law, only after providing the Companies an opportunity to respond to the
21 notification described in Paragraph 30(a) above; provided, however, that a
22 Signatory Attorney General may take any action where the Signatory Attorney
23 General concludes that, because of the specific practice, a threat to the health or
24 safety of the public requires immediate action.

25 31. Entire Agreement: This AOD represents the entire agreement entered into by the
26 Parties hereto and shall bind the Parties hereto. In any action undertaken by either the

1 Attorneys General, or any of them, or the Companies, no prior versions of this AOD,
2 and no prior versions of any of its terms may be introduced for any purpose
3 whatsoever.

4 32. Modification: Any Party to the AOD may seek modification of the AOD if it believes
5 that facts and circumstances underlying the AOD have changed in any material respect.
6 The Multistate Executive Committee agrees to coordinate discussions with the
7 Companies regarding any such modification and to make recommendations to the
8 Multistate Working Group. This AOD shall be modified only by mutual assent of the
9 parties and only by a written instrument, signed by or on behalf of the Parties, and,
10 where required, by court order. If, after the date of entry of this AOD, an Individual
11 State, its Attorney General, or any agency of an Individual State enacts or promulgates
12 legislation, rules or regulations with respect to matters governed by this AOD that
13 conflict with any provision of this AOD, or if the applicable law of the Individual State
14 shall otherwise change so as to conflict with any provision of this AOD, the Attorney
15 General shall not unreasonably withhold his or her consent to the modification of such
16 provision to the extent necessary to eliminate such conflict. Laws, rules, or regulations,
17 or other changes in Individual State law, with respect to the matters governed by this
18 AOD, shall not be deemed to conflict with a provision of this AOD unless the
19 Companies cannot reasonably comply with both such law, rule, or regulation and the
20 applicable provision of this AOD.

21 33. Severability: If any portion of this AOD is held invalid or unenforceable by operation
22 of law, the remaining terms of this AOD shall not be affected.

23 34. Certification: The Parties certify that their undersigned representative is fully
24 authorized to enter into the terms and conditions of this AOD and to legally bind the
25 party represented.
26

1 FOR SCHERING-PLOUGH CORPORATION:

2 By: 
3 THOMAS J. SABATINO JR.
4 Executive Vice President and General Counsel
5 Schering-Plough Corporation
6 2000 Galloping Hill Road
7 Kenilworth, New Jersey 07033

Date: 7/9/09

7 FOR MERCK & CO., INC.:

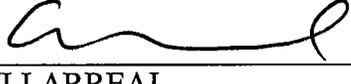
8 By: 
9 BRUCE N. KUHLIK
10 Executive Vice President and General Counsel
11 Merck & Co., Inc.
12 One Merck Drive
13 Whitehouse Station, New Jersey 08889

Date: 7-9-09

13 FOR MSP SINGAPORE COMPANY, LLC:

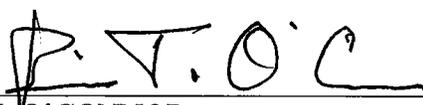
14
15 By: 
16 JAMES GRASTY
17 Vice President and Assistant General Counsel
18 Merck & Co., Inc.
19 One Merck Drive
20 Whitehouse Station, New Jersey 08889

Date: 7-9-09

21 By: 
22 PD VILLARREAL
23 Vice President and Associate General Counsel
24 Schering-Plough Corporation
25 2000 Galloping Hill Road
26 Kenilworth, New Jersey 07033

Date: 7-9-09

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By: 
BRIEN T. O'CONNOR

Date: 7/10/09

JOAN MCPHEE
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Counsel to Schering-Plough Corporation,
Merck & Co., Inc., and
MSP Singapore Company LLC

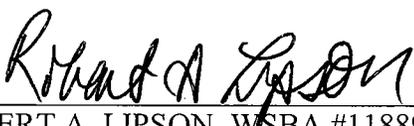
By: 
DOUGLAS A. HOFFMANN, WSBA # 06393

Date: 7/14/09

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Local Counsel to Schering-Plough Corporation, Merck & Co., Inc., and
MSP Singapore Company, LLC

ROBERT M. MCKENNA
Attorney General

By: 
ROBERT A. LIPSON, WSBA #11889

Date: 7/14/09

Senior Counsel
Consumer Protection Division
Attorney General Office of the State of Washington