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July 14, 2009

Michele Lumbert, Clerk  
Kennebec County Superior Court  
95 State Street  
Augusta, ME 04330

Re: *Assurance of Discontinuance – Maine Attorney General, Merck  
& Co., Inc. Schering-Plough Corporation, MSP Singapore  
Company, LLC*

Dear Michele:

Enclosed for filing in accordance with 5 M.R.S. § 210, please find an Assurance of Discontinuance executed by the Maine Attorney General, Merck & Co., Inc., Schering-Plough Corporation and MSP Singapore Company, LLC. The Assurance incorporates the terms of a Consent Judgment entered in *State of Maine v. Merck & Co., Inc.*, Kennebec County Superior Court Docket No. CV-08-177. Thank you for your assistance in this matter and please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

A handwritten signature in cursive script that reads "Christina M. Moylan".

CHRISTINA M. MOYLAN  
Assistant Attorney General  
207/626-8838  
[christina.moylan@maine.gov](mailto:christina.moylan@maine.gov)

CMM/s  
Enclosure

cc: Danielle Pelfrey Duryea, Esq.  
David Hart, Oregon AAG

## **ASSURANCE OF DISCONTINUANCE**

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

### **PREAMBLE**

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

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

**WHEREAS**, the Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this AVC;

**WHEREAS**, the Companies have voluntarily cooperated with the investigation and consented to the entry of this Assurance, and have not admitted any violation of law or finding of fact;

**WHEREAS**, no court has entered any findings of fact or conclusions of law relating to this investigation;

**IT IS** on this 29<sup>th</sup> day of June, 2009 **AGREED**, as follows:

## DEFINITIONS

1. “Companies” shall mean Schering, Merck, and MSP collectively.
2. “Covered Conduct” shall mean the Companies’ promotional and marketing practices regarding the prescription drugs Vytorin® and Zetia®, the Companies’ practices related to Data Safety Monitoring Boards, the Companies’ publication of clinical trials and disclosure of clinical trial results, and the Companies’ support of continuing medical education that were the subject of an investigation by the Signatory Attorneys General under the State Consumer Protection Laws.
3. “Effective Date” shall mean the date by which all Parties have executed the Assurance.
4. “FDA Amendments Act of 2007 (“or FDA Amendments Act” or “the Act”) shall mean Public Law No. 110-85, which, among other things, creates a federal clinical trial registry and results data bank.
5. “FDA’s Guidances for Industry” shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration (FDA), that represent the FDA’s current recommendations on a topic.
6. “Individual States” and “State” shall mean each Signatory Attorney General who is participating in the Multistate Working Group.
7. “Joint Venture(s)” shall mean any entity in which Merck or Schering maintains a direct and/or indirect ownership interest of 50% or less on the date this Agreement is signed.
8. “Merck” shall mean Merck & Co., Inc., and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns, but shall not include any Joint Ventures (as that term is defined in the prior subparagraph) except for MSP.

9. “MSP” shall mean MSP Singapore Company, LLC.
10. “Multistate Executive Committee” shall mean the Attorneys General and their staffs representing Arizona, California, the District of Columbia, Florida, Illinois, New Jersey, Ohio, Oregon, Pennsylvania, South Carolina, and Texas.
11. “Multistate Working Group” (“MSWG”) shall mean the Attorneys General and their staffs representing Arizona, Arkansas, California, Colorado, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, West Virginia, Washington, and Wisconsin.
12. “Parties” shall mean the Companies and the Individual States.
13. “Product” shall mean any prescription drug or biological product manufactured, distributed, sold, marketed, or promoted in the United States in any way.
14. “Schering” shall mean Schering-Plough Corporation and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns, but shall not include any Joint Ventures (as that term is defined in the prior subparagraph) except for MSP.
15. “Signatory Attorney(s) General” shall mean the Attorney General, or his or her designee, of each state in the Multistate Working Group.
16. “State Consumer Protection Laws” shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.<sup>1</sup>

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<sup>1</sup> ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – *Arkansas Deceptive Trade Practices Act*, Ark. Code Ann. § 4-88-101, *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA,

17. “Vytorin®” shall mean ezetimibe/simvastatin.
18. “Zetia®” shall mean ezetimibe or any product that contains ezetimibe other than Vytorin®.

### ASSURANCES

19. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 2 through 4 of the Consent Judgment attached hereto as Exhibit A (hereinafter “Exhibit A”).
20. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraph 8 of Exhibit A. The Companies’ obligations with respect to the provisions contained in Paragraph 8 of Exhibit A shall remain in effect for six years following the Effective Date. With respect to the provisions contained in Paragraph 8 of Exhibit A, the Companies shall abide by

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*Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.001-501.164, 501.207; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA – *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KENTUCKY – *Kentucky Consumer Protection Act*, KRS Ch. 367.110, *et seq.*; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, *et seq.*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MISSISSIPPI – *Mississippi Consumer Protection Act*, Miss. Code Ann. § 75-24-1 *et seq.* (1972 as amended); MISSOURI – *Missouri 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-1-101 *et seq.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

any such written recommendation when such submission is made within six years of the Effective Date.

21. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 10 through 13 of Exhibit A. The Companies' obligations with respect to the provisions contained in Paragraph 13 of Exhibit A shall remain in effect for eight years following the Effective Date. The Companies' obligations with respect to the provisions contained in Paragraph 13(b) of Exhibit A shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the Effective Date.
22. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 15 and 17 through 19 of Exhibit A. The provisions contained in subparagraph 15(d)(ii) of Exhibit A shall also apply to consulting relationships with Schering-Plough Research Institute. The Companies' obligations with respect to the provisions contained in Paragraph 15 of Exhibit A shall remain in effect for six years following the Effective Date.
23. Nothing in this Assurance shall require the Companies to:
  - a. take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or
  - b. fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this Assurance which is the same, or materially the same, as the language required or agreed to by the Director of DDMAC or the Director of the Center for Drug

- Evaluation or their authorized designees in writing shall not constitute a violation of this Assurance.
24. All obligations undertaken by the Companies in this Assurance shall apply prospectively, except, to the extent permitted by the National Library of Medicine, the Companies shall submit, as soon as practicable, clinical trial results to the clinical trial registry and results data bank created by the FDA Amendments Act for all “applicable clinical trials” (as that term is defined by the Act) of Vytorin® and/or Zetia® that were initiated after July 1, 2005.
25. The Companies shall be bound by the provisions of paragraphs 19 through 24 of this Assurance beginning 120 days after the Effective Date.

#### **GENERAL PROVISIONS**

26. Release of Claims: By its execution of this Assurance, each Individual State releases the Companies and all of their past and present subsidiaries, affiliates, predecessors and successors (collectively, the “Released Parties”) from all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the Individual State under the consumer protection statutes listed in footnote 1 of this Assurance arising from the Covered Conduct that is the subject of this Assurance.
27. Claims Reserved: Notwithstanding any term of the Assurance, specifically reserved and excluded from the Release in Paragraph 26 as to any entity or person, including Released Parties, are any and all of the following:
- a. Any criminal liability that any person or entity, including Released Parties, has or may have to any State;

- b. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to any State under any statute, regulation or rule not expressly covered by the release in Paragraph 26 above, including but not limited to 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 Assurance 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 Assurance under those laws.



No part of this Assurance, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by the Companies.

- b. This Assurance 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 Assurance. This Assurance is made without trial or adjudication of any issue of fact or law or finding of liability of any kind.
  - c. It is the intent of the Parties that this Assurance not be admissible in other cases or binding on the Companies in any respect other than in connection with the enforcement of this Assurance.
  - d. No part of this Assurance shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Assurance.
29. Reimbursement for Investigative Costs: Within ten business days of the Effective Date of this Assurance, the Companies shall pay a total amount of \$5,400,000.00 to the Signatory Attorneys General. A portion of this amount designated by the Multistate Executive Committee in the sole discretion of that Committee shall be paid by the Companies directly to each Signatory Attorney General. Said payments shall be made in reimbursement of the Multistate Working Group's attorneys' fees and other costs of investigation and shall be put to use as permitted by state law at the sole discretion of each Signatory Attorney General.

30. Compliance: For purposes of resolving disputes with respect to compliance with this Assurance:
- a. Should any of the Signatory Attorneys General have a reasonable basis to believe that the Companies have engaged in a practice that violates a provision of this Assurance subsequent to the Effective Date of this Assurance, then such Attorney General shall notify the Companies in writing of the specific objection, identify with particularity the provisions of this Assurance that the practice appears to violate, and give the Companies thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.
  - b. Upon receipt of written notice, the Companies shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why the Companies believe they are in compliance with the Assurance, or a detailed explanation of how the alleged violation occurred and a statement explaining how the Companies intend to cure the alleged breach.
  - c. Upon giving the Companies thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to relevant, non-privileged, non-work product records and documents in the possession, custody, or control of the Companies that relate to the Companies' compliance with each provision of this Assurance as to which cause that is legally sufficient in the State has been shown. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General

will provide a list of those documents to the Companies. Nothing in this paragraph shall be interpreted to limit the State's Civil Investigative Demand ("CID") or subpoena authority, to the extent such authority exists under applicable state law, and the Companies reserve all rights with respect to a CID or subpoena issued pursuant to such authority.

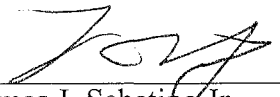
- d. The State may assert any claim that the Companies have violated this Assurance in a separate civil action to enforce this Assurance, or to seek any other relief afforded by law, only after providing the Companies an opportunity to respond to the notification described in Paragraph 30(a) above; provided,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

- 31. Entire Agreement: This Assurance represents the entire agreement entered into by the Parties hereto and shall bind the Parties hereto. In any action undertaken by either the Attorneys General, or any of them, or the Companies, no prior versions of this Assurance, and no prior versions of any of its terms may be introduced for any purpose whatsoever.
- 32. Modification: Any Party to the Assurance may seek modification of the Assurance if it believes that facts and circumstances underlying the Assurance have changed in any material respect. The Multistate Executive Committee agrees to coordinate discussions with the Companies regarding any such modification and to make recommendations to the Multistate Working Group. This Assurance shall be modified only by mutual assent of the parties and only by a written instrument, signed by or on behalf of the Parties, and, where required, by court order. If, after the date of entry of this Assurance, an Individual

State, its Attorney General, or any agency of an Individual State enacts or promulgates legislation, rules or regulations with respect to matters governed by this Assurance that conflict with any provision of this Assurance, or if the applicable law of the Individual State shall otherwise change so as to conflict with any provision of this Assurance, the Attorney General shall not unreasonably withhold his or her consent to the modification of such provision to the extent necessary to eliminate such conflict. Laws, rules, or regulations, or other changes in Individual State law, with respect to the matters governed by this Assurance, shall not be deemed to conflict with a provision of this Assurance unless the Companies cannot reasonably comply with both such law, rule, or regulation and the applicable provision of this Assurance.


33. Severability: If any portion of this Assurance is held invalid or unenforceable by operation of law, the remaining terms of this Assurance shall not be affected.
34. Certification: The Parties certify that their undersigned representative is fully authorized to enter into the terms and conditions of this Assurance and to legally bind the party represented.

FOR SCHERING-PLOUGH CORPORATION:

  
\_\_\_\_\_  
Thomas J. Sabatino Jr.  
Executive Vice President and General Counsel  
Schering-Plough Corporation  
2000 Galloping Hill Road  
Kenilworth, New Jersey 07033

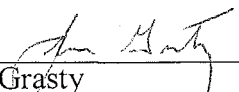
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FOR MERCK & CO., INC.:

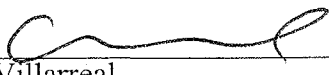
  
\_\_\_\_\_  
Bruce N. Kuhlik  
Executive Vice President and General Counsel  
Merck & Co., Inc.  
One Merck Drive  
Whitehouse Station, New Jersey 08889

Date: 7-9-09


FOR MSP SINGAPORE COMPANY, LLC:

  
\_\_\_\_\_  
James Grasty  
Vice President and Assistant General Counsel  
Merck & Co., Inc.  
One Merck Drive  
Whitehouse Station, New Jersey 08889

Date: 7-9-09

  
\_\_\_\_\_  
PD Villarreal  
Vice President and Associate General Counsel  
Schering-Plough Corporation  
2000 Galloping Hill Road  
Kenilworth, New Jersey 07033

Date: 7-9-09

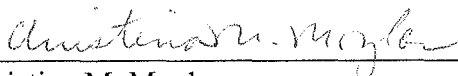


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Counsel to Schering-Plough Corporation,  
Merck & Co., Inc., and  
MSP Singapore Company LLC

Date: 7/10/09

STATE OF MAINE  
Attorney General Janet T. Mills



Christina M. Moylan  
Assistant Attorney General

Date: 7-14-09