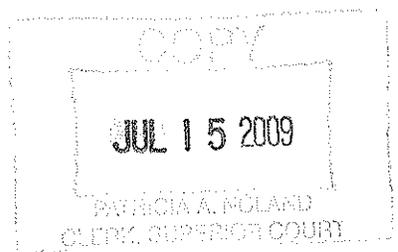


1 TERRY GODDARD
Attorney General
2 Firm Bar No. 14000
3 NOREEN R. MATTS
Assistant Attorney General
4 State Bar No. #10363
Pima County Computer No. 36732
5 noreen.matts@azag.gov
TAREN M. ELLIS
6 Assistant Attorney General
State Bar No. 022431
7 Pima County Computer No. 65731
taren.ellis@azag.gov
8 Consumer Protection & Advocacy Section
400 W. Congress, South Bldg., Suite 315
9 Tucson, Arizona 85701-1367
Telephone: (520) 628-6504
10 Attorneys for Petitioner



11 ARIZONA SUPERIOR COURT

12 COUNTY OF PIMA

13 No. C 20095482

14 In the Matter of:

15 ASSURANCE OF DISCONTINUANCE

16 Schering-Plough Corporation, Merck &
Co., Inc., and MSP Singapore Company,
17 LLC,

MICHAEL MILLER

18 Respondents.

19
20 This Assurance of Voluntary Compliance ("AVC") is entered into by the
21 Attorneys General of Arizona, Arkansas, California, Colorado, Delaware, the District of
22 Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine,
23 Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New
24 Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania,
25 South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, West
26 Virginia, and Wisconsin, acting pursuant to their respective State Consumer Protection
27 Laws, and Schering-Plough Corporation, Merck & Co., Inc., and MSP Singapore
28 Company, LLC.

- 1 5. "FDA's Guidances for Industry" shall mean documents published by the United
2 States Department of Health and Human Services, Food and Drug
3 Administration (FDA), that represent the FDA's current recommendations on a
4 topic.
- 5 6. "Individual States" and "State" shall mean each Signatory Attorney General who
6 is participating in the Multistate Working Group.
- 7 7. "Joint Venture(s)" shall mean any entity in which Merck or Schering maintains a
8 direct and/or indirect ownership interest of 50% or less on the date this
9 Agreement is signed.
- 10 8. "Merck" shall mean Merck & Co., Inc., and its United States-based affiliates,
11 subsidiaries, predecessors, successors, and assigns, but shall not include any
12 Joint Ventures (as that term is defined in the prior subparagraph) except for
13 MSP.
- 14 9. "MSP" shall mean MSP Singapore Company, LLC.
- 15 10. "Multistate Executive Committee" shall mean the Attorneys General and their
16 staffs representing Arizona, California, the District of Columbia, Florida, Illinois,
17 New Jersey, Ohio, Oregon, Pennsylvania, South Carolina, and Texas.
- 18 11. "Multistate Working Group" ("MSWG") shall mean the Attorneys General and
19 their staffs representing Arizona, Arkansas, California, Colorado, Delaware, the
20 District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana,
21 Maine, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska,
22 Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio,
23 Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas,
24 Vermont, West Virginia, Washington, and Wisconsin.
- 25 12. "Parties" shall mean the Companies and the Individual States.
- 26 13. "Product" shall mean any prescription drug or biological product manufactured,
27 distributed, sold, marketed, or promoted in the United States in any way.
- 28

- 1 14. "Schering" shall mean Schering-Plough Corporation and its United States-
2 based affiliates, subsidiaries, predecessors, successors, and assigns, but shall
3 not include any Joint Ventures (as that term is defined in the prior
4 subparagraph) except for MSP.
- 5 15. "Signatory Attorney(s) General" shall mean the Attorney General, or his or her
6 designee, of each state in the Multistate Working Group.
- 7 16. "State Consumer Protection Laws" shall mean the consumer protection laws
8 under which the Signatory Attorneys General have conducted their
9 investigation.¹
- 10 17. "Vytorin®" shall mean ezetimibe/simvastatin.

11
12

13 ¹ ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – *Arkansas*
14 *Deceptive Trade Practices Act*, Ark. Code Ann. § 4-88-101, *et seq.*; CALIFORNIA – *Bus. & Prof Code* §§
15 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. §
16 6-1-101 *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527;
17 DISTRICT OF COLUMBIA, *Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*;
18 FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes,
19 501.001-501.164, 501.207; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A
20 and Haw. 501.201 *et seq.*; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*;
21 ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA –
22 *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KENTUCKY – *Kentucky Consumer Protection*
23 *Act*, KRS Ch. 367.110, *et seq.*; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*,
24 LSA-R.S. 51:1401, *et seq.*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*;
25 MASSACHUSETTS – *Mass. Gen. Laws c. 93A*, §§ 2 and 4; MICHIGAN – *Michigan Consumer*
26 *Protection Act*, MCL § 445.901 *et seq.*; MISSISSIPPI – *Mississippi Consumer Protection Act*, Miss.
27 *Code Ann. § 75-24-1 et seq.* (1972 as amended); MISSOURI – *Missouri Merchandising Practices Act*,
28 *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. And 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 18. "Zetia®" shall mean ezetimibe or any product that contains ezetimibe other than
2 Vytorin®.

3 **ASSURANCES**

4 19. The Companies agree that each of them shall, with respect to the products
5 Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 3
6 through 5 of the Stipulated General Judgment attached hereto as Exhibit A
7 (hereinafter "Exhibit A").

8 20. The Companies agree that each of them shall, with respect to the products
9 Vytorin® and Zetia®, be bound by the provisions contained in Paragraph 9 of
10 Exhibit A. The Companies' obligations with respect to the provisions contained
11 in Paragraph 9 of Exhibit A shall remain in effect for six years following the
12 Effective Date. With respect to the provisions contained in Paragraph 9 of
13 Exhibit A, the Companies shall abide by any such written recommendation
14 when such submission is made within six years of the Effective Date.

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

23 22. The Companies agree that each of them shall, with respect to the products
24 Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 16
25 and 18 through 20 of Exhibit A. The provisions contained in subparagraph
26 16(d)(ii) of Exhibit A shall also apply to consulting relationships with Schering-
27 Plough Research Institute. The Companies' obligations with respect to the
28

1 provisions contained in Paragraph 16 of Exhibit A shall remain in effect for six
2 years following the Effective Date.

3 23. Nothing in this AVC shall require the Companies to:

- 4 a. take an action that is prohibited by the FDCA or any regulation promulgated
5 thereunder, or by FDA; or
6 b. fail to take an action that is required by the FDCA or any regulation
7 promulgated thereunder, or by FDA. Any written or oral promotional claim
8 subject to this AVC which is the same, or materially the same, as the
9 language required or agreed to by the Director of DDMAC or the Director of
10 the Center for Drug Evaluation or their authorized designees in writing shall
11 not constitute a violation of this AVC.

12 24. All obligations undertaken by the Companies in this AVC shall apply
13 prospectively, except, to the extent permitted by the National Library of
14 Medicine, the Companies shall submit, as soon as practicable, clinical trial
15 results to the clinical trial registry and results data bank created by the FDA
16 Amendments Act for all "applicable clinical trials" (as that term is defined by the
17 Act) of Vytorin® and/or Zetia® that were initiated after July 1, 2005.

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

20 **GENERAL PROVISIONS**

21 26. Release of Claims: By its execution of this AVC, each Individual State releases
22 the Companies and all of their past and present subsidiaries, affiliates,
23 predecessors and successors (collectively, the "Released Parties") from all civil
24 claims, causes of action, damages, restitution, fines, costs, and penalties on
25 behalf of the Individual State under the consumer protection statutes listed in
26 footnote 1 of this AVC arising from the Covered Conduct that is the subject of
27 this AVC.
28

- 1 27. Claims Reserved: Notwithstanding any term of the AVC, specifically reserved
2 and excluded from the Release in Paragraph 26 as to any entity or person,
3 including Released Parties, are any and all of the following:
- 4 a. Any criminal liability that any person or entity, including Released Parties,
5 has or may have to any State;
 - 6 b. Any civil or administrative liability that any person or entity, including
7 Released Parties, has or may have to any State under any statute,
8 regulation or rule not expressly covered by the release in Paragraph 26
9 above, including but not limited to any and all of the following claims:
 - 10 i. State or federal antitrust violations;
 - 11 ii. Reporting practices, including "best price," "average wholesale price," or
12 "wholesale acquisition cost";
 - 13 iii. Medicaid violations, including federal Medicaid drug rebate statute
14 violations, Medicaid fraud or abuse, and/or kickback violations related to
15 any State's Medicaid program; and
 - 16 iv. State false claims violations.
 - 17 c. Any liability under the State Consumer Protection Laws which any person or
18 entity, including Released Parties, has or may have to individual consumers
19 or State program payors of said State, and which have not been specifically
20 enumerated as included herein.
- 21 28. Mutual Understanding: The Parties mutually recognize the following:
- 22 a. The Companies are entering into this AVC solely for the purpose of
23 settlement, and nothing contained herein may be taken as or construed to
24 be an admission or concession of any violation of law, rule, or regulation, or
25 any other matter of fact or law, or of any liability or wrongdoing, all of which
26 the Companies expressly deny. The Companies do not admit any violation
27 of the State Consumer Protection Laws set forth in footnote 1, and do not
28 admit any wrongdoing that was or could have been alleged by any Attorney

1 General before the date of the AVC under those laws. No part of this AVC,
2 including its statements and commitments, shall constitute evidence of any
3 liability, fault, or wrongdoing by the Companies.

4 b. This AVC shall not be construed or used as a waiver or limitation of any
5 defense otherwise available to the Companies in any action, or of the
6 Companies' right to defend themselves from, or make any arguments in, any
7 private individual or class claims or suits relating to the subject matter or
8 terms of this AVC. This AVC is made without trial or adjudication of any
9 issue of fact or law or finding of liability of any kind.

10 c. It is the intent of the Parties that this AVC not be admissible in other cases
11 or binding on the Companies in any respect other than in connection with
12 the enforcement of this AVC.

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

16 29. Reimbursement for Investigative Costs: Within ten business days of the
17 Effective Date of this AVC, the Companies shall pay a total amount of
18 \$5,400,000.00 to the Signatory Attorneys General. A portion of this amount
19 designated by the Multistate Executive Committee in the sole discretion of that
20 Committee shall be paid by the Companies directly to each Signatory Attorney
21 General. Said payments shall be made in reimbursement of the Multistate
22 Working Group's attorneys' fees and other costs of investigation and shall be
23 put to use as permitted by state law at the sole discretion of each Signatory
24 Attorney General. The Arizona Attorney General shall deposit its
25 reimbursement into the Consumer Fraud Revolving Fund and such monies
26 shall be used by the Attorney General for consumer fraud education and
27 investigative and enforcement operations of the consumer protection division
28 pursuant to A.R.S. §§ 44-1531.01 and 44-1534.

- 1 30. Compliance: For purposes of resolving disputes with respect to compliance with
2 this AVC:
- 3 a. Should any of the Signatory Attorneys General have a reasonable basis to
4 believe that the Companies have engaged in a practice that violates a
5 provision of this AVC subsequent to the Effective Date of this AVC, then
6 such Attorney General shall notify the Companies in writing of the specific
7 objection, identify with particularity the provisions of this AVC that the
8 practice appears to violate, and give the Companies thirty (30) days to
9 respond to the notification; provided, however, that a Signatory Attorney
10 General may take any action where the Signatory Attorney General
11 concludes that, because of the specific practice, a threat to the health or
12 safety of the public requires immediate action.
- 13 b. Upon receipt of written notice, the Companies shall provide a good-faith
14 written response to the Attorney General notification, containing either a
15 statement explaining why the Companies believe they are in compliance
16 with the AVC, or a detailed explanation of how the alleged violation occurred
17 and a statement explaining how the Companies intend to cure the alleged
18 breach.
- 19 c. Upon giving the Companies thirty (30) days to respond to the notification
20 described above, the Signatory Attorney General shall also be permitted
21 reasonable access to relevant, non-privileged, non-work product records
22 and documents in the possession, custody, or control of the Companies that
23 relate to the Companies' compliance with each provision of this AVC as to
24 which cause that is legally sufficient in the State has been shown. If the
25 Signatory Attorney General makes or requests copies of any documents
26 during the course of that inspection, the Signatory Attorney General will
27 provide a list of those documents to the Companies. Nothing in this
28 paragraph shall be interpreted to limit the State's Civil Investigative Demand

1 ("CID") or subpoena authority, to the extent such authority exists under
2 applicable state law, and the Companies reserve all rights with respect to a
3 CID or subpoena issued pursuant to such authority.

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

11 31. Entire Agreement: This AVC represents the entire agreement entered into by
12 the Parties hereto and shall bind the Parties hereto. In any action undertaken
13 by either the Attorneys General, or any of them, or the Companies, no prior
14 versions of this AVC, and no prior versions of any of its terms may be
15 introduced for any purpose whatsoever.

16 32. Modification: Any Party to the AVC may seek modification of the AVC if it
17 believes that facts and circumstances underlying the AVC have changed in any
18 material respect. The Multistate Executive Committee agrees to coordinate
19 discussions with the Companies regarding any such modification and to make
20 recommendations to the Multistate Working Group. This AVC shall be modified
21 only by mutual assent of the parties and only by a written instrument, signed by
22 or on behalf of the Parties, and, where required, by court order. If, after the
23 date of entry of this AVC, an Individual State, its Attorney General, or any
24 agency of an Individual State enacts or promulgates legislation, rules or
25 regulations with respect to matters governed by this AVC that conflict with any
26 provision of this AVC, or if the applicable law of the Individual State shall
27 otherwise change so as to conflict with any provision of this AVC, the Attorney
28 General shall not unreasonably withhold his or her consent to the modification

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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 AVC, shall not be deemed to conflict with a provision of this AVC unless the Companies cannot reasonably comply with both such law, rule, or regulation and the applicable provision of this AVC.

33. Severability: If any portion of this AVC is held invalid or unenforceable by operation of law, the remaining terms of this AVC 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 AVC and to legally bind the party represented.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

FOR THE STATE:

TERRY GODDARD
Attorney General

By: Noreen R. Matts

Date: 7/15/09

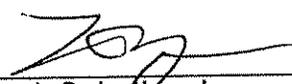
Noreen R. Matts
Unit Chief Counsel
Consumer Protection and Advocacy Section
400 W. Congress, S-Bldg., Suite 315
Tucson, Arizona 85701

BY Taren M. Ellis

Date: 7/14/09

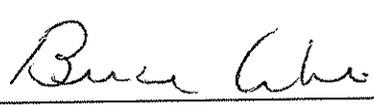
Taren M. Ellis
Assistant Attorney General
Consumer Protection and Advocacy Section
400 W. Congress, S-Bldg., Suite 315
Tucson, Arizona 85701

1 FOR SCHERING-PLOUGH CORPORATION:

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

Date: 7/9/09

8 FOR MERCK & CO., INC.:

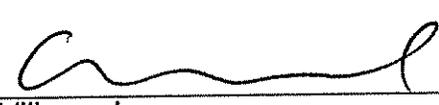
9
10 By: 
11 Bruce N. Kuhlik
12 Executive Vice President and General Counsel
13 Merck & Co., Inc.
14 One Merck Drive
15 Whitehouse Station, New Jersey 08889

Date: 7-9-09

16 FOR MSP SINGAPORE COMPANY, LLC:

17
18 By: 
19 James Grasty
20 Vice President and Assistant General Counsel
21 Merck & Co., Inc.
22 One Merck Drive
23 Whitehouse Station, New Jersey 08889

Date: 7-9-09

24 By: 
25 PD Villarreal
26 Vice President and Associate General Counsel
27 Schering-Plough Corporation
28 2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Date: 7-9-09

By: B.T.O.C

Date: 7/10/09

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

Brien T. O'Connor
Joan McPhee
Joshua S. Levy
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624

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

EXHIBIT A

1 TERRY GODDARD
Attorney General
2 (Firm State Bar No. 14000)
3 NOREEN R. MATTS
State Bar No. 10363
4 DENA ROSEN EPSTEIN
State Bar No. 015421
5 Assistant Attorneys General
Consumer Protection & Advocacy
6 400 West Congress, South Bldg., Suite 315
Tucson, Arizona 85701-1367
7 Telephone: (520) 628-6504
Pima County Computer No. 36732
8 Attorneys for Plaintiff

COPY
MAY 22 2008
PATRICIA A. NOLAND
CLERK, SUPERIOR COURT

9 ARIZONA SUPERIOR COURT
10 COUNTY OF PIMA

11 STATE OF ARIZONA, ex rel. TERRY
GODDARD, Attorney General,
12 Plaintiff,
13 -vs-
14 MERCK & CO., INC.,
15 Defendant(s).

Case No: **C20083361**
ORDER RE: CONSENT JUDGMENT
LESLIE MILLER

17 Based on the parties' Joint Motion to Enter Consent Judgment and good cause
18 appearing,

19 THE COURT HEREBY FINDS AND ORDERS:

20 1. The State of Arizona filed a Complaint alleging violations of A.R.S. § 44-1521 *et*
21 *seq.*, the Consumer Fraud Act, against defendants MERCK & CO., INC. MERCK & CO.,
22 INC. denies the allegations of the Complaint and denies any alleged violations of the Act as
23 alleged in the Complaint.

24 2. The State of Arizona, by its counsel, and Merck & Co., Inc., by its counsel, have
25 agreed to the entry of this Order by the Court without trial or adjudication of any issue of fact or
26 law, and without admission of any wrongdoing or admission of any of the violations of the Act

State v. Merck & Co., Inc.

1 as alleged in the Complaint.

2 3. This Order incorporates the parties' Joint Motion to Enter Consent Judgment in
3 *State v. Merck & Co., Inc.*

4 4. This Court has jurisdiction over the subject matter of this lawsuit and over all
5 parties.

6 5. The terms of the Consent Judgment ("Judgment") shall be governed by the laws
7 of the State of Arizona.

8 1.

9 **Definitions:**

10 a. "Covered Conduct" shall mean Merck's promotional and marketing practices
11 regarding the prescription drug Vioxx®, as well as Merck's practices related to Data Safety
12 Monitoring Boards, publication of clinical trials, and the support of continuing medical education
13 that were the subject of an investigation by the Signatory Attorneys General under the State
14 Consumer Protection Laws. "Covered Conduct" shall not include conduct relating to promotion
15 and marketing of the prescription drugs Vytorin® and/or Zetia® and to publication of clinical
16 trials, practices related to Data Safety Monitoring Boards, and the support of continuing medical
17 education, relating to Vytorin® and/or Zetia®.

18 b. "Effective Date" shall mean the date by which all Parties have executed the
19 Consent Judgment.

20 c. "FDA Amendments Act of 2007" (or "FDA Amendments Act" or "the Act") shall
21 mean Public Law No. 110-85, which among other things, creates a federal clinical trial registry
22 and results data bank.

23 d. "FDA's Guidances for Industry" shall mean documents published by the United
24 States Department of Health and Human Services, Food and Drug Administration (FDA), that
25 represent the FDA's current recommendations on a topic.

26

State v. Merck & Co., Inc.

1 e. "Individual States" and "State" shall mean each Signatory Attorney General who is
2 participating in the Multistate Working Group.

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

5 g. "Merck" shall mean Merck & Co., Inc. and its United States-based affiliates,
6 subsidiaries, predecessors, successors, and assigns, but shall not include any Joint Ventures
7 (as that term is defined in the prior sub-paragraph).

8 h. "Multistate Executive Group" shall mean the Attorneys General and their staffs
9 representing Arizona, California, Florida, Illinois, Ohio, Oregon, Pennsylvania, Texas, and
10 Vermont.

11 i. "Multistate Working Group" ("MSWG") shall mean the Attorneys General and their
12 staffs representing Arizona, Arkansas, California, Connecticut, Florida, District of Columbia,
13 Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Nebraska,
14 Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South
15 Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

16 j. "Parties" shall mean Merck and the Individual States.

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

19 l. "Signatory Attorney(s) General" shall mean the Attorney General, or his or her
20 designee, of each state in the Multistate Working Group.

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

23
24 ¹The States' consumer protection statutes are: ARIZONA - *Consumer Fraud Act*, A.R.S. § 44-1521, *et*
25 *seq.*; ARKANSAS - Ark. Code Ann. § 4-88-101, *et seq.*, CALIFORNIA - Bus. & Prof. Code, §§ 17200 *et*
26 *seq.*, and 17500 *et seq.*; CONNECTICUT - Conn. Gen. Stat., §§ 42-110a *et seq.*; DISTRICT OF
COLUMBIA - *Consumer Protection Procedures Act*, D.C. Code § 28-3901, *et seq.*; HAWAII - *Uniform*
Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. § 480-2.; FLORIDA -
Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 *et seq.*; IDAHO - *Consumer*

State v. Merck & Co., Inc.

1 n. "Vioxx®" shall mean rofecoxib.

2 2.

3 The parties have agreed to resolve the issues raised by the Covered Conduct by
4 entering into this Consent Judgment (hereinafter "Judgment").

5 (a) Merck is entering into this Judgment solely for the purpose of settlement, and
6 nothing contained herein may be taken as or construed to be an admission or concession of
7 any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or
8 wrongdoing, all of which Merck expressly denies. Merck does not admit any violation of the
9 State Consumer Protection Laws set forth in footnote 1, and does not admit any wrongdoing
10 that was or could have been alleged by any Attorney General before the date of the Judgment
11
12

13
14 *Protection Act, Idaho Code Section 48-601 et seq.; ILLINOIS - Consumer Fraud and Deceptive*
15 *Business Practices Act, 815 ILCS § 505/1 et seq. (2006 State Bar Edition); IOWA - Iowa Consumer*
16 *Fraud Act, Iowa Code Section 714.16; KANSAS - Consumer Protection Act, K.S.A. 50-623 et seq.;*
17 *MAINE - Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Consumer Protection Act,*
18 *Md. Code Ann., Com. Law § 13-101 et seq.; MASSACHUSETTS - Consumer Protection Act, M.G.L. c.*
19 *93A et seq.; MICHIGAN - Michigan Consumer Protection Act, MCL 445.901 et seq.; NEBRASKA -*
20 *Uniform Deceptive Trade Practices Act, NRS §§ 87-301 et seq.; NEW JERSEY - New Jersey*
21 *Consumer Fraud Act, 56:8-1 et seq.; NEVADA - Deceptive Trade Practices Act, Nevada Revised*
22 *Statutes 598.0903 et seq.; NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C. Gen.*
23 *Stat. § 75-1.1 et seq.; NORTH DAKOTA - Unlawful Sales or Advertising Practices, N.D. Cent. Code. §*
24 *51-15-02 et seq.; OHIO - Consumer Sales Practices Act, R.C. 1345.01, et seq.; OREGON - Unlawful*
25 *Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and*
26 *Consumer Protection Law, 73 P.S. § 201-1 et seq.; SOUTH CAROLINA - Unfair Trade Practices Act, S.*
C. CODE. ANN. Sections 39-5-10, et seq.; SOUTH DAKOTA - Deceptive Trade Practices Act, S.D.
Codified Laws § 37-24, et seq.; TENNESSEE - Tennessee - Consumer Protection Act, Tenn. Code Ann.
§§ 47-18-101 et seq.; TEXAS - Deceptive Trade Practices - Consumer Protection Act, Tex. Bus. and
Com. Code § 17.47, et seq.; VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 et seq.;
WASHINGTON - Unfair Business Practices/Consumer Protection Act, R.C.W. 19.86 et seq.;
WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

1 under those laws. No part of this Judgment, including its statements and commitments, shall
2 constitute evidence of any liability, fault, or wrongdoing by Merck.

3 (b) This Judgment shall not be construed or used as a waiver or limitation of any
4 defense otherwise available to Merck in any action, or of Merck's right to defend itself from, or
5 make any arguments in, any private individual or class claims or suits relating to the subject
6 matter or terms of this Judgment. This Judgment is made without trial or adjudication of any
7 issue of fact or law or finding of liability of any kind.

8 (c) It is the intent of the Parties that this Judgment not be admissible in other cases
9 or binding on Merck in any respect other than in connection with the enforcement of this
10 Judgment.

11 (d) No part of this Judgment shall create a private cause of action or confer any right
12 to any third party for violation of any federal or state statute except that a State may file an
13 action to enforce the terms of this Judgment.

14 (e) All obligations undertaken by Merck in this Judgment shall apply prospectively,
15 except to the extent permitted by the National Library of Medicine, Merck shall submit, as soon
16 as practicable, clinical trial results to the clinical trial registry and results data bank created by
17 the FDA Amendments Act for all "applicable clinical trials" (as that term is defined by the Act)
18 of FDA-approved Merck Products that were initiated after July 1, 2005.

19 3.

20 Merck shall register clinical trials and submit results to the registry and results data bank
21 as required by the FDA Amendments Act and any accompanying regulations that may be
22 promulgated pursuant to that Act.

23 4.

24 Merck shall not make any written or oral claim that is false, misleading or deceptive
25 regarding any FDA-approved Merck Product.

26

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

5.

Merck shall not make any written or oral promotional claims of safety or effectiveness for any FDA-approved Merck Product in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), accompanying regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

6.

A written or oral claim made by Merck in connection with a Joint Venture Product which written or oral claim has not been approved by the Joint Venture shall be subject to the provisions of Paragraphs 4 and 5. In no event, however, shall Paragraphs 4 and 5 apply to Vytorin® or Zetia®.

7.

Nothing in this Judgment shall require Merck to:

- i. take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or
- ii. 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 Judgment 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 Judgment.

8.

Merck agrees to delay direct to consumer ("DTC") television advertising for any Merck Product indicated for pain relief immediately following such Product's approval by the FDA, if the Director of the Center for Drug Evaluation at FDA recommends such a delay in writing to

1 Merck. Merck's delay would be for the same period as recommended by the Director of the
2 Center for Drug Evaluation at FDA.

3 9.

4 Merck agrees to submit all new DTC television advertising campaigns for any Merck
5 Product to FDA for pre-review, wait until Merck receives a response from FDA prior to running
6 the advertising campaign, and to modify such advertising consistent with any written
7 comments received from FDA.

8 10.

9 Merck's obligations with respect to Paragraph 8 shall remain in effect for ten years
10 following the Effective Date. Merck's obligations with respect to Paragraph 9 shall remain in
11 effect for seven years following the Effective Date. With respect to Paragraph 8, Merck shall
12 abide by any such written recommendation as long as the submission of the TV advertising
13 campaign is made within ten years following the Effective Date. With respect to Paragraph 9,
14 Merck shall abide by any such written recommendation when such submission is made within
15 seven years of the Effective Date.

16 11.

17 When presenting information in detailing pieces, brochures, booklets, mailing pieces,
18 published journals, magazines, other periodicals and newspapers, and broadcast through
19 media such as radio, television, the Internet, and telephone communications systems, about a
20 Clinical Study that relates to an FDA-approved Merck Product, Merck shall (1) accurately
21 reflect the methodology used to conduct the Clinical Study; (2) shall not present favorable
22 information or conclusions from a study that is inadequate in design, scope, or conduct to
23 furnish significant support for such information or conclusions; and (3) shall not use statistical
24 analyses and techniques on a retrospective basis to discover and cite findings not soundly
25 supported by the study, or to suggest scientific validity and rigor for data from studies the
26 design or protocol of which are not amenable to formal statistical evaluations.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

12.

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Merck Product's safety, Merck shall not (1) present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; nor (2) use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

13.

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Merck Product's safety, Merck shall not (1) present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; (2) use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; nor (3) use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluation.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

14.

(a) Merck shall comply with the ACCME Standards for Commercial Support, a copy of which is attached hereto as Appendix 1.

(b) Any person who acts in a promotional capacity for Merck with respect to an FDA approved Merck Product shall be obligated under his or her contract with Merck, as a condition for any future promotional relationship with Merck, to disclose to CME participants orally and to the CME provider for inclusion in the written materials the existence, nature and purpose of his or her arrangement with Merck when speaking at a CME program if: (i) the Product the speaker promoted for Merck is in the same therapeutic category as the subject of the CME program, and (ii) the CME program occurs within 12 months of the speaker performing work for or receiving compensation from Merck. Such disclosure shall set forth the type of promotional work engaged in by the speaker and the name of the therapeutic category with respect to which such promotion was performed.

(c) Merck shall not provide funding for CME when Merck has knowledge at the time the decision to fund the CME is made that a speaker at the CME has also been a promotional speaker in the past 12 months at a Merck-sponsored promotional event related to the class of drugs to be discussed in the CME.

15.

Merck's obligations with respect to CME shall remain in effect for 9 years following the Effective Date. Merck's obligations with respect to Paragraph 14(b) shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the date of this Agreement.

16.

All members of any external Data Safety Monitoring Board ("DSMB") constituted by

1 Merck after the Effective Date for a Merck-Sponsored Clinical Trial shall be prohibited from:

2 (a) holding more than \$25,000 of Merck stock (exclusive of mutual fund holdings) at
3 the time of DSMB membership;

4 (b) trading in Merck stock during their DSMB service;

5 (c) serving as a clinical trial investigator in the trial being monitored by the DSMB;

6 and

7 (d) consulting for, being employed by, or entering into any future consulting or
8 employment relationships with, Merck while serving on the DSMB, except that DSMB
9 members may (i) concurrently serve on other DSMBs for Merck, and/or (ii) consult for Merck
10 Research Laboratories where the annual aggregate compensation for such non-promotional
11 consulting services does not exceed \$15,000.

12 17.

13 Merck's obligations with respect to DSMB membership set forth in Paragraph 16 shall
14 remain in effect for DSMBs constituted within 7 years following the Effective Date.

15 18.

16 Merck agrees to enhance further its process for reviewing potential conflicts of interest
17 such that all members of a DSMB shall, prior to service thereon, complete a "competing
18 interests" form which shall include questions regarding consulting arrangements or frequent
19 speaking arrangements with the sponsor; career involvement with a product or technique
20 under study; hands-on participation in the trial; emotional involvement in the trial; intellectual
21 conflicts; involvement in regulatory issues relevant to trial procedures; investment in competing
22 products; and involvement in the publication. The forms shall carry a continued updating
23 obligation and shall be forwarded to, and reviewed by, the DSMB chair who, in turn, will
24 forward them to the study's Steering Committee chair or other appropriate individual for review
25 and action, as needed, in advance of the first DSMB meeting and on an ongoing basis.

26

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

19.

Merck shall require all individuals who are named as authors on a Merck-sponsored manuscript reporting the results of a Merck-sponsored study to fulfill the following conditions: (a) the individual shall have made substantial contribution to the conception and design, or acquisition of data, or analysis and interpretation of data; (b) the individual shall have been involved in drafting the article or revising it critically for important intellectual content; and (c) the individual shall have final approval rights of the version to be published.

20.

When a large, multi-center group has conducted the research, the manuscript should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined in Paragraph 19 above.

21.

By its execution of this Judgment, State of Arizona releases Merck and all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the State of Arizona under the above-cited consumer protection statutes arising from the Covered Conduct that is the subject of this Judgment.

22.

Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims 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 the State of Arizona.
- b. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Arizona under any statute, regulation or rule not

1 expressly covered by the release in Paragraph 21 above, including but not limited to any and
2 all of the following claims:

- 3 i) State or federal antitrust violations;
- 4 ii) Reporting practices, including "best price", "average wholesale price" or "wholesale
5 acquisition cost;"
- 6 iii) Medicaid violations, including federal Medicaid drug rebate statute violations,
7 Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid
8 program; and,
- 9 iv) State false claims violations.

10
11 c. Any liability under the State of Arizona's above-cited consumer protection laws
12 which any person or entity, including Released Parties, has or may have to individual
13 consumers or State program payors of said State, and which have not been specifically
14 enumerated as included herein.

15 23.

16 Within ten (10) days of the Effective Date of this Judgment, Merck shall pay a total
17 amount of fifty eight million dollars (\$58,000,000.00) to be divided and paid by Merck directly to
18 each Signatory Attorney General in an amount to be designated by and in the sole discretion
19 of the Multistate Executive Committee. Said payment shall be used by the States for
20 attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to,
21 the consumer protection enforcement fund, consumer education, litigation or local consumer
22 aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other
23 uses permitted by state law, at the sole discretion of each Signatory Attorney General.

24
25
26 24.

1 For the purposes of resolving disputes with respect to compliance with this Judgment,
2 should any of the Signatory Attorneys General have a reasonable basis to believe that Merck
3 has engaged in a practice that violates a provision of this Judgment subsequent to the
4 Effective Date of this Judgment, then such Attorney General shall notify Merck in writing of the
5 specific objection, identify with particularity the provisions of this Judgment that the practice
6 appears to violate, and give Merck thirty (30) days to respond to the notification; provided,
7 however, that a Signatory Attorney General may take any action where the Signatory Attorney
8 General concludes that, because of the specific practice, a threat to the health or safety of the
9 public requires immediate action.

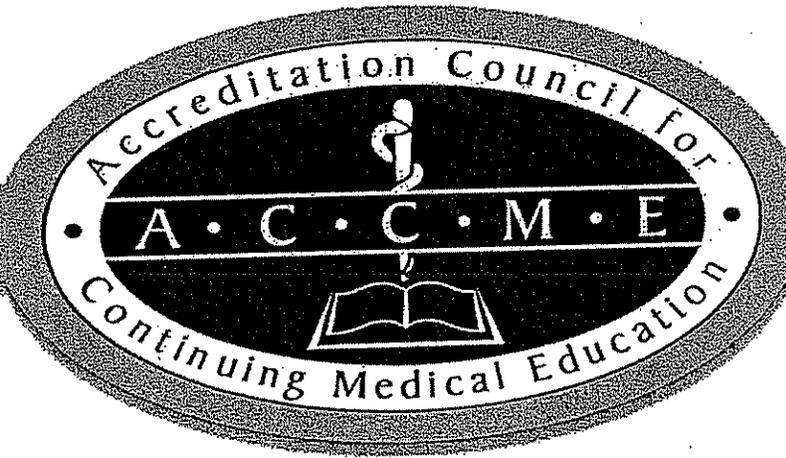
10 Upon receipt of written notice, Merck shall provide a good-faith written response to the
11 Attorney General notification, containing either a statement explaining why Merck believes it is
12 in compliance with the Judgment, or a detailed explanation of how the alleged violation
13 occurred and a statement explaining how Merck intends to cure the alleged breach.

14 25.

15 Upon giving Merck thirty (30) days to respond to the notification described above, the
16 Signatory Attorney General shall also be permitted reasonable access to inspect and copy
17 relevant, non-privileged, non-work product records and documents in the possession, custody
18 or control of Merck that relate to Merck's compliance with each provision of this Judgment as
19 to which cause that is legally sufficient in the State has been shown. If the Signatory Attorney
20 General makes or requests copies of any documents during the course of that inspection, the
21 Signatory Attorney General will provide a list of those documents to Merck. Nothing in this
22 paragraph shall be interpreted to limit the state's Civil Investigative Demand ("CID") or
23 subpoena authority, to the extent such authority exists under applicable state law, and Merck
24 reserves all of its rights with respect to a CID or subpoena issued pursuant to such authority.

25
26 26.

APPENDIX 1



ACCME STANDARDS FOR COMMERCIAL SUPPORTSM

*Standards to Ensure the
Independence of CME
Activities*

The ACCME Standards for Commercial SupportSM

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ¶

STANDARD 4: Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For *print*, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.
- For *computer based*, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content
- For *audio and video recording*, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For *live, face-to-face CME*, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ¶

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company. ¶

STANDARD 6: Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ¶