STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON, Plaintiff, v. MERCK & CO., INC., Defendant.	NO. 08-2-17107-8 SEA CONSENT DECREE [Clerk's Action Required]

I. JUDGMENT SUMMARY

1.1	Judgment Creditor:	State of Washington
1.2	Judgment Debtor:	Merck & Co., Inc.
1.3	Principal Judgment Amount:	$58,000,000 for all 30 participating states and the District of Columbia of which the State of Washington shall receive approximately $1,638,727.96 Washington State's share may be used for any purpose permitted under Paragraph 7.1 of the Consent Decree, including but not limited to attorneys' fees, other costs of investigation and litigation, cy pres, general consumer protection education and enforcement, and/or any other purpose permitted by law.
	a. Costs and Fees	See above
	b. Total Judgment Amount:	$1,638,727.96
1.4	Post Judgment interest rate:	Not applicable if paid within 10 days pursuant to Paragraph 7.1
1.5	Attorneys for Judgment Creditor:	Robert M. McKenna, Attorney General; and Robert Lipson, Senior Counsel
1.6	Attorneys for Judgment Debtor:	Douglas A. Hofmann, Williams, Kastner & Gibbs PLLC

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Plaintiff, State of Washington, through its attorneys, Robert M. McKenna, Attorney General, and Robert Lipson, Senior Counsel, has filed a Complaint for a permanent injunction and other relief in this matter pursuant to the Consumer Protection Act, RCW 19.86, *et seq.*, alleging defendant Merck & Co., Inc., committed violations of the Act. Defendant denies the allegations of the Complaint and denies any alleged violations of the Act.

Plaintiff, by its counsel, and defendant, by its counsel, have agreed to the entry of this Consent Decree by the Court without trial or adjudication of any issue of fact or law, and without admission of any wrongdoing or admission of any of the violations of the Act as alleged in the Complaint.

II. PARTIES

2.1 The State of Washington ("the State") is the Plaintiff in this case.

2.2 Merck & Co., Inc. ("Merck"), is the Defendant in this case. Its principal place of business is One Merck Drive, Whitehouse Station, New Jersey, and it is incorporated under the laws of New Jersey.

III. DEFINITIONS

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

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

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3.3 "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.

3.4 "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.

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

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

3.7 "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 sub-paragraph).

3.8 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing: Arizona, California, Florida, Illinois, Ohio, Oregon, Pennsylvania, Texas, and Vermont.

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

3.10 "Parties" shall mean Merck and the Individual States.

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

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

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

3.14 "Vioxx®" shall mean rofecoxib.

IV. GENERAL TERMS AND PROVISIONS

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

4.2 Merck is entering into this Judgment 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 of any other matter of fact or law, or of any liability or wrongdoing, all of which Merck expressly denies. Merck does not admit any violation of the State Consumer Protection Laws set forth in footnote 1, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Merck.

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[1] The States' consumer protection statutes are: ARIZONA - *Consumer Fraud Act,* A.R.S. § 44-1521, *et seq.*; ARKANSAS - Ark. Code Ann. § 4-88-101, *et seq.*, CALIFORNIA - Bus. & Prof. Code, §§ 17200 *et 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 Protection Act,* Idaho Code Section 48-601 *et seq.*; ILLINOIS - *Consumer Fraud and Deceptive Business Practices Act,* 815 ILCS § 505/1 *et seq.* (2006 State Bar Edition); IOWA - *Iowa Consumer Fraud Act,* Iowa Code Section 714.16; KANSAS - *Consumer Protection Act,* K.S.A. 50-623 *et seq.*; MAINE - *Unfair Trade Practices Act,* 5 M.R.S.A. § 207 *et seq.*; MARYLAND - *Consumer Protection Act,* Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS - *Consumer Protection Act,* M.G.L. c. 93A *et seq.*; MICHIGAN - *Michigan Consumer Protection Act,* MCL 445.901 *et seq.*; NEBRASKA - *Uniform Deceptive Trade Practices Act,* NRS §§ 87-301 *et seq.*; NEW JERSEY - *New Jersey Consumer Fraud Act,* 56:8-1 *et seq.*; NEVADA - *Deceptive Trade Practices Act,* Nevada Revised Statutes 598.0903 *et seq.*; NORTH CAROLINA - *Unfair and Deceptive Trade Practices Act,* N.C. Gen. Stat. § 75-1.1 *et seq.*; NORTH DAKOTA -*Unlawful Sales or Advertising Practices,* N.D. Cent. Code. § 51-15-02 *et seq.*; OHIO- *Consumer Sales Practices Act,* R.C. 1345.01, *et seq.*; OREGON - *Unlawful Trade Practices Act,* ORS 646.605 to 646.656; PENNSYLVANIA - *Unfair Trade Practices and 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).

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

4.4 It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Merck in any respect other than in connection with the enforcement of this Judgment.

4.5 No part of this Judgment 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 Judgment.

4.6 All obligations undertaken by Merck in this Judgment shall apply prospectively, except to the extent permitted by the National Library of Medicine, Merck 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 FDA-approved Merck Products that were initiated after July 1, 2005.

V. ORDER AND INJUNCTIVE PROVISIONS

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

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

5.3 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

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agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

5.4 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 5.2 and 5.3. In no event, however, shall Paragraphs 5.2 and 5.3 apply to Vytorin® or Zetia®.

5.5 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.

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

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

5.8 Merck's obligations with respect to Paragraph 5.6 shall remain in effect for ten years following the Effective Date. Merck's obligations with respect to Paragraph 5.7 shall remain in effect for seven years following the Effective Date. With respect to Paragraph 5.6,

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Merck shall abide by any such written recommendation as long as the submission of the TV advertising campaign is made within ten years following the Effective Date. With respect to Paragraph 5.7, Merck shall abide by any such written recommendation when such submission is made within seven years of the Effective Date.

5.9 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 that relates to an FDA-approved Merck Product, Merck shall (1) accurately reflect the methodology used to conduct the Clinical Study; (2) shall not 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; and (3) shall not 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 evaluations.

5.10 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.

5.11 When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast

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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.

5.12

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

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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.

5.13 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 5.12(b) shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the date of this Agreement.

5.14 All members of any external Data Safety Monitoring Board ("DSMB") constituted by Merck after the Effective Date for a Merck-Sponsored Clinical Trial shall be prohibited from:

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

b) trading in Merck stock during their DSMB service;

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

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

5.15 Merck's obligations with respect to DSMB membership set forth in Paragraph 5.14 shall remain in effect for DSMBs constituted within 7 years following the Effective Date.

5.16 Merck agrees to enhance further its process for reviewing potential conflicts of interest such that all members of a DSMB shall, prior to service thereon, complete a "competing interests" form which shall include questions regarding consulting arrangements or frequent speaking arrangements with the sponsor; career involvement with a product or technique under study; hands-on participation in the trial; emotional involvement in the trial;

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intellectual conflicts; involvement in regulatory issues relevant to trial procedures; investment in competing products; and involvement in the publication. The forms shall carry a continued updating obligation and shall be forwarded to, and reviewed by, the DSMB chair who, in turn, will forward them to the study's Steering Committee chair or other appropriate individual for review and action, as needed, in advance of the first DSMB meeting and on an ongoing basis.

5.17 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.

5.18 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 5.17 above.

VI. RELEASE

6.1 By its execution of this Judgment, the State of Washington 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 Washington under the above-cited consumer protection statutes arising from the Covered Conduct that is the subject of this Judgment.

6.2 Notwithstanding any term of this Judgment, specifically reserved and excluded from the Release in Paragraph 6.1 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 Washington.

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b) Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Washington under any statute, regulation or rule not expressly covered by the release in Paragraph 6.1 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 of Washington's above-cited 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.

VII. PAYMENT

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

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VIII. OTHER PROVISIONS

8.1 For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Merck has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Merck in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Merck 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.

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

8.2 Upon giving Merck thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody or control of Merck that relate to Merck's compliance with each provision of this Judgment 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 Merck. 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 Merck reserves all of its rights with respect to a CID or subpoena issued pursuant to such authority.

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8.3 The State may assert any claim that Merck has violated this Judgment in a separate civil action to enforce this Judgment, or to seek any other relief afforded by law, only after providing Merck an opportunity to respond to the notification described in Paragraph 8.1 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.

8.4 This Judgment represents the full and complete terms of the settlement entered into by the parties hereto. In any action undertaken by either the Attorneys General, or any of them, or Merck, no prior versions of this Judgment, and no prior versions of any of its terms, that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

DATED this 30th day of May, 2008.

JOAN ALLISON

Judge/Court Commissioner

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Approved for Entry and Presented by:

ROBERT M. McKENNA
Attorney General of Washington

5/19/08
ROBERT LIPSON, WSBA # 11889
Senior Counsel, Office of the Attorney General
Attorneys for State of Washington

Approved for Entry,
Notice of Presentation Waived:

MERCK & CO., INC.

By: _____
Bruce Kuhlik
Executive Vice President & General Counsel
Merck & Co., Inc.

By: _____
Douglas A. Hofmann, WSBA # 06393
Williams, Kastner & Gibbs PLLC
601 Union Street, Suite 4100
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Telephone: (206) 628-6600
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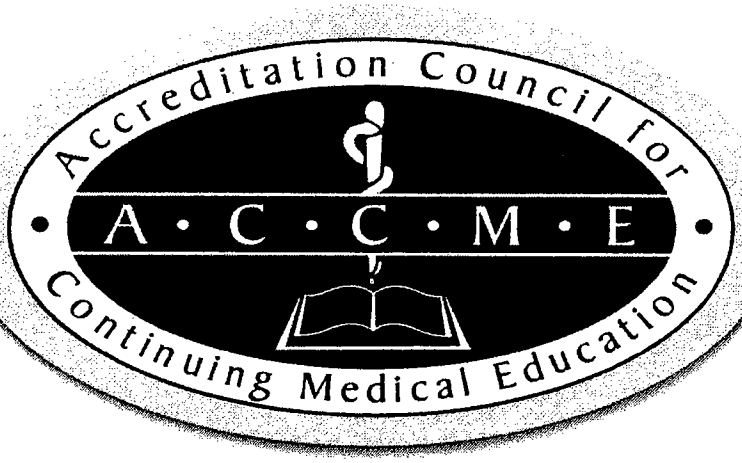
APPENDIX 1



ACCME STANDARDS FOR COMMERCIAL SUPPORT℠

Standards to Ensure the Independence of CME Activities

The ACCME Standards for Commercial Support℠

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 interleafed 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 interleafed 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. ⌘