CAUSE NO. 08-5552

STATE OF TEXAS,	§	**IN THE DISTRICT COURT OF**
	§	
Plaintiff,	§	
	§	
vs.	§	
	§	
MERCK & CO., INC.	§	**DALLAS COUNTY, T E X A S**
	§	
Defendant.	§	68-101 **JUDICIAL DISTRICT**

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the State of Texas, acting by and through Attorney General Greg Abbott ("State of Texas"), and Defendants Merck & Co., Inc., (hereinafter referred to as "Merck"), having consented to the entry of this Final Judgment and Agreed Permanent Injunction ("Judgment"), and before any testimony is taken in this case and without Defendant admitting to any violations of the Texas Deceptive Trade Practices - Consumer Protection Act, Tex. Bus. & Com. Code Ann. §17.41 *et seq.* ("DTPA") or any other law, have jointly moved that the Court enter this Judgment for the purposes of settlement only, without this Judgment constituting evidence against or any admission by any party, and without trial of any issue of fact or law.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED THAT:

1. This Court has jurisdiction of the subject matter of this case and of the parties consenting hereto pursuant to Tex. Bus. & Com. Code § 17.47(b).

2. Venue of this lawsuit lies in Dallas County, Texas pursuant to Tex. Bus. & Com. Code § 17.47(b).

3. Merck has done business in Texas by promoting and marketing Vioxx to persons who are consumers in Texas.

I. DEFINITIONS

4. The following definitions shall be used in construing this Final Judgment and Agreed Permanent Injunction (hereinafter "Final Judgment"):

A. "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®.

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

C. "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.

D. "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.

E. "Individual State" and "State" shall mean the State of Texas and its Signatory

Attorney General who is participating in the Multistate Working Group.

F. "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.

G. "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).

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

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

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

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

L. "Signatory Attorney General" shall mean the Texas Attorney General, or his or her designee.

M. "State Consumer Protection Laws" shall mean the Texas Deceptive Trade

Practices Act.

N. "Vioxx®" shall mean rofecoxib.

II. INJUNCTION

5. **IT IS FURTHER ORDERED THAT**:

A. The parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Final Judgment.

(i.) 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 Texas Deceptive Trade Practices Act, and does not admit any wrongdoing that was or could have been alleged by the Texas Attorney General before the date of the Final Judgment under those laws. No part of this Final Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Merck.

(ii.) This Final 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 Final Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind.

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

(iv.) No part of this Final 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 Final Judgment.

(v.) All obligations undertaken by Merck in this Final 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.

B. 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.

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

D. 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.

E. 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.C. and 5.D. In no event, however, shall Paragraphs 5.C. and 5.D. apply to Vytorin® or Zetia®.

F. Nothing in this Final 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 Final 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.

G. 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.

H. 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.

I. Merck's obligations with respect to Paragraph 5.G. shall remain in effect for ten years following the Effective Date. Merck's obligations with respect to Paragraph 5.H. shall remain in effect for seven years following the Effective Date. With respect to Paragraph 5.G., 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.H., Merck shall abide by any such written recommendation when such submission is made within seven years of the Effective Date.

J. 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.

K. 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.

L. 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.

M. Merck shall

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

(ii.) 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.

(iii.) 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.

N. 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 M.(ii.) shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the date of this Final Judgment.

O. 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:

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

(ii.) trading in Merck stock during their DSMB service;

(iii.) serving as a clinical trial investigator in the trial being monitored by the DSMB; and

(iv.) 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 (a.) concurrently serve on other DSMBs for Merck, and/or (b.) consult for Merck Research Laboratories where the annual aggregate compensation for such non-promotional consulting services does not exceed $15,000.

P. Merck's obligations with respect to DSMB membership set forth in Paragraph 5.O. shall remain in effect for DSMBs constituted within 7 years following the Effective Date.

Q. 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; 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.

R. 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.

S. 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.R. above.

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

7. Notwithstanding any term of this Final Judgment, specifically reserved and excluded from the Release in Paragraph 6. 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 Texas.

B. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Texas under any statute, regulation or rule not expressly covered by the release in Paragraph 6. 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;

(iv.) The causes of action pled in or encompassed by the State of Texas' First Amended Petition in *State v. Merck*, Cause No. GV 503021 in the 345th Judicial District Court, Travis County, Texas (*State v. Merck*); and,

(v.) State false claims violations.

C. Any liability under the State of Texas's Deceptive Trade Practices Act which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of Texas, and which have not been specifically enumerated as included herein.

D. Notwithstanding any term of this Final Judgment, Merck agrees that it will not assert this Final Judgment as a bar to the discovery or presentation of any evidence in *State v. Merck*. Texas and Merck agree that no provision of this Final Judgment limits or otherwise affects the parties' objections or defenses in law or equity in *State v. Merck*.

8. Within ten (10) days of the Effective Date of this Final 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, with the State of Texas receiving Four Million Thirty-three Thousand Two Hundred and Seventy-one Dollars and Seventy-six Cents ($4,033,271.76), as part of the consideration for the termination of its investigation under the State Consumer Protection Law regarding the Covered Conduct of this Final Judgment. Said payment to the State of Texas shall be allocated as follows:

A. One Million Thirty-three Thousand Two Hundred and Seventy-one Dollars and Seventy-six Cents ($1,033,271.76) to the Office of the Attorney General for its attorneys' fees and costs and

B. Three Million Dollars ($3,000,000.00) as follows:

(i.) Texas shall make a *cy pres* distribution of these funds, pursuant to a Cy Pres Distribution Plan, to a political subdivision(s) thereof or to a state agency or

program, a non-profit corporation(s) and/or a charitable organization(s), or paid into the general revenue of the State, with the express condition that the funds be used to promote the use of lower cost drugs for residents of Texas if the drugs are as safe and effective, to educate consumers concerning the cost differences among medications, or to fund other programs reasonably targeted to benefit a substantial number of persons affected by the issues addressed in this Final Judgment.

(ii.) The State of Texas shall direct that these funds shall only be utilized to fund activities which have not been funded and which, but for the receipt of money from this Final Judgment, would not be fully funded. If Texas uses its designated cy pres money to fund an activity which has previously been partially funded, it will direct that the distributed funds do not supplant existing funding and are only used to fund shortfalls in existing funding.

(iii.) The State of Texas may present its recommended Cy Pres Distribution Plan to the District Court of Dallas County, Texas for court approval.

9. For the purposes of resolving disputes with respect to compliance with this Final Judgment, should the Texas Attorney General have a reasonable basis to believe that Merck has engaged in a practice that violates a provision of this Final Judgment subsequent to the Effective Date of this Final Judgment, then such Attorney General shall notify Merck in writing of the specific objection, identify with particularity the provisions of this Final Judgment that the practice appears to violate, and give Merck thirty (30) days to respond to the notification; provided, however, that the Texas Attorney General may take any action where the Texas 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 Texas Attorney General notification, containing either a statement explaining why Merck believes it is in compliance with the Final Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Merck intends to cure the alleged breach.

10. Upon giving Merck thirty (30) days to respond to the notification described above, the Texas 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 Final Judgment as to which cause that is legally sufficient in the State has been shown. If the Texas Attorney General makes or requests copies of any documents during the course of that inspection, the Texas Attorney General will provide a list of those documents to Merck. Nothing in this paragraph shall be interpreted to limit Texas' 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.

11. The State may assert any claim that Merck has violated this Final Judgment in a separate civil action to enforce this Final Judgment, or to seek any other relief afforded by law, only after providing Merck an opportunity to respond to the notification described in Paragraph 9. above; provided, however, that the Texas Attorney General may take any action where the Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

12. This Final 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 Final Judgment, and no prior versions of any of its terms, that were not entered by the Court in this Final Judgment, may be introduced for any purpose whatsoever.

13. This Final Judgment shall be governed by the laws of the State of Texas.

14. This Final Judgment is entered into by the Parties as their own free and voluntary act and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Final Judgment.

15. This Final Judgment does not constitute an approval by the Texas Attorney General of any of Merck's business practices, including its promotional or marketing practices, and Merck shall make no representation or claim to the contrary.

16. **IT IS FURTHER ORDERED THAT** Merck shall pay all costs of the Court.

17. The clerk of the Court is authorized to issue such writs of execution or other process necessary to collect and enforce this Final Judgment.

18. The Court retains jurisdiction to enforce this Final Judgment and Agreed Permanent Injunction.

19. All relief not granted herein is hereby denied.

SO ORDERED, this 20th day of May 2008.

District Judge

THE UNDERSIGNED, WHO HAVE THE AUTHORITY TO CONSENT AND SIGN ON BEHALF OF THE PARTIES IN THIS ACTION, HEREBY CONSENT TO THE FORM AND CONTENTS OF THE FOREGOING FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION AND TO ITS ENTRY:

Date: May 19, 2008

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Attorney General of Texas

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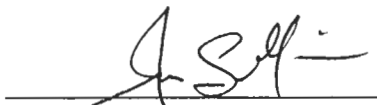
Date: 5-13-08



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Date: 5/15/08

APPENDIX 1

ACCME STANDARDS FOR COMMERCIAL SUPPORT[SM]

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. ⌘