

STATE OF OREGON } ss  
County of Marion

The foregoing copy has been compared and is certified by me as a full, true and correct copy of the original on file in my office and in my custody.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the

Court on: 10/22/08  
TRIAL COURT ADMINISTRATOR

By \_\_\_\_\_

STATE OF OREGON  
Marion County Circuit Courts  
OCT 22 2008  
**FILED**

IN THE CIRCUIT COURT OF THE STATE OF OREGON  
FOR THE COUNTY OF MARION

STATE OF OREGON ex rel HARDY  
MYERS, Attorney General for the STATE OF  
OREGON,

Plaintiff,

v.

PFIZER INC,

Defendant.

Case No. **08C23533**

STIPULATED GENERAL JUDGMENT

The parties voluntarily enter in this Stipulated General Judgment on the terms and conditions set forth below:

1.

Definitions:

a. "Covered Conduct" shall mean Pfizer's promotional and marketing practices regarding the prescription drugs Celebrex® and Bextra®, that were the subject of an investigation by the Signatory Attorneys General under the State Consumer Protection Laws.

b. "Effective Date" shall mean the date by which Pfizer and ninety percent (90%) of the States that comprise the Multistate Working Group 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.

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

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

6 f. "Pfizer" shall mean Pfizer Inc and its United States-based affiliates, subsidiaries,  
7 predecessors, successors, and assigns.

8 g. "Multistate Executive Committee" shall mean the Attorneys General and their  
9 staffs representing Arizona, California, Florida, Illinois, Massachusetts, New York, Ohio,  
10 Oregon, Texas, and Vermont.

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

17 i. "Off-Label" shall mean related to an indication that was not approved by the FDA  
18 at the time of dissemination or relating to information that was not contained in the FDA label.

19 j. "Prescriber" shall mean any physician, dentist, physician assistant, nurse  
20 practitioners, and all others with legal authority to prescribe any Pfizer product, as well as  
21 pharmacists, members of Pharmacy & Therapeutics committees and others who potentially have  
22 an impact on the prescribing of any Pfizer product.

23 k. "Parties" shall mean Pfizer and the Individual States.

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

26

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

3 n. "State Consumer Protection Laws" shall mean the consumer protection laws  
4 under which the Signatory Attorneys General have conducted their investigation.<sup>1</sup>

5 o. "Celebrex" shall mean celecoxib.

6 p. "Bextra" shall mean valdecoxib.

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8  
9 <sup>1</sup> The States' consumer protection statutes are: ALASKA - *Unfair Trade Practices and*  
10 *Consumer Protection Act*, AS 45.50.471 *et seq.*; ARIZONA - *Consumer Fraud Act*, A.R.S. § 44-  
11 1521 *et seq.*; ARKANSAS - Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA - Bus. & Prof.  
12 Code §§ 17200 *et seq.* and 17500 *et seq.*; CONNECTICUT - Conn. Gen. Stat. §§ 42-110a *et*  
13 *seq.*; DISTRICT OF COLUMBIA - *Consumer Protection Procedures Act*, D.C. Code § 28-3901  
14 *et seq.*; FLORIDA - *Deceptive and Unfair Trade Practices Act*, Fla. Stat. Ch. 501.201 *et seq.*;  
15 IDAHO - *Consumer Protection Act*, Idaho Code Section § 48-601 *et seq.*; ILLINOIS - *Consumer*  
16 *Fraud and Deceptive Business Practices Act*, 815 ILCS § 505/1 *et seq.* (2006 State Bar Edition);  
17 IOWA - *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Consumer*  
18 *Protection Act*, K.S.A. 50-623 *et seq.*; KENTUCKY - *Consumer Protection Statute*, KRS  
19 367.110 *et seq.*; MAINE - *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND -  
20 *Consumer Protection Act*, Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS -  
21 *Consumer Protection Act*, M.G.L. c. 93A *et seq.*; MICHIGAN - *Michigan Consumer Protection*  
22 *Act*, MCL 445.901 *et seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA -  
23 *Uniform Deceptive Trade Practices Act*, NRS § 87-301 *et seq.*; NEW JERSEY - *New Jersey*  
24 *Consumer Fraud Act*, 56:8-1 *et seq.*; NEW YORK - General Business Law Article 22-A  
25 Sections 349, 350 and Executive Law Section 63 (12); NEW MEXICO - *Unfair Practices Act*,  
26 NMSA 1978, § 57-12-1 *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 -  
*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 *et*  
*seq.* (Fraudulent Representations) and Wis. Stat. § 100.182 *et seq.* (Fraudulent Drug  
Advertising).

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

(a) Pfizer 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 Pfizer expressly denies. Pfizer 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 Pfizer. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

(b) This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, 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. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

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

(d) 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.

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

6 3.

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

10 4.

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

13 5.

14 Pfizer shall not make any written or oral promotional claims of safety or effectiveness for  
15 any FDA-approved Pfizer Product in a manner that violates the Food, Drug and Cosmetic Act,  
16 21 U.S.C. § 301 et seq. ("FDCA"), accompanying regulations, or voluntary agreements with  
17 FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at  
18 the FDA.

19 6.

20 Nothing in this Judgment shall require Pfizer to:

21 (a) take an action that is prohibited by the FDCA or any regulation  
22 promulgated thereunder, or by FDA; or

23 (b) fail to take an action that is required by the FDCA or any regulation  
24 promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this  
25 Judgment which is the same, or materially the same, as the language required or agreed to by the  
26 Director of Division of Drug Marketing, Advertising and Communication or the Director of the

1 Center for Drug Evaluation and Research or their authorized designees in writing shall not  
2 constitute a violation of this Judgment.

3 7.

4 Following the initial approval of any Pfizer Product indicated for pain relief, Pfizer shall  
5 delay direct to consumer ("DTC") television advertising that relates to such indication, if the  
6 Director of the Center for Drug Evaluation and Research at FDA recommends such a delay in  
7 writing to Pfizer. Pfizer's delay shall be for the same period as recommended by the Director of  
8 the Center for Drug Evaluation and Research at FDA, but in no event shall the period of delay  
9 required by this provision of this Judgment exceed 18 months from approval. Should Pfizer run  
10 television DTC advertising contrary to a recommendation from the Director of the Center for  
11 Drug Evaluation and Research after the expiration of this 18 month period, Pfizer shall provide  
12 written notice to the Multistate Executive Committee 30 days prior to running the subject  
13 advertisement and shall also provide a copy of all correspondence with FDA relating to the  
14 subject advertisement.

15 8.

16 Pfizer agrees to submit all new DTC television advertising campaigns for any Pfizer  
17 Product to FDA for pre-review, to wait a reasonable time (not less than 45 days) until Pfizer  
18 receives a response from FDA prior to running the advertising campaign, and to modify such  
19 advertising consistent with any written comments from FDA, whenever received. Simultaneous  
20 with running any new DTC television advertisement for which FDA has not provided Pfizer with  
21 a pre-review response addressing the substance of the advertisement within the 45-day waiting  
22 period prescribed herein, Pfizer shall provide written notice to the Multistate Executive  
23 Committee that Pfizer is running the advertisement and that the FDA has not provided Pfizer  
24 with a pre-review response addressing the substance of the advertising within the 45-day waiting  
25 period, and also provide a copy of all material submitted to FDA for the review of the subject  
26 advertisement.

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9.

Pfizer's obligations with respect to Paragraph 7 shall remain in effect for eight years following the Effective Date. Pfizer's obligations with respect to Paragraph 8 shall remain in effect for seven years following the Effective Date. With respect to Paragraph 7, Pfizer shall abide by any such written recommendation so long as the submission of the TV advertising campaign is made within eight years following the Effective Date. With respect to Paragraph 8, Pfizer shall abide by any such written recommendation so long as the submission of the TV advertising campaign is made within seven years of the Effective Date.

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 that relates to an FDA-approved Pfizer Product, Pfizer shall: (a) accurately reflect the methodology used to conduct the Clinical Study; (b) 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 (c) 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.

11.

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 Pfizer Product's safety, Pfizer shall not: (a) 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; or (b) use

1 statistics on numbers of patients, or counts of favorable results or side effects derived from  
2 pooling data from various insignificant or dissimilar studies in a way that suggests either that  
3 such statistics are valid if they are not or that they are derived from large or significant studies  
4 supporting favorable conclusions when such is not the case.

5 12.

6 When presenting information in detailing pieces, brochures, booklets, mailing pieces,  
7 published journals, magazines, other periodicals and newspapers, and broadcast through media  
8 such as radio, television, the Internet, and telephone communications systems, about a Clinical  
9 Study or analysis of Clinical Studies as evidence of an FDA-approved Pfizer Product's safety,  
10 Pfizer shall not: (a) present favorable information or conclusions from a study that is inadequate  
11 in design, scope, or conduct to furnish significant support for such information or conclusions;  
12 (b) use the concept of statistical significance to support a claim that has not been demonstrated to  
13 have clinical significance or validity, or fails to reveal the range of variations around the quoted  
14 average results; or (c) use statistical analyses and techniques on a retrospective basis to discover  
15 and cite findings not soundly supported by the study, or to suggest scientific validity and rigor  
16 for data from studies the design or protocol of which are not amenable to formal statistical  
17 evaluation.

18 13.

19 (a) Pfizer shall comply with the ACCME Standards for Commercial Support (a  
20 copy of the current version is attached hereto as Appendix 1).

21 (b) Any person who acts in a promotional capacity for Pfizer with respect to an  
22 FDA approved Pfizer Product shall be obligated under his or her contract with Pfizer, as a  
23 condition for any future promotional relationship with Pfizer, to disclose to Continuing Medical  
24 Education ("CME") participants orally and to the CME provider for inclusion in the written  
25 materials the existence, nature and purpose of his or her arrangement with Pfizer when a member  
26 of the faculty at a CME program if: (i) the Product the faculty member promoted for Pfizer is in

1 the same therapeutic category as the subject of the CME program, and (ii) the CME program  
2 occurs within 12 months of the faculty member performing work for or receiving compensation  
3 from Pfizer. Such disclosure shall set forth the type of promotional work engaged in by the  
4 faculty member and the name of the therapeutic category with respect to such promotion.

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

9 14.

10 Pfizer's obligations with respect to CME shall remain in effect for 9 years following the  
11 Effective Date. Pfizer's obligations with respect to Paragraph 13(b) shall only apply to speakers'  
12 contracts entered into, amended to extend the contract period, or renewed after the date of this  
13 Judgment.

14 15.

15 Pfizer shall require all individuals who are named as authors on a Pfizer-sponsored  
16 manuscript reporting the results of a Pfizer-sponsored study to fulfill the following conditions:  
17 (a) the individual shall have made a substantial contribution to the conception and design, or  
18 acquisition of data, or analysis and interpretation of data; (b) the individual shall have been  
19 involved in drafting the article or revising it critically for important intellectual content; and (c)  
20 the individual shall have final approval rights of the version to be published. When a large,  
21 multi-center group has conducted the research, the manuscript shall identify the individuals who  
22 accept direct responsibility for the manuscript. These individuals should fully meet the criteria  
23 for authorship as set forth in (a), (b), and (c) above.

24 16.

25 Pfizer shall not disseminate in a promotional context any patient testimonial relating to a  
26 Product that does not clearly and conspicuously disclose what the generally expected

1 performance would be in the depicted circumstances or clearly and conspicuously disclose the  
2 limited applicability of the experience described by the patient testimonial to what consumers  
3 may generally expect to achieve.

4 17.

5 Pfizer shall not market two or more Products in a manner that falsely or misleadingly  
6 conflates the various properties of the respective Products.

7 18.

8 Pfizer shall not compensate physicians for conducting individual, observational teaching  
9 sessions in their offices or in the hospital ("mentorships") in which sales representatives who  
10 detail a Product participate.

11 19.

12 Pfizer shall instruct investigators of Pfizer sponsored clinical trials regarding a Product to  
13 obtain a legally effective informed consent from all study subjects or from the subject's legally  
14 authorized representative. If Pfizer provides the investigator (or the investigator's Institutional  
15 Review Board) with a model informed consent, Pfizer shall not fail to include (a) a statement  
16 that the study involves research, an explanation of the purposes of the research and the expected  
17 duration of the subject's participation, a description of the procedures to be followed, and  
18 identification of any procedures which are experimental; (b) a description of any reasonably  
19 foreseeable risks or discomforts to the subject; and (c) for research involving more than minimal  
20 risk, an explanation as to whether any compensation and an explanation as to whether any  
21 medical treatments are available if injury occurs and, if so, what they consist of, or where further  
22 information may be obtained.

23 20.

24 Pfizer shall not affirmatively seek the inclusion of a Product in hospital protocols or  
25 standing orders unless the Product at issue has been approved by the FDA for the indication for  
26 which it is to be included in the protocol or standing order. Notwithstanding the foregoing,

1 Pfizer may disclose to insurance companies and other third party payors any information  
2 regarding the inclusion of a Product in hospital protocols or standing orders even if the Product  
3 at issue has not been approved by the FDA for the indication for which it is to be included in the  
4 protocol or standing order.

5 21.

6 Pfizer shall not award prizes or other incentives to its sales force as rewards for  
7 specifically increasing the Off-Label use of a Product.

8 22.

9 Pfizer shall not disseminate any information describing any Off-Label use of a Product if  
10 such use has been submitted to the FDA for approval and the FDA has either advised Pfizer that  
11 it refuses to approve such application or that FDA-identified deficiencies must be resolved  
12 before approval can be granted unless Pfizer has first clearly and conspicuously disclosed to the  
13 information recipient that FDA had issued such advice regarding such Off-Label use. Pfizer may  
14 disclose to any recipient of such information whether the information was presented to the FDA  
15 prior to the FDA's issuance of such advice regarding the Off-Label use.

16 23.

17 Pfizer shall not disseminate a Medical Information Letter, an unabridged reprint or copy  
18 of an article from a Peer Reviewed Journal or a Reference Publication, or written information  
19 through a Regional Medical Research Specialist ("RMRS") describing any Off-Label use of a  
20 Product in response to an unsolicited request by a prescriber or other health care professional  
21 unless (a) the information is about a clinical investigation with respect to the Product and experts  
22 qualified by scientific training or experience to evaluate the safety or effectiveness of the Product  
23 would consider the subject of the clinical investigation to be scientifically sound or the  
24 information is an unabridged reprint or copy of an article from a Peer Reviewed Journal or a  
25 Reference Publication; (b) the information is accompanied by a comprehensive bibliography of  
26 publications discussing adequate and well-controlled clinical studies published in a medical

1 journal or medical or scientific text that have been previously published about the use of the  
2 Product covered by the information (unless the information is a Peer Reviewed Journal or  
3 Reference Publication which already includes such a bibliography); and (c) in cases in which  
4 experts qualified by scientific training or experience to evaluate the safety or effectiveness of the  
5 Product would consider the conclusion of the information to have been specifically called into  
6 question by another article(s) or text(s) that experts qualified by scientific training or experience  
7 to evaluate the safety or effectiveness of the Product would consider to be scientifically sound,  
8 the information must be disseminated with a representative publication that reaches contrary or  
9 different conclusions regarding the Off-Label use.

10 24.

11 Pfizer shall not disseminate any reprint or copy of an article from a Peer Reviewed  
12 Journal or a Reference Publication describing any Off-Label use of the Product to physician  
13 specialties that do not customarily prescribe the Product if these materials combined with  
14 detailing, advertising, sampling, or other promotional activities promote Off-Label use of the  
15 Product.

16 25.

17 In the event that FDA issues a final "Guidance For Industry: Good Reprint Practices For  
18 The Distribution Of Medical Journal Articles And Medical Or Scientific Reference Publications  
19 On Unapproved New Uses Of Approved Drugs And Approved Or Cleared Medical Devices,"  
20 and a provision of said Guidance materially conflicts with any of the provisions of Paragraphs 22  
21 through 24 of this Judgment, Pfizer may petition the Court for modification of those paragraphs,  
22 after providing thirty (30) days' notice to the Attorney General. The parties by stipulation may  
23 agree to such a modification, which agreement shall be presented to this Court for consideration  
24 provided that the parties may jointly agree to a modification only by a written instrument signed  
25 by or on behalf of both Pfizer and the Attorney General. If Pfizer wishes to seek a stipulation for  
26 a modification from the State, it shall send a written request for agreement to such modification

1 to the Attorney General at least 30 days prior to filing a motion with the Court for such  
2 modification. Within 30 days of receipt from Pfizer of a written request for agreement to  
3 modify, the Attorney General shall notify Pfizer in writing if the Attorney General agrees to the  
4 requested modification. The Attorney General shall not unreasonably withhold his/her consent  
5 to the modification. The parties agree it would be unreasonable to withhold consent to the terms  
6 provided in the draft "Guidance For Industry: Good Reprint Practices For The Distribution Of  
7 Medical Journal Articles And Medical Or Scientific Reference Publications On Unapproved  
8 New Uses Of Approved Drugs And Approved Or Cleared Medical Devices," dated February 15,  
9 2008, and attached hereto as Appendix 2, in the event that all such terms are included in the final  
10 Guidance For Industry. In the event that all such terms are not included in the final Guidance for  
11 Industry, the parties agree to consider whether any such terms that are included in the final  
12 Guidance for Industry should form the basis of a modification of Paragraphs 22 through 24 of  
13 this Judgment.

14 26.

15 Pfizer shall not disseminate any Medical Information Letter describing any Off-Label use  
16 of a Product that makes any false or misleading representation regarding a Product.

17 27.

18 Pfizer shall not disseminate samples of a Product with the intent of increasing Off-label  
19 prescribing of the Product.

20 28.

21 When submitting clinical trials relating to Off-label indications to journals for  
22 publication, Pfizer shall disclose to the journal that the FDA has not approved the drug for the  
23 indication that was the subject of the clinical trial.

24 29.

25 The Pfizer Medical Education Grants Office shall manage all requests for funding related  
26 to CME regarding Products. Approval decisions shall be made by the Pfizer Medical Education

1 Grants Office alone, and shall be kept separate from the Sales and Marketing function.  
2 Notwithstanding the foregoing, decisions to approve a request for funding made by the Pfizer  
3 Medical Education Grants Office may be subject to actual funding approval by Pfizer's Chief  
4 Financial Officer or other designated officials.

5 30.

6 Pfizer shall not use grants to advantage or promote Products. This provision includes, but  
7 is not limited to, the following prohibitions:

- 8 (a) Sales and Marketing personnel shall not initiate, coordinate or implement  
9 grant applications on behalf of any customer or Prescriber;  
10 (b) Sales and Marketing personnel shall not be involved in selecting grantees  
11 or CME-funded speakers; and  
12 (c) Sales and Marketing personnel shall not measure or attempt to track in any  
13 way the impact of grants or speaking fees on the participating Prescribers'  
14 subsequent prescribing habits, practices or patterns.

15 31.

16 Pfizer Sales and Marketing personnel shall not approve grant requests regarding  
17 Products, nor attempt to influence the Pfizer Medical Education Grants Office to reward any  
18 customers or Prescribers with grants for their prescribing habits, practices or patterns.

19 32.

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

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1  
2 Notwithstanding any term of this Judgment, specifically reserved and excluded from the  
3 Release in Paragraph 32 as to any entity or person, including Released Parties, are any and all of  
4 the following:

5 (a) Any criminal liability that any person or entity, including Released Parties, has or  
6 may have to the State of Oregon.

7 (b) Any civil or administrative liability that any person or entity, including Released  
8 Parties, has or may have to the State of Oregon not expressly covered by the release in Paragraph  
9 32 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 any State's  
15 Medicaid program; and,

16 iv) State false claims violations.

17 (c) Any liability under the State of Oregon's above-cited consumer protection laws  
18 which any person or 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 enumerated as  
20 included herein.

21  
22 Within ten (10) days of the Effective Date of this Judgment, Pfizer shall pay a total  
23 amount of sixty million dollars (\$60,000,000) to be divided and paid by Pfizer directly to each  
24 Signatory Attorney General in an amount to be designated by and in the sole discretion of the  
25 Multistate Executive Committee. Said payment shall be used by the States for attorneys' fees  
26 and other costs of investigation and litigation, or to be placed in, or applied to, the consumer

1 protection enforcement fund, consumer education, litigation or local consumer aid fund or  
2 revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted  
3 by state law, at the sole discretion of each Signatory Attorney General.

4 35.

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

14 Upon receipt of written notice, Pfizer shall provide a good-faith written response to the  
15 Attorney General notification, containing either a statement explaining why Pfizer believes it is  
16 in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred  
17 and a statement explaining how Pfizer intends to cure the alleged breach. Nothing in this  
18 paragraph shall be interpreted to limit the state's Civil Investigative Demand ("CID") or  
19 subpoena authority, to the extent such authority exists under applicable state law, and Pfizer  
20 reserves all of its rights with respect to a CID or subpoena issued pursuant to such authority.

21 36.

22 Upon giving Pfizer thirty (30) days to respond to the notification described above, the  
23 Signatory Attorney General shall also be permitted reasonable access to inspect and copy  
24 relevant, non-privileged, non-work product records and documents in the possession, custody or  
25 control of Pfizer that relate to Pfizer's compliance with each provision of this Judgment as to  
26 which cause that is legally sufficient in the State has been shown. If the Signatory Attorney

1 General makes or requests copies of any documents during the course of that inspection, the  
2 Signatory Attorney General will provide a list of those documents to Pfizer.

3 37.

4 The State may assert any claim that Pfizer has violated this Judgment in a separate civil  
5 action solely to enforce compliance with this Judgment, or to seek any other relief afforded by  
6 law, but only after providing Pfizer an opportunity to respond to the notification described in  
7 Paragraph 35 above; provided, however, that a Signatory Attorney General may take any action  
8 if the Signatory Attorney General concludes that, because of the specific practice, a threat to the  
9 health or safety of the public requires immediate action.

10 38.

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

15

16 *IT IS SO STIPULATED:*

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24

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26

1 Accepted this 17<sup>th</sup> day of October, 2008.

2  
3 FOR PFIZER INC

4 

5 \_\_\_\_\_  
6 Michael J. Sandmire, OSB No. 904410  
7 Ater Wynne LLP  
8 222 S.W. Columbia, Suite 1800  
9 Portland, OR 97201  
10 Phone: (503) 226-1191  
11 Email: mjs@aterwynne.com

12 Attorney for Pfizer Inc

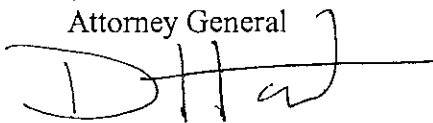
13 

14 Markus Green  
15 Corporate Counsel  
16 Pfizer Inc

17 **ACCEPTANCE OF DOJ**

18 Accepted this 21<sup>st</sup> day of October, 2008.

19 HARDY MYERS  
20 Attorney General

21 

22 David Hart #00275  
23 Senior Assistant Attorney General  
24 1162 Court Street, N.E.  
25 Salem, OR. 97301-4096  
26 Phone: (503) 934-4400  
Fax: (503) 378-5017  
Email: [david.hart@state.or.us](mailto:david.hart@state.or.us)

1 This STIPULATED GENERAL JUDGMENT is hereby accepted for entry of  
JUDGMENT for all purposes as set forth herein.

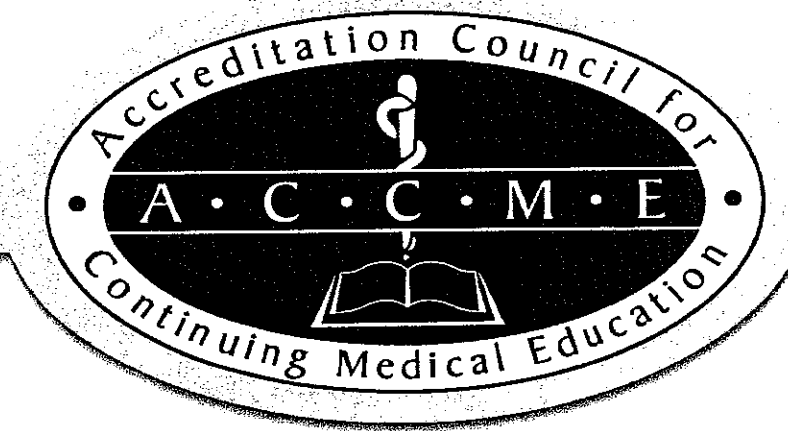
2 **IT IS SO ADJUDGED AND ORDERED:**

3 DATED this 22 day of October, 2008.

4   
5 \_\_\_\_\_  
CIRCUIT COURT JUDGE for Marion County

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## **APPENDIX 1**



# **ACCME STANDARDS FOR COMMERCIAL SUPPORT<sup>SM</sup>**

*Standards to Ensure the  
Independence of CME  
Activities*

# The ACCME Standards for Commercial Support<sup>SM</sup>

## 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](http://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. ¶

**APPENDIX 2**



---

**Guidance for Industry:**  
**Good Reprint Practices for the Distribution of Medical  
Journal Articles and Medical or Scientific Reference  
Publications on Unapproved New Uses of Approved Drugs  
and Approved or Cleared Medical Devices**

**DRAFT GUIDANCE**

**This guidance document is being distributed for comment purposes only**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For single copies of this draft guidance, please contact: Office of Policy, Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, HF-11, Rockville, MD 20857, (301) 827-3360.

For questions regarding this draft document, contact Jarilyn Dupont, Office of Policy, Food and Drug Administration, (301) 827-3360.

U.S. Department of Health and Human Services  
Food and Drug Administration

February 2008

**Contains Nonbinding Recommendations**  
*Draft – Not for Implementation*

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**Table of Contents**

I. Introduction

II. Background

III. Purpose

IV. Agency Recommendations for Good Reprint Practices

- A. Types of Reprints/Articles/Reference Publications
- B. Manner in which to Disseminate Scientific and Medical Information

V. Summary

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**Contains Nonbinding Recommendations**  
*Draft – Not for Implementation*

**Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles  
and Medical or Scientific Reference Publications on Unapproved New Uses of Approved  
Drugs and Approved or Cleared Medical Devices**

*This draft guidance document represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the appropriate FDA staff.*

## I. Introduction

This draft guidance is intended to describe the Food and Drug Administration's (FDA or Agency) current thinking regarding "Good Reprint Practices" with regard to the distribution of medical journal articles and scientific or medical reference publications (referred to generally as medical and scientific information) that discuss unapproved new uses for approved drugs<sup>1</sup> or approved or cleared medical devices marketed in the United States to healthcare professionals and healthcare entities.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

## II. Background

Section 401 of the Food and Drug Administration Modernization Act (FDAMA (21 U.S.C. § 360aaa, § 551, Federal Food, Drug, and Cosmetic Act (FD&C Act))), described certain conditions under which a drug or medical device manufacturer<sup>2</sup> could choose to disseminate medical and scientific information discussing unapproved uses of approved drugs and cleared or approved medical devices to healthcare professionals and certain entities (including pharmacy benefits managers, health insurance issuers, group health plans, and Federal or State governmental agencies). FDAMA section 401 provided that, if these conditions were met, dissemination of such journal articles or reference publications would not be considered as evidence of the manufacturer's intent that the product be used for an unapproved new use. FDA implementing regulations were codified at 21 C.F.R. Part 99.

In 2000, subsequent to a decision by the United States Court of Appeals for the District of Columbia Circuit, FDA published a Notice (65 Fed. Reg. 14286, March 16, 2000) clarifying the applicability of the FDAMA section 401 provision and the FDA implementing regulations. In that Notice, FDA stated that the statute and implementing regulations constituted a "safe harbor" for a manufacturer that complies with them before and while disseminating journal articles and reference publications about "new uses" of approved or cleared products. If a manufacturer complied with the FDAMA provision, the distribution of such journal articles or reference publications would not be used as evidence of an intent that the product distributed by the manufacturer be used for an unapproved use. The Notice stated that if a manufacturer chose to disseminate materials but not proceed under FDAMA section 401, that failure would not constitute an independent violation of law.

FDAMA section 401 ceased to be effective on September 30, 2006, and the implementing regulations are no longer applicable. In light of the statute's sunset, FDA is providing its current views on the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities.

## III. Purpose

As explained in FDA's March 16, 2000 Notice, the FD&C Act and FDA's implementing regulations generally prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not approved as safe and effective or cleared through a substantial equivalence determination. (E.g., FD&C Act §§ 505(a), 502(o), 501(f)(1)(B), 301(a) and (d); 21 U.S.C. §§ 355, 352(o), 351(f)(1)(B), 331(a) and (d)). An approved new drug that is marketed for an unapproved use becomes misbranded and an unapproved new drug with respect to that use. Similarly, a medical device that is promoted for a use that has not been approved or cleared by FDA is adulterated and misbranded.

FDA does, however, recognize the important public policy reasons for allowing manufacturers to disseminate truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities. Once a drug or medical device has been approved or cleared by FDA, generally healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses). These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals' receipt of medical journal articles and medical or scientific reference publications on unapproved or new uses of approved or cleared medical products that are truthful and not misleading.

FDA's legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved "new use," or whether such activities cause a product to be misbranded or adulterated has not changed. In recognition of the public health value to healthcare professionals of receiving truthful and non-misleading scientific and medical information, FDA is providing recommendations concerning "Good Reprint Practices" for the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of drugs and medical devices.<sup>3</sup>

#### **IV. Agency Recommendations for Good Reprint Practices**

Scientific and medical information that concerns the safety or effectiveness of an approved drug or approved or cleared medical device for a new use that is not included in the product's approved labeling or statement of intended uses (including unapproved or new uses of approved drugs and approved or cleared devices) is often published in journal articles or reference publications. These publications are often distributed by manufacturers to healthcare professionals or healthcare entities. When a manufacturer disseminates such medical and scientific information, FDA recommends that the following principles of "Good Reprint Practices" be followed.

##### **A. Types of Reprints/Articles/Reference Publications**

A scientific or medical journal article that is distributed should:

- be published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles, and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;
- be peer-reviewed and published in accordance with the peer-review procedures of the organization; and
- not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.

A scientific or medical reference publication that is distributed should not be:

- primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels where medical textbooks are sold;
- written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or
- edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

The information contained in the above scientific or medical journal article or reference publications should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug or device<sup>4</sup>. The information must not:

- be false or misleading, such as a journal article or reference text that is inconsistent with the weight of credible evidence derived from adequate and well-controlled clinical investigations (e.g., where a significant number of other studies contradict the article or reference text's conclusions), that has been withdrawn by the journal or disclaimed by the author, or that discusses a clinical investigation where FDA has previously informed the company that the clinical investigation is not adequate and well-controlled; or
- pose a significant risk to the public health.

The following publications are examples of publications that would not be considered consistent with the Good Reprint Practices outlined in this draft guidance:

- letters to the editor;
- abstracts of a publication;
- reports of Phase 1 trials in healthy subjects; or
- reference publications that contain little or no substantive discussion of the relevant investigation or data.

##### **B. Manner in which to Disseminate Scientific and Medical Information**

Scientific or medical information that is distributed should:

- be in the form of an unabridged reprint, copy of an article, or reference publication;
- not be marked, highlighted, summarized, or characterized by the manufacturer in any way;
- be accompanied by the approved labeling for the drug or medical device;
- be accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography);
- in cases where the conclusions of article or text to be disseminated have been specifically called into question by another article(s) or text(s), be disseminated with a representative publication that reaches contrary or different conclusions regarding the unapproved use; and

- be distributed separately from information that is promotional in nature. For example, if a sales representative delivers a reprint to a physician in his office, the reprint should not be physically attached to any promotional material the sales representative uses or delivers during the office visit and should not be the subject of discussion between the sales representative and the physician during the sales visit.<sup>5</sup> Similarly, while reprints may be distributed at medical or scientific conferences in settings appropriate for scientific exchange, reprints should not be distributed in promotional exhibit halls or during promotional speakers' programs.

The journal reprint or reference publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses described in the information have not been approved or cleared by FDA, as applicable to the described drug or medical device;
- the manufacturer's interest in the drug or medical device that is the subject of the journal reprint or reference text;
- any author known to the manufacturer as having a financial interest in the product or manufacturer or receiving compensation from the manufacturer, if applicable;
- any person known to the manufacturer who has provided funding for the study, if applicable; and
- any significant risks or safety concerns known to the manufacturer concerning the unapproved use that are not discussed in the journal article or reference text.

## V. Summary

FDA recognizes that the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products. Accordingly, if a manufacturer follows the recommendations described in Section IV of this draft guidance and there is no unlawful promotion of the product, FDA does not intend to use the distribution of such medical and scientific information as evidence of an intent by the manufacturer that the product be used for an unapproved use.<sup>6</sup>

### Footnotes

<sup>1</sup> As used in this draft guidance, the term "drug" includes biological products licensed under Section 351(a) of the Public Health Service Act. See 42 U.S.C. § 262(j).

<sup>2</sup> As used in this draft guidance, the term "manufacturer" means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. The term may also include the sponsor of the approved, licensed, or cleared drug or device.

<sup>3</sup> This draft guidance does not apply to scientific or medical information distributed in response to unsolicited requests for scientific or medical information from health care professionals. See 59 Fed. Reg. 59820, 59823 (November 18, 1994).

<sup>4</sup> In the case of medical devices, journal articles or reference publications discussing significant non-clinical research may be consistent with this draft guidance.

<sup>5</sup> To the extent that the recipients of such information have questions, the Agency recommends that the sales representative refer such questions to a medical/scientific officer or department, and that the officer or department to which the referral is made be separate from the sales and/or marketing departments.

<sup>6</sup> Given the sunset of FDAMA § 401, the other elements that comprised § 401 which are not specifically described in this draft guidance are no longer applicable.

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### For More Information

Press Release (February 15, 2008)  
*Federal Register* (Docket No. FDA-2008-D-0053, OC 2007268)

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STATE OF OREGON  
Marion County Circuit Courts  
OCT 22 2008  
**FILED**

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4 IN THE CIRCUIT COURT OF THE STATE OF OREGON  
5 FOR THE COUNTY OF MARION

6 STATE OF OREGON ex rel HARDY  
7 MYERS, Attorney General for the STATE OF  
8 OREGON,

9 Plaintiff,

10 v.

11 PFIZER, INC.

12 Defendant.

Case No. 08C23533

COMPLAINT ALLEGING VIOLATIONS OF  
THE UNLAWFUL TRADE PRACTICES ACT  
(ORS 646.605 TO 646.656)

CLAIM NOT SUBJECT TO MANDATORY  
ARBITRATION

13 This Complaint alleges claims for relief based upon violation of Oregon's Unlawful  
14 Trade Practices Act (UTPA), ORS 646.605 to 646.656. Plaintiff, State of Oregon for its  
15 Complaint alleges that at all times material herein:

16 ALLEGATIONS COMMON TO ALL COUNTS

17 1.

18 HARDY MYERS is the Attorney General for the State of Oregon and is suing in his  
19 official capacity pursuant to ORS 646.632.

20 2.

21 Defendant Pfizer, a Delaware corporation with its principle place of business in New  
22 York, is one of the world's largest pharmaceutical companies. At all relevant times, Pfizer did  
23 business in Oregon selling and promoting prescription drugs, including Bextra® and Celebrex®.

24 3.

25 Pharmacia Corp was a Delaware corporation with its principal place of business in New  
26 Jersey. In 2002, Pfizer purchased Pharmacia and merged the two companies Bextra and Celebrex

1 sales forces. Prior to this sale, the two companies co-marketed Bextra and Celebrex and closely  
2 coordinated all promotional efforts. Pfizer is now responsible for all of Pharmacia's conduct  
3 relating to the promotion of Celebrex and Bextra. Defendant Pfizer and Pharmacia shall  
4 hereinafter be referred to collectively as DEFENDANT.

5 4.

6 The Circuit Court for the State of Oregon has personal jurisdiction over DEFENDANT  
7 pursuant to ORCP 4A. DEFENDANT has engaged in substantial activities within the State by  
8 operating a business that provides services that are primarily for personal, family, and household  
9 use. All transactions took place in the course of DEFENDANT'S business.

10 5.

11 DEFENDANT was given the Notice required by ORS 646.632(2).

12 6.

13 The DEFENDANT'S conduct described in this Complaint was willful within the  
14 meaning of ORS 646.605(10).

15 SUMMARY OF THE ACTION

16 7.

17 DEFENDANT engaged in repeated unfair and deceptive acts, methods and practices with  
18 the purpose of achieving greater sales of Bextra than they otherwise would have been able to  
19 achieve had they complied with the law. DEFENDANT achieved these sales in large part by  
20 misleading physicians and health professionals, consumers and others about the safety and  
21 efficacy of Bextra, and about the indications for which Bextra was approved as a new drug.  
22

23 8.

24 DEFENDANT'S unlawful marketing of Bextra began in 2001 after the U.S. Food and  
25 Drug Administration ("FDA") declined to approve Bextra for all of the uses and indications that  
26 DEFENDANT was counting on to make Bextra a financial "blockbuster." Rather than simply

1 marketing Bextra for the more limited FDA-approved indications, DEFENDANT engaged in an  
2 aggressive, deceptive, and unlawful "off label" marketing campaign to increase sales of Bextra, a  
3 COX-2 inhibitor, to treat acute pain, perioperative pain and to reduce use of narcotics ("opioid  
4 sparing"). These indications or uses for Bextra are referred to as "off-label" uses because they  
5 have not been approved by the FDA. Bextra's FDA-approved "on-label" use is limited to 10  
6 milligram doses for the treatment of pain associated with rheumatoid arthritis and osteo-arthritis  
7 and 20 milligram doses for pain associated with primary dysmenorrhea (menstrual pain).  
8

9 9.

10 As a part of its "off-label" campaign, DEFENDANT misrepresented that Bextra was a  
11 safe alternative to schedule 2 narcotics and traditional nonsteroidal anti-inflammatories  
12 ("NSAIDs") typically used in the treatment of acute and perioperative pain, marketed Bextra as  
13 reducing serious gastrointestinal side effects without possessing competent and reliable evidence  
14 to support this claim, and failed to disclose that Bextra increased the risk of serious adverse  
15 events including death.  
16

17 10.

18 DEFENDANT also commissioned and disseminated hundreds of thousands of copies of  
19 positive studies relating to off-label uses of Bextra without also providing negative studies;  
20 distributed hundreds of thousands of 20 milligram doses of Bextra to medical professionals such  
21 as orthopedic surgeons who do not generally prescribe for menstrual pain with the intent that the  
22 sample would be used off label; co-opted influential doctors to encourage off-labeling  
23 prescribing; provided meals and gifts to doctors who prescribed Bextra off-label; promoted  
24 Continuing Medical Education ("CME") classes that encouraged off-label uses; rewarded high  
25 off-label prescribers with paid "mentorships" and consultancies; disseminated print  
26

1 advertisements with text and imagery that communicated Bextra's supposed efficacy against  
2 acute pain; and encouraged sales representatives to promote off-label uses in their sales calls.  
3 Instead of marketing Bextra safely and responsibly for the benefit of patients, DEFENDANT  
4 promoted Bextra unsafely and irresponsibly, driven by their narrow desire to maximize profits.

5  
6 STATEMENT OF FACTS

7 **Cox-2 Painkillers Were Developed in a Lucrative Market.**

8 11.

9 NSAIDs such as naproxen (Aleve) and ibuprofen (Advil) have been widely prescribed for  
10 many years to treat the symptoms of arthritis as well as chronic and acute pain from other causes.  
11 NSAIDs are highly effective against pain and inflammation; however, they can cause  
12 gastrointestinal ("GI") side effects, including serious adverse events such as obstructions, bleeds,  
13 and perforations. These drugs are also sold over-the-counter ("OTC") at dosages lower than  
14 prescription strength. For the most part, NSAIDs are available generically and are thus  
15 significantly cheaper than branded COX-2 drugs.

16  
17 12.

18 NSAIDs work against pain and inflammation by inhibiting enzymes known as  
19 cyclo-oxygenase or COX. There are two forms of COX enzymes: COX-1 and COX-2. COX-1  
20 is involved in the maintenance and repair of the GI system.

21 13.

22 Selective COX-2 inhibitors ("COX-2 drugs") are drugs that block COX-2 without  
23 affecting COX-1. This class of drugs was developed in the 1990s in hope of reducing pain and  
24 inflammation without blocking COX-1's beneficial effect on the GI system; however, the  
25 scientific studies of COX-2 drugs have been inconclusive regarding gastrointestinal safety.  
26

14.

1  
2 The scientific rationale and justification for COX-2 drugs was safety, not efficacy. No  
3 scientifically valid clinical trial has ever found COX-2 drugs to be more effective for treatment  
4 of pain and inflammation than traditional NSAIDs.

15.

5  
6 There are significant concerns that COX-2 drugs as a class may increase the risk of  
7 cardiovascular ("CV") adverse events such as stroke and heart attacks.  
8

16.

9  
10 In total, three COX-2 drugs have been approved for sale in the United States: Celebrex  
11 (celecoxib), Vioxx (rofecoxib), and Bextra (valdecoxib). DEFENDANT began marketing  
12 Celebrex in early 1999 and Merck followed several months later with Vioxx. In early 2002,  
13 DEFENDANT began marketing Bextra. Ultimately, Vioxx was withdrawn from the market in  
14 2004; Bextra was withdrawn in 2005, and that same year, Celebrex was given a "black box"  
15 warning on its label.  
16

17.

17  
18 DEFENDANT competed vigorously with Merck for the rapidly expanding COX-2  
19 market. DEFENDANT analogized this competition to warfare; sales representatives were paid  
20 bonuses to get doctors to switch patients from Vioxx to Celebrex or Bextra.  
21

18.

22  
23 Celebrex was disadvantaged in its competition with Vioxx because unlike Vioxx,  
24 Celebrex was not initially approved for the treatment of acute pain. Although eventually  
25 Celebrex was approved for this indication, the late approval impaired Celebrex's ability to  
26

1 compete in the acute pain market and many doctors considered Celebrex less effective against  
2 acute pain.

3 **Defendant Developed Bextra to Be a "Blockbuster" Painkiller but Studies Revealed**  
4 **Safety Concerns.**

5 19.

6 DEFENDANT planned to "create the next [COX-2] blockbuster" by marketing Bextra as  
7 a "powerful agent" for both acute and chronic pain with strength equal to that of a schedule 2  
8 narcotic. Bextra's initial product profile identified acute pain, opioid sparing, and preemptive  
9 analgesia associated with the treatment of surgical pain as Bextra's distinguishing qualities. By  
10 focusing on these qualities, DEFENDANT sought to supplement Celebrex's perceived  
11 weaknesses against acute pain with Bextra's strength and prevent Bextra from cannibalizing  
12 Celebrex sales. Bextra would primarily target young active patients with acute pain while  
13 Celebrex would primarily target older patients with chronic pain (e.g. – pain associated with  
14 arthritis). Bextra would compete directly against Vioxx in the acute pain market while Celebrex  
15 would compete primarily against traditional NSAIDs including OTC drugs, for chronic pain.  
16

17 20.

18 On November 27, 2001, the FDA approved the 10mg dose Bextra for the treatment of  
19 pain associated with rheumatoid arthritis and osteo-arthritis and the 20 milligram dose for pain  
20 associated with primary dysmenorrhea, but expressly rejected Bextra's use at any dose for acute  
21 and perioperative pain and opioid sparing indications. The FDA rejected Bextra for those uses  
22 primarily because the Coronary Artery Bypass Graft Study 035 ("CABG I") demonstrated an  
23 excess of serious adverse events including death in association with Bextra and Bextra's pro-  
24 drug, paracoxib.  
25

26 ///

21.

1  
2 CABG I was a randomized, double-blind comparison of two groups of patients who  
3 underwent coronary artery bypass graft surgery. One group in the study received Bextra and  
4 paracoxib, along with narcotics, to treat perioperative pain. The other group only received  
5 narcotics (also known as the "standard of care"). DEFENDANT'S goal for CABG I was to  
6 demonstrate that Bextra was safe and effective to treat surgical pain and reduce the incidence of  
7 narcotic related adverse events such as nausea, constipation, and somnambulence. The results of  
8 the CABG I study, however, showed that although patients given Bextra used fewer narcotics,  
9 there was no reduction in narcotic related side effects. Further, patients given Bextra suffered  
10 twice as many Serious Adverse Events ("SAEs") compared to patients who did not receive  
11 Bextra.  
12

22.

13  
14 To minimize the safety concerns raised by CABG I, DEFENDANT compared Bextra's  
15 SAE rate with observational reports outside the study and claimed that Bextra's SAE rate was  
16 within normal limits. This substitution of an after the fact control group data is scientifically  
17 dishonest and contrary to generally accepted scientific methods. DEFENDANT attempted to  
18 further minimize the negative results of CABG I by claiming there was a "failure of  
19 randomization" that caused weaker patients to be placed in the Bextra test group.  
20

23.

21  
22 In an attempt to frame the negative CABG I results as a fluke, on or about January 28,  
23 2003, DEFENDANT began a second clinical trial relating to Bextra and CABG surgery. The  
24 "CABG II" study compared three similarly sized groups: patients who received narcotics;  
25  
26

1 patients who received narcotics plus Bextra; and patients who received narcotics, Bextra, and  
2 paracoxib.

3 24.

4 DEFENDANT enrolled patients into their CABG II study without disclosing to them that  
5 their counterparts in CABG I experienced a doubling of SAEs. Rather, the increased SAE rate  
6 was minimized and potential subjects were told that side effects in CABG I were within the  
7 expected number of side effects typically seen in CABG surgeries.  
8

9 25.

10 CABG II confirmed the risk of high dose Bextra for post-operative pain relief: patients  
11 who received Bextra experienced significantly more heart attacks and other cardiovascular  
12 problems compared to patients who did not receive Bextra.’

13 26.

14 CABG II combined with CABG I raised significant concerns about the safety of Bextra  
15 for all patients, even at low doses. Nonetheless, DEFENDANT continued to promote high dose  
16 Bextra for acute pain and peri-operative uses.  
17

18 27.

19 In November 2004, the FDA required DEFENDANT to disclose the negative SAE data  
20 results of both CABG studies in a revised package insert for Bextra.  
21

22 28.

23 Despite clear evidence of CV risks associated with high dosing of Bextra, DEFENDANT  
24 proceeded with their original marketing plan to market Bextra for the now FDA-disapproved  
25 indications of acute, perioperative pain and opioid sparing indications.  
26



1 proof that Bextra could be used for perioperative pain without causing increased bleeding after  
2 surgery.

3 32.

4 DEFENDANT also distributed hundreds of thousands of copies of an article entitled  
5 "The analgesic efficacy of valdecoxib vs. oxycodone/acetaminophen after oral surgery, by  
6 Stephen E. Daniels, D.O., which was published in the Journal of the American Dental  
7 Association (JADA) in 2002. DEFENDANT commissioned the Daniels study as part of a  
8 strategy to create and disseminate medical studies that supported prescribing Bextra for  
9 perioperative pain and opioid sparing. The Daniels study was not conducted by a mainstream  
10 academic organization; rather DEFENDANT hired SCIREX, a contract research organization  
11 owned by a large advertising company. The Daniels study was deceptively designed to produce  
12 misleading study results because it compared Bextra to a single dose of a medicine that is usually  
13 given in multiple doses. Although Daniels was published by Journal of the American Dental  
14 Association ("JADA"), one of the journal's editors later explained that they were not told that  
15 Bextra was disapproved for the treatment of acute pain. Had JADA's editors known the truth,  
16 Daniels would not have been published.  
17  
18

19 33.

20 DEFENDANT widely disseminated the Camu, Leese, and Daniels studies to its sales  
21 representatives, urged them to distribute the articles on their sales calls, and provided them with  
22 discussion notes that enabled sales representatives to discuss these off-label studies during their  
23 sales calls. Although the materials DEFENDANT produced for sales representatives often  
24 contained a "do not detail" advisement cautioning against any discussion of the studies during  
25 sales calls, the warning was illusory and widely ignored.  
26

34.

1  
2 DEFENDANT also attempted to hire influential medical professionals to present the  
3 results of these studies in order to give a false appearance of reliability to DEFENDANT'S self-  
4 generated study results.

5  
6 35.

7 In 2003, the Journal of Thoracic and Cardiac Surgery published CABG I as an article  
8 entitled "Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in  
9 Patients Undergoing Coronary Artery Bypass Surgery" by Elisabeth Ott, M.D. This article  
10 raised important concerns about the safety of high dose Bextra for treatment of acute and  
11 perioperative pain and for opioid sparing uses and suggested the need for a comprehensive  
12 evaluation of a large-scale trial before using Bextra to treat vulnerable patients. DEFENDANT  
13 promoted Bextra for acute and perioperative pain and opioid sparing yet failed to disseminate  
14 this article to the medical community and did not allow distribution of the study by  
15 DEFENDANT'S sales representatives.  
16

17 36.

18 DEFENDANT also promoted off-label uses of Bextra in medical inquiry response letters.  
19 FDA regulations permit drug manufacturers to provide off-label information in response to an  
20 unsolicited inquiry from a medical professional so long as the responsive material contains  
21 balanced information and is not promotional. Similar to their strategy of distributing only  
22 favorable off-label medical articles, DEFENDANT disclosed only favorable data about acute and  
23 perioperative pain and opioid sparing indications in their responses to medical inquiries and  
24 omitted negative CABG I results and the FDA denials.  
25  
26

1 **Defendant Improperly Distributed Free Samples of Bextra with the Intent to Have Samples**  
2 **Used for Off-label Indications.**

3  
4 37.

5 DEFENDANT promoted off-label use of Bextra to treat acute and perioperative pain and  
6 opioid sparing by giving hundreds of thousands of 20 milligram Bextra starter samples to  
7 surgeons, anesthesiologists and other surgical and pain specialists who do not customarily treat  
8 severe menstrual cramps but who do treat acute and peri-operative pain. DEFENDANT intended  
9 for medical specialists to use the 20 milligram samples to treat acute and perioperative pain and  
10 for opioid sparing but failed to disclose the negative results from the CABG I and CABG II  
11 studies and failed to disclose that FDA had rejected these indications due to concerns about their  
12 safety.

13 **Defendant Employed an Enormous Sales Staff to Market Bextra for Off-Label Uses.**

14 38.

15 DEFENDANT relied heavily on their enormous sales staff to market Bextra for off-label  
16 and FDA-denied indications. DEFENDANT produced deceptive sales messages that promoted  
17 Bextra for acute and perioperative pain and opioid sparing and trained sales representatives to  
18 effectively use this messaging to increase off-label sales. Sales representatives promoted  
19 Bextra's off-label indications to health care providers and were encouraged to detail health care  
20 providers extensively about these FDA-denied indications.  
21

22 39.

23 Sales managers carefully tracked sales representatives' success in conveying  
24 DEFENDANT'S messages by monitoring electronic call notes submitted by sales representatives  
25 and accompanying them on sales calls. DEFENDANT also knew sales representatives were  
26

1 detailing Bextra for acute and perioperative pain based on surveys conducted by consultants  
2 hired by DEFENDANT to track and monitor prescribing information.

3 40.

4 DEFENDANT sought to increase Bextra sales for acute and perioperative pain and  
5 opioid sparing by aggressively targeting surgeons, surgery centers, and hospitals to get Bextra  
6 placed on "standing orders" and "protocols" for these indications. Surgery centers and hospitals  
7 rely on standing orders and protocols for analgesic dosing regimes associated with perioperative  
8 pain. DEFENDANT'S success in placing Bextra on surgical standing orders directly increased  
9 Bextra sales, served as a powerful tool for promoting Bextra to other doctors and hospitals, and  
10 increased the likelihood that surgical patients would remain on Bextra to treat chronic pain  
11 conditions after surgery.  
12

13 41.

14 DEFENDANT also obtained examples of surgical protocols and standing orders that  
15 included analgesic dosing regimes for Bextra and disseminated these samples to sales  
16 representatives. DEFENDANT held contests and rewarded sales representatives with  
17 recognition, accolades, and cash equivalent prizes for obtaining high volume standing order  
18 sales.  
19

20 **Defendant Engaged in Off-Label Advertising to Consumers and Providers Using the**  
21 **Pretense of Education.**

22 42.

23 Physician education programs were another integral part of DEFENDANT'S scheme to  
24 promote Bextra for acute and perioperative pain and opioid sparing indications. DEFENDANT  
25 hired surgeons, anesthesiologists, and other pain specialists to conduct physician education  
26 programs ranging from informal luncheon presentations to Continuing Medical Education

1 programs. DEFENDANT knew off-label topics would be discussed at these programs and  
2 provided speakers with presentation slides containing favorable off-label data and information  
3 about Bextra.

4 43.

5 DEFENDANT'S market research indicated that more patients suffered from non-arthritis  
6 pain than arthritis pain. To reach beyond the arthritis pain market, DEFENDANT developed and  
7 widely used marketing materials that promoted Bextra to treat acute pain caused by sprains,  
8 strains, tendonitis, and bursitis. To avoid the appearance of off-label marketing, however,  
9 DEFENDANT'S sales messages used euphemisms for acute pain such as "tough pain," "flare  
10 pain," "acute pain condition," and "episodic pain" and visual imagery that evoked strong and  
11 powerful pain relief.  
12

13 44.

14 DEFENDANT also used patient-type marketing to enhance its acute pain message for  
15 Bextra. Throughout its marketing campaign, DEFENDANT consistently targeted the young  
16 active "weekend warrior" patient with tough episodic pain for Bextra. In contrast, and to  
17 distinguish the target market for Celebrex, DEFENDANT promoted Celebrex for the older  
18 patient suffering from chronic pain.  
19

20 45.

21 DEFENDANT'S marketing surveys, focus groups, and feedback from its field sales force  
22 confirmed that doctors consistently perceived Bextra's strong powerful pain relief messaging as  
23 targeting the acute pain market.  
24

25 ///

26 ///

46.

1  
2 DEFENDANT also promoted its “weekend warrior” imagery in its direct-to-consumer  
3 advertising. DEFENDANT distributed hundreds of thousands of copies of a self-published  
4 periodical called Perform Magazine that contained multiple images and messages promoting  
5 Bextra's strong powerful pain relief. Perform Magazine was sent to subscribers of People  
6 magazine and widely distributed in patient waiting rooms.

7  
8 47.

9 DEFENDANT invited surgeons and other pain specialists who were likely to prescribe  
10 Bextra off-label to so-called “consultant” meetings. Although DEFENDANT claimed these  
11 meetings were not promotional, they conducted return on investment analysis on some attendees  
12 to determine whether there was a sufficient increase in prescriptions to financially justify the  
13 costs of the meetings.

14 **Defendant Gave Improper Inducements, Payments, and Gifts to Physicians.**

15  
16 48.

17 To illegally promote Bextra off-label from within the medical community,  
18 DEFENDANT hired surgeons, anesthesiologists, and other specialties to conduct Bextra off-  
19 label dinner talks and round tables. DEFENDANT sought out and developed physician speakers  
20 who were high prescribers of Bextra and supported its off-label use – these health care providers  
21 were then paid to give lunch or dinner talks relating to off-label use of Bextra.

22  
23 49.

24 DEFENDANT maintained a stable of recommended and paid physician-speakers that  
25 sales staff could use for off-label Bextra dinner talks. Sales staff often worked with physicians  
26 on their presentations, and encouraged health care providers to talk about off-label uses, even

1 though this practice is prohibited. Talks were conducted at expensive top flight restaurants.  
2 DEFENDANT conducted analyses on physicians to confirm that their prescribing behavior  
3 increased after speaking or after attending dinner programs.

4 50.

5 DEFENDANT rewarded doctors who were high off-label prescribers of Bextra with  
6 "mentorships" in which the doctor was paid up to \$500 to allow Bextra sales representatives to  
7 follow him or her around on clinical rounds and attend surgeries.  
8

9 51.

10 DEFENDANT used mentorships to gain access to doctors who otherwise would not  
11 allow sales representatives to visit their office. During the mentorship, the sales representatives  
12 were encouraged to discuss using Bextra to treat acute and perioperative pain.  
13

14 52.

15 DEFENDANT also cultivated off-label Bextra prescribers by rewarding certain  
16 prescribers with clinical research grants and contracts.  
17

18 53.

19 In addition to gifts to prescribers, DEFENDANT provided grants to certain medical  
20 centers and hospitals and leveraged the resultant "goodwill" to promote off-label use of Bextra.

21 **To Enhance Their Unlawful Marketing Campaign, Defendant Concealed and**  
22 **Misrepresented Bextra's Safety and Risks.**

23 54.

24 As DEFENDANT marketed Bextra to more health care providers, for more patients, and  
25 for a wider assortment of illnesses and pain types, DEFENDANT consistently avoided,  
26 minimized, and failed to disclose material health and safety risks. DEFENDANT deceptively  
27 marketed Bextra as the most powerful non-narcotic medication without clinically reliable

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1 evidence for such a claim, while omitting important information that showed Bextra was no  
2 better and potentially more dangerous than traditional NSAIDs in treating pain.

3 55.

4 DEFENDANT'S decision to minimize or fail to disclose the results from CABG I, the  
5 study which was the basis for the FDA's denial of Bextra for acute pain prevented doctors from  
6 fully educating themselves about Bextra and created a dangerous situation where health care  
7 providers were prescribing a drug without knowing all of the dangers.

8 56.

9  
10 DEFENDANT also deceptively promoted Bextra's gastrointestinal safety in brochures  
11 mailed directly to consumers. Although Bextra's FDA approval label cautioned that Bextra  
12 could cause serious and life-threatening gastrointestinal side effects, including bleeding in the  
13 stomach and intestines, DEFENDANT'S direct to consumer brochures misrepresented that, for  
14 patients who take Bextra, the "stomach stays protected." DEFENDANT ran a similarly  
15 deceptive advertisement in Perform magazine.

16 57.

17  
18 DEFENDANT'S sales staff told health care providers that Bextra was safe and effective,  
19 without affirmatively explaining side effects or adverse events. DEFENDANT'S sales  
20 executives specifically told sales staff not to initiate discussion of Bextra safety.

21 58.

22  
23 DEFENDANT also attempted to confuse health care providers to believe positive  
24 Celebrex data also applied to Bextra. DEFENDANT promoted both Bextra and Celebrex at the  
25 same time and their marketing materials and representations intentionally conflated research data

1 so that Celebrex studies were used to explain the safety and efficacy of Bextra, even though  
2 Celebrex was a different drug and approved for different indications.

3 **Defendant's Unlawful Marketing Scheme Had a Powerful Effect.**

4 59.

5 DEFENDANT'S promotional scheme for Bextra was highly successful. Total Bextra  
6 sales approached four billion dollars, most of which were for acute and perioperative pain and  
7 opioid sparing indications and not for the 10 milligram dose treatment of pain associated with  
8 rheumatoid arthritis and osteo-arthritis and the 20 milligram dose treatment for pain associated  
9 with primary dysmenorrhea.  
10

11 **CAUSE OF ACTION**

12 **UNLAWFUL TRADE PRACTICES**

13 **FIRST CLAIM FOR RELIEF**

14 **ORS 646.608(1)(e)**

15 **Count I**

16 60.

17  
18 Plaintiff, STATE, realleges and incorporates each and every allegation contained in the  
19 preceding paragraphs as if fully alleged herein.  
20

21 61.

22 DEFENDANT violated ORS 646.608(1)(e) by promoting Bextra off-label for acute pain,  
23 post surgery analgesia and opioid sparing without disclosing that FDA rejected DEFENDANT  
24 application to promote for these indications. Each time DEFENDANT promoted Bextra for acute  
25 pain, post surgery analgesia, and opioid sparing, without disclosing FDA rejected their  
26 application for these indications, was a separate and distinct violation of ORS 646.608 (1)(e).

1 **Count II**

2 62.

3 Plaintiff, STATE, realleges and incorporates each and every allegation contained in the  
4 preceding paragraphs 1 through 60 as if fully alleged herein.

5 63.

6 DEFENDANT violated ORS 646.608(1)(e) by misrepresenting the safety and efficacy of  
7 Bextra for treatment of acute pain, post surgery analgesia, and opioid sparing. Each time  
8 DEFENDANT misrepresented Bextra's safety or efficacy for these indications was a separate  
9 and distinct violation of ORS 646.608 (1)(e).

10 **Count III**

11 64.

12 Plaintiff, STATE, realleges and incorporates each and every allegation contained in the  
13 preceding paragraphs 1 through 60 as if fully alleged herein.

14 65.

15 DEFENDANT violated ORS 646.608(1)(e) by misrepresenting the gastrointestinal safety  
16 of Bextra. Each time DEFENDANT misrepresented the GI safety of Bextra was a separate and  
17 distinct violation of ORS 646.608(1)(e).

18 **Count IV**

19 66.

20 Plaintiff, STATE, realleges and incorporates each and every allegation contained in the  
21 preceding paragraphs 1 through 60 as if fully alleged herein.

22 67.

23 DEFENDANT violated ORS 646.608(1)(e) by conflating information about Bextra and  
24 Celebrex to mislead doctors to believe that positive information about one drug also applied to  
25 the other. Each time DEFENDANT conflated information about Celebrex and Bextra was a  
26 separate and distinct violation of ORS 646.608(1)(e).

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**Count V**

68.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 60 as if fully alleged herein.

69.

DEFENDANT violated ORS 646.608(1)(e) by misrepresenting Bextra’s cardiovascular safety. Each time DEFENDANT misrepresented Bextra’s CV safety was a separate and distinct violation of ORS 646.608(1)(e).

**SECOND CLAIM FOR RELIEF**

**ORS 646.607 (1)**

**Count VI**

70.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the paragraphs 1 through 60 as if fully alleged herein.

71.

DEFENDANT’S deceptive promotion of unsafe high dose Bextra for off-label indications, after FDA had expressly rejected these indications because of concerns about safety, was an unconscionable tactic within the meaning of ORS 646.607 (1). Each time DEFENDANT promoted high dose Bextra for acute pain, post-surgery analgesia/opioid sparing without disclosing FDA’s rejection of these indications or providing the data that was the basis for FDA’s rejection, was a separate and distinct violation of ORS 646.607 (1).

**PRAYER FOR RELIEF**

72.

WHEREFORE, Plaintiff respectfully request that a judgment be entered that:

- A. Permanently enjoins DEFENDANT from making any false, misleading or deceptive claim regarding any pharmaceutical product in advertising or promotion, including,

1 but not limited to, any false, misleading or deceptive claim regarding: the safety, effectiveness,  
2 benefits or risks of the product; any medical rationale for specifying the use or continued use of  
3 the product for a particular indication; the findings, existence or significance of any scientific  
4 study, whether published or not, concerning the product.

5 B. Directs DEFENDANT to comply with all applicable laws and regulations relating  
6 to the marketing, sale, and promotion of pharmaceutical products.

7 C. Directs DEFENDANT to pay civil penalties of \$25,000.00 for each and every  
8 willful violation of ORS 646.608(1) (e) and ORS 646.607 (1).

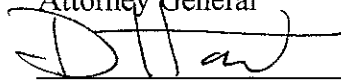
9 D. Awards Plaintiffs costs and attorneys fees, pursuant to ORS 646.632 (8);

10 E.. Grants all other relief as the Court deems appropriate.

11 Dated October 21, 2008.

12 Respectfully submitted,

13 HARDY MYERS  
14 Attorney General

15 

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22 Of Attorneys for Plaintiffs  
23  
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25  
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