UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA EX REL. [UNDER SEAL] Relators, v. [UNDER SEAL] Defendant	CA No. 05-CV-12115-RCL THIRD AMENDED COMPLAINT

FILED IN CAMERA AND UNDER SEAL

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA EX REL. JOHN KOPCHINSKI Relators, v. PFIZER, INC. and PHARMACIA CORP. Defendants	C.A. No. 05-CV-12115-RCL THIRD AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. §1201; GEORGIA FALSE MEDICAID CLAIMS ACT [Ga. Code Ann. §49-4-168 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [Ind. Code Ann. §5-11-5.5-1 et seq.]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. §175 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 §5 et seq]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp. Laws §400.601 et seq]; MONTANA FALSE CLAIMS ACT [Mont. Code Ann. §17-8-401 et seq.]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Rev. Stat. Ann. §167.61 et seq.]; NEW JERSEY FALSE CLAIMS ACT [N.J. Stat. §2A:32C-1 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. §27-2F-1 et seq.]; NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. §187 et seq.]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [Okla. Stat. tit. 63 §5053 et seq.]; RHODE ISLAND FALSE CLAIMS ACT [R.I. Gen. Laws §9-1.1 et seq.]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.];WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT [Wis. Stat. §20.931 et seq]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.13 et seq.]

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JURY TRIAL DEMANDED

Relator John Kopchinski, through his attorneys Phillips & Cohen LLP and Bartlett Hackett Feinberg P.C., on behalf of the United States of America, the States of California, Delaware, Georgia, Hawaii, Illinois, Indiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia (collectively "the States"), for his Complaint against defendants Pfizer, Inc. and Pharmacia Corporation allege based upon personal knowledge and relevant documents, as follows.

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America, the States and the District of Columbia arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendants Pfizer, Inc. ("Pfizer") and Pharmacia Corporation ("Pharmacia"), and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et seq., as amended ("the FCA" or "the Act").

2. As set forth below, Pfizer and Pharmacia's acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §5-11-5.5-1 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Michigan Medicaid

False Claims Act, Mich. Comp. Laws §400.601 et seq.; the Montana False Claims Act, Mont. Code Ann. §17-8-401 et seq; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167.61 et seq; the New Jersey False Claims Act, N.J. Stat. §2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-1 et seq.; the New York False Claims Act, N.Y. State Fin. §187 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053 et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; the Wisconsin False Claims Act for Medical Assistance, Wis. Stat. §20.931 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 et seq.

3. As alleged herein, Pfizer and Pharmacia caused thousands of false claims to be made on federal and state health care programs. Since at least late 2001, Pfizer and Pharmacia systematically and improperly promoted a prescription drug - Bextra - for unapproved, off-label uses. In addition, Pfizer gave substantial and illegal financial inducements to providers to encourage them to prescribe Bextra and/or to switch from competitor products. These false claims cheated the federal and state governments out of funds that should not have been paid, unlawfully enriched Pfizer and Pharmacia and subjected patients to non-approved, non-effective, and unsafe uses and dosages of Bextra.

4. Through their fraud, Pfizer and Pharmacia:

- knowingly disregarded federal Food and Drug Administration ("FDA") regulations concerning off-label promotion, and concealed such disregard from the

regulatory authorities;

- knowingly misrepresented to physicians the evidence regarding the safety and efficacy of off-label usage of Bextra;

- knowingly promoted off-label uses of Bextra and dosages that were neither effective nor safe, all for the purpose of significantly increasing Bextra sales;

- knowingly created publications concerning Bextra's off-label uses and that appeared to be written by neutral independent researchers, but in fact were created and written by defendants and their agents;

- improperly disseminated such publications to physicians, as a result of improper "solicited" requests from such physicians, or with no physician "request" at all;

- paid illegal financial inducements to prescribers to attend seminars, ostensibly for "consulting," but in fact to expose physicians to intensive Bextra promotion and influence prescribing practices; and

- paid illegal financial inducements to prescribers to participate in "preceptorships," "clinical article review," "journal clubs," "speaker roundtable" and "speaker training," all of which was to expose prescribers to intensive Bextra promotion and to influence their prescribing practices

II. PARTIES

5. Relator John Kopchinski ("Kopchinski" or "Relator") is a resident of the State of South Carolina, and was, until recently, an employee of Pfizer, Inc. He is the original source of the facts and information hereinafter set forth concerning the activities of Pfizer, Inc., and its affiliated corporation and/or joint venturer Pharmacia Corporation ("Pharmacia"). The facts averred herein are based upon his personal observation and upon documents and information in

his possession.

6. Relator Kopchinski is a 1989 graduate of the United States Military Academy ("West Point") and a decorated veteran of the Gulf War. Prior to attending West Point, he served as an enlisted service-member for three years acting as an air traffic controller. After West Point, he served for three years as an officer, and was discharged honorably at the rank of First Lieutenant. He still serves in the Individual Ready Reserves, currently at the rank of Captain.

7. During his military service, Relator Kopchinski received the Meritorious Service Medal for his service during Operation Desert Shield (the first stage of the 1990-91 Gulf War against Iraq); the Army Commendation Medal, for his service during Operation Desert Storm (the second stage of the 1990-91 Gulf War against Iraq); an Army Achievement Medal for exemplary service while serving in Panama; the Southwest Asia Service Medal with two bronze stars, for his service in the Gulf War; the Kuwaiti Liberation Medal; and numerous other awards and citations.

8. Relator Kopchinski was hired directly out of the Army in January 1992 by the then Chief Executive Officer and Chairman of Pfizer, Edward Pratt, to work as a Pfizer sales representative. During his employment with Pfizer he earned a Masters in Business Administration in 1994 from Washburn University, and Medical Representative Certification in 1997 from the Certified Medical Representative Institute. He was continuously employed by Pfizer from January 1992 until his wrongful, retaliatory discharge on March 7, 2003. At the time of his employment discharge, and at all times material hereto, Kopchinski was employed by Pfizer as a Senior Specialty Representative in the fields of Rheumatology, Orthopedics and Neurology covering the territory of Broward County, Florida.

9. Defendant Pfizer, Inc. is a Delaware corporation with a principal place of business

in New York, New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals with total revenues in 2002 in excess of $32 billion.

10. Pharmacia Corporation is a Delaware corporation with a principal place of business in New Jersey. Pharmacia is principally engaged in the manufacture and sale of pharmaceuticals with total revenues in 2002 of $14 billion.

11. On April 16, 2003, Pfizer acquired Pharmacia and combined operations to create the world's largest pharmaceutical company. The new company, operating under the Pfizer name, is the world's third largest company in market capitalization.

12. With respect to the drug at issue in this Complaint, Bextra, Pfizer and Pharmacia acted as joint venturers with respect to its development, testing, and marketing. Each is thus responsible for the actions of the other. In addition, Pfizer and Pharmacia have merged. As a result of the merger, the surviving corporation, Pfizer, is responsible for the liabilities of both Pfizer and Pharmacia for the actions set forth herein.[1]

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[1] This Complaint and its exhibits are replete with examples showing the cooperation of Pfizer and Pharmacia in the marketing of Bextra. As but one significant example only, Exhibit 1, a list of Bextra questions and answers disseminated by Pfizer national sales director Mark Brown, answers the question "Is Pharmacia's promotional message going to be the same as ours?" by stating "Yes, the promotional materials and co-positioning statement were crafted by and delivered to Pharmacia as a unified story." See Exhibit 1 at 5, "Co-Positioning" question 6.

As another example, the attached Exhibit 2, a PowerPoint Presentation of Pfizer Legal titled "Bextra Launch Plans," clearly discusses the "Pfizer/Pharmacia Alliance" with respect to Bextra. See Exhibit 2 at 3 Pfizer/Pharmacia Alliance"); at 6 ("Co-promote territories (most major markets)"); at 7 ("New Pfizer/Pharmacia Cox-2 Alliance Structure").

In any event, the merger of Pfizer and Pharmacia rendered this issue moot, as the surviving entity, Pfizer, is responsible for the liabilities of both Pfizer and Pharmacia.

13. At all times material hereto, Pfizer and Pharmacia were each principally engaged in the sale and manufacture of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the United States Food and Drug Administration ("FDA").

III. JURISDICTION AND VENUE

14. Jurisdiction is based on 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. In addition, 31 U.S.C. §3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint.

15. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, or transact or have transacted business in this District.

16. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendants can be found in and transact or have transacted business in this district. At all times relevant to this Complaint, defendants regularly conducted substantial business within this district, maintained employees and offices in this district, and made significant sales within this district. In addition, statutory violations, as alleged herein, occurred in this district.

IV. BACKGROUND

17. Bextra is Pfizer's trade name for the drug valdecoxib. Bextra/valdecoxib is a so-called "COX-2 Inhibitor." The "COX-2" class of drugs includes the previously released drug Celebrex, which is also marketed by Pfizer, and the competing drug Vioxx, manufactured by Merck. The COX-2 class of drugs is designed to relieve various forms of pain and inflammation.

18. In November 2001, Bextra was first approved by the FDA for relief of the symptoms of osteoarthritis and adult rheumatoid arthritis, and for treatment of primary dysmenorrhea. Significantly, Pfizer had also sought approval for several additional indications, including acute pain, pre-operative dosing and opiod sparing, but was rejected by the FDA.

19. Since Bextra's FDA-approval nearly three years ago, Pfizer has sought to expand its approved indication only once. On or about December 23, 2002, Pfizer submitted a supplemental new drug application to the FDA for approval to market Bextra for the treatment of migraine headache pain in adults. The FDA has not yet approved Bextra for the treatment of adult migraines.

20. Bextra's narrow FDA-approved indication limits the potential sales growth of the drug, particularly in view of the fact that numerous other approved pain medications are also available to the public. As alleged below, to grow drug sales in a constrained environment, Pfizer and Pharmacia resorted to marketing strategies prohibited by federal law, including kickback schemes and off-label promotion.

21. As alleged below, Pfizer and Pharmacia circumvented federally mandated FDA approval processes by aggressively marketing Bextra for numerous unapproved uses - including, but not limited to, treatment for general acute pain; chronic arthritis at doses greater than 10 mg/day; pre-surgical dosing; and, post-surgical pain, among many others. Indeed, Pfizer's requests for approval for treatment for acute pain other than dysmenorrhea; chronic arthritis at doses greater than 10 mg/day; and dysmenorrhea at doses greater than two 20 mg doses/day, were specifically rejected by the FDA.

22. In addition, Pfizer and Pharmacia have violated federal anti-kickback laws by paying and offering to pay financial inducements to physicians and other providers to influence

their Bextra prescribing practices.

V. APPLICABLE LAW

A. Prescription Drug Reimbursement Under Medicaid and Other Federal Health Care Programs

23. Medicaid is a public assistance program providing for payment of medical expenses for the poor and disabled. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

24. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. §§1396 et seq.

25. Federal reimbursement for prescription drugs under the Medicaid program is available for "covered outpatient drugs." 42 U.S.C. §1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. §1396r-8(k)(3).

26. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or that is included in one of the drug compendia identified in the Medicaid statute. Id. §1396r-8(k)(6). During the time period relevant to this Complaint, with one exception, the off-label uses of Bextra promoted by Pfizer and Pharmacia were not eligible for reimbursement from Medicaid because the drug's off-label uses were neither listed in the labeling approved by the FDA nor included in the drug compendia specified by the Medicaid statute. That single exception, as noted in the Drugdex compendia, is for treatment of post-operative pain. However, even with respect to this limited off-label use identified by Drugdex, any

prescriptions written prior to Drugdex's inclusion of post-operative pain as an off-label indication, were not entitled to reimbursement under Medicaid.

27. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/ TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

28. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of Bextra prescriptions under these programs is similar to coverage under the Medicaid program. See, e.g.,TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

29. Although prescriptions for Bextra are generally eligible for reimbursement under these federal health care programs, kickback-induced prescriptions are not eligible for federal program reimbursement. The applicable provisions of the federal Anti-Kickback law are discussed below.

B. The Anti-Kickback Statute

30. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care

programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

31. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

32. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

33. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices that violate the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the suspect practices cited by the Inspector General were drug companies' payments to physicians who had offered no particular services of benefit to the drug company but who had generated in the past, or had the potential to generate in the future, a large volume of business for the drug company. Id.

34. In May 2003, the Inspector General of HHS released a further Guidance identifying in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" infecting federal health care programs. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) ("2003 Guidance"). The 2003 Guidance cautions manufacturers against engaging in the following suspect practices, several of which are involved in the present case:

a. Improper Consulting and Advisory Payments: These are payments made pursuant to less than bona fide consulting or advisory arrangements, such as payments to physicians for simply attending meetings or conferences in a passive capacity, or for services connected with a manufacturer's marketing activities (e.g., "[c]ompensating physicians as "consultants" when they are expected to attend meetings or conferences primarily in a passive capacity is suspect").

b. Improper Payments for Detailing: These are payments to physicians for time spent listening to sales representatives market pharmaceutical products, for accessing web sites to view marketing information, or for performing "research."

c. Improper Business Courtesies and Other Gratuities: These are gifts such as merchandise of more than trivial value, entertainment, recreation, travel, meals, and other gratuities furnished in association with information or marketing presentations. Id. at 23731-39.

35. In addition, the 2003 Guidance stresses that "under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)." Id.

36. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal

Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In New York and a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

37. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

38. Any party convicted under the Anti-Kickback statute must be excluded (i.e., not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

39. The enactment of these various provisions and amendments demonstrates Congress's commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback statute is a

prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from the public fisc for the resulting claims.

C. FDA Prohibition on The Promotion of Off-Label Indications

40. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

41. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

42. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which must also be reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

43. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses

not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

44. The FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication. However, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

45. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

46. An off-label use of a drug can cease to be off label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

47. In addition to prohibiting manufacturers from directly marketing and promoting a

product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

48. With regard to the first practice, disseminating written information, the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

49. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's

funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

50. In sum, the FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. See 21 U.S.C. §§ 331, 352, 355(d). This off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

VI. PFIZER'S UNLAWFUL MARKETING STRATEGY

51. To grow sales of Bextra, a drug with limited approval and strong market competition, Pfizer has engaged in an extensive fraudulent marketing scheme. As described below, the scheme has two integral components: (1) the aggressive and improper off-label promotion of numerous unapproved uses of Bextra and (2) the payment of illegal kickbacks to providers in order to induce them to prescribe Bextra, both on-label and off-label. Pfizer's fraudulent scheme grossly disregards federal Anti-Kickback laws prohibiting the payment of financial inducements to promote drug prescriptions, as well as Food and Drug laws prohibiting pharmaceutical manufacturer promotion of drugs off-label.

52. Although Pfizer and Pharmacia did not directly provide Bextra to federal and state health insurance programs or issue prescriptions for the drug, it embarked on a course of unlawful conduct that it knew would lead to the submission by physicians and pharmacists of thousands of

claims for Bextra when such prescriptions were not eligible for federal or state health care program reimbursement. Pfizer and Pharmacia knew their actions would inevitably cause these providers to submit false claims to the federal and state governments. Accordingly, Relator Kopchinski, on behalf of the United States and the States, seeks to hold Pfizer liable for knowingly causing these false claims to be presented to the United States for payment in violation of 31 U.S.C. §3729.

53. As set forth more fully below, Pfizer and Pharmacia pursued aggressive marketing goals for Bextra by promoting it for uses and dosages that the FDA had found were neither safe nor effective, and for uses and dosages that were not approved for reimbursement by Medicaid.

A. The Defendants Engaged In Extensive Off-Label Promotion Of Bextra

54. In November 2001, the FDA approved Bextra for the following limited indications: (a) for treatment of osteoarthritis, but only up to a dosage of 10 mg once per day; (b) for treatment of rheumatoid arthritis, but also only up to a dosage of 10 mg once per day; and (c) for treatment of "primary dysmenorrhea" (painful menstrual cramps), but only up to a dosage of 20 mg once or twice a day. See attached Exhibit 6, copy of the FDA approved labeling (package insert) for Bextra. (Henceforth, the term "chronic arthritis" will be used to refer to both "osteoarthritis" and "rheumatoid arthritis")

55. A copy of the FDA's medical review of Bextra is attached as Exhibit 7. This document contains numerous deletions from its original form. These deletions are caused by the fact that the FDA does not release information to the public regarding potential applications of drugs that do not obtain FDA approval. Such information is currently considered trade secret and proprietary information, not subject to release under the federal Freedom of Information Act.

1. The Highly Aggressive Marketing Strategy For Bextra Was Driven By Lucrative Off-Label Markets

56. Pfizer and Pharmacia's aggressive marketing plans for Bextra and Celebrex are set forth in the attached Exhibit 2, a PowerPoint presentation of Pfizer Legal Division dated March 13, 2002, titled "Bextra Launch Plans." The presentation shows Pfizer's entry into the aggressively growing arthritis and pain market, with sales expected to expand from $6 billion in 1999, to more than $15 billion in 2005. See Exhibit 2 at 21. For Bextra alone, Pfizer projected sales of $350 Million in 2002 (the year it was introduced), and sales of at least $1 billion by 2004. See Exhibit 2 at 26.

57. These goals were to be achieved by marketing Bextra and Celebrex as a combination portfolio of drugs for all types of pain relief. See generally Exhibit 2. This presentation makes clear that Pfizer intended to circumvent the Food and Drug Administration's ("FDA") limited approval of Bextra, discussed more fully below, to fulfill these aggressive plans. The internal presentation acknowledges that, while the FDA only approved Bextra for chronic arthritis and menstrual pain, Pfizer had also sought approval for the use of Bextra for "acute pain," "pre-op[erative] dosing," and "opiod sparing [meaning use of Bextra to reduce narcotic pain relievers]," and the FDA had denied approval for those uses. See Exhibit 2 at 18. Despite this, the presentation makes it clear that Pfizer still intended to market Bextra for "perioperative pain," and that it was pursuing clinical trials on Bextra for many types of acute pain. See id. at 17; id. at 47-50 (clinical trials on Bextra and acute pain).

58. It is evident from the FDA's medical review (Exhibit 7) that there were serious concerns over the safety and effectiveness of Bextra if used for other than the indicated purposes at the indicated dosages. For example, the FDA medical reviewer recommended "non-approval" for all acute pain uses other than primary dysmenorrhea. While the reasons for non-approval of other acute pain uses are deleted from the version released to the public, the report indicates that

"the extensive safety database at 10-80 mg daily in the arthritis safety database is adequate to support approval of the chronic therapy at 10 mg/day for arthritis and acute dose of 20 mg bid [twice a day] for short term use in dysmenorrhea." See Exhibit 7 at 3, item 1B. As set forth more fully below, the non-deleted portions of the FDA medical report clearly indicate that the agency's medical review demonstrated concerns about the safety of Bextra, if used at dosages over 10 mg in the long-term, and if used for short-term pain at dosages over 20 mg twice a day.

59. For example, the FDA concluded that significant health risks did not justify the approval of Bextra for chronic arthritis at dosages above the approved dose of 10 mg/day. The FDA medical review indicates significant concern about the safety of higher dosages.

> The safety profile with chronic use in RA [rheumatoid arthritis] and OA [osteoarthritis] is adequate at 10 mg/d. At higher total daily doses, the findings of more hypertension and edema are frequently reproduced, and they are formally affirmed in a prospective manner in Trial 47, which directly tested the hypothesis of renal safety at 40 and 80 mg/day. In the analysis of older subpopulations over the age of 65 years edema and hypertension appear to be greater at 20 mg/day compared to 10 mg/day.

Exhibit 7 at 3 ¶2(a).

> Valdecoxib [Bextra] should be limited to 10 mg/d[ay] in chronic use in OA and RA [chronic arthritis]. At this dose the rates of edema and hypertension appear to be similar to the competitor NSAIDS although formal hypothesis testing was not done in this regard. Edema and hypertension appeared increased at higher doses compared to other NSAIDS.

Exhibit 7 at 7 ¶6 "Dosing." Using less technical terms, the FDA concluded that Bextra, when used for long periods of time at doses over 10 mg per day, and for long-term relief of chronic arthritis, may damage the kidneys ("renal safety"), may cause the body to retain fluid ("edema"), and may cause an increase in blood pressure ("hypertension"). For these reasons, the FDA limited its approval of short-term uses of Bextra, at doses over 10 mg/day, to the relatively short usages (a few days) for women with acute pain associated with menstruation ("dysmenorrhea");

and limited its approval of chronic arthritis use to 10 mg/day.

60. With respect to these "renal safety" issues, the FDA concluded that Bextra's rate of such incidents were significantly higher, at doses of 40 mg/day or 80 mg/day, than other analgesics used for comparative purposes in the safety tests:

> The significant renal adverse event profile of valdecoxib 40 and 80 mg/day appears to be inferior to that of naproxen 1 gram/day. The comparative profile of 10-20 mg/day of valdecoxib in studies at these doses did not suggest inferiority to the comparator NSAIDS.

Exhibit 7 at 48-49. In simpler terms, the FDA concluded that Bextra is riskier than other available pain relievers when used at doses of 40 mg/day and up. This likely contributed to the FDA's decision to deny approval of indications of Bextra for general acute pain at any dosage, and for dysmenorrhea at any dosage over 20 mg/twice a day.

61. In addition to the FDA's concerns about the safety of long-term use of Bextra at doses over 10 mg/day, the FDA also concluded that long-term use of Bextra at dosages over 10 mg/day were no more effective in relieving chronic arthritis pain than dosages of 10 mg/day:

> Adequate efficacy has been demonstrated in osteoarthritis and rheumatoid arthritis at 10 mg/d[ay] **with no additional efficacy at 20 mg/d[ay].**

Exhibit 7 at 3 ¶2(a) (emphasis added).

> [For arthritis, t]**here was no added efficacy at 20 mg/d[ay], compared to 10 mg/d[ay].**

Exhibit 7 at 6 "Arthritis" (emphasis added).

62. The FDA medical report indicates that Pfizer requested approval of Bextra for general use in acute pain and was rejected. The report quotes Pfizer's "request for claims" as:

> An indication for the treatment of acute pain and dysmenorrhea at 40 mg/d[ay], with an additional 40 mg on day one if needed, and an indication for chronic treatment of the signs and symptoms of osteoarthritis and rheumatoid arthritis at a dose of 10 mg/day, with the proviso that "some may receive additional benefit at 20 mg/day."

Exhibit 7 at 4 section 3, "Overview of Clinical Program," "Analgesia."

63. Accordingly, it is apparent that the FDA specifically rejected the following uses of Bextra proposed by Pfizer: (a) uses for any acute pain other than dysmenorrhea; (b) uses for chronic arthritis at a dose of more than 10 mg/day; (c) uses for acute pain of dysmenorrhea at a dose of more than 20 mg/twice a day (40 mg total). This limited FDA approval greatly restricted the market potential and potential profitability of Bextra, and frustrated the overall plan of Pfizer and Pharmacia to use Bextra to supplement its tremendously successful drug Celebrex.

64. As discussed above, Pfizer's business goal was to establish Bextra, along with their drug Celebrex, as the dominant products in the market for non-aspirin, non-narcotic acute and chronic pain relief. To reach that goal, however, Pfizer needed Bextra to take "on-label" market share from COX-2 competitors such as Vioxx, as well as expand the potential market through off-label uses.

65. Pfizer and Pharmacia are prohibited from marketing prescription drugs for indications not approved by the FDA. To legally expand Bextra's approved indications, Pfizer and Pharmacia should conduct solid, scientific research on new indications, submit a "Supplemental New Drug Application" to the FDA for expanded approval based on such research, and have the FDA evaluate and approve Bextra as safe and effective for the requested, expanded indications.

66. This FDA approval process, however, can take years and is not guaranteed. Furthermore, to maximize profits from a new drug, a drug company must maximize sales during the patent period - the period when only the company holding the patent can market the drug, and can thus charge a premium price. After this period, other companies may market generic versions of the drug. Once a drug is made generic, the company holding the original patent

generally loses market share to generic competitors.

67. In the case of Bextra, Pfizer and Pharmacia maximized profits by undertaking a fraudulent scheme by which Pfizer (a) paid substantial and illegal financial inducements to promote both on-label and off-label prescriptions of Bextra, and (b) extensively marketed Bextra for non-approved usages. This scheme violated the FDA laws and regulations concerning marketing of drugs; violated federal and state health insurance drug reimbursement statutes and regulations; and violated federal Anti-Kickback laws. It is estimated to have already resulted in the submission of hundreds of thousands of false claims for federal and state health care program reimbursement, pursuant to the Federal False Claims Act and the States false claims statutes.

2. Pfizer And Pharmacia Improperly Promoted Bextra For Off-Label Uses And High Doses Rejected By The FDA

68. In spite of the FDA's rejection of expansive indications for Bextra, Pfizer and Pharmacia developed and employed a marketing strategy that promoted Bextra for unapproved uses and dosages. Bextra was promoted, inter alia, for chronic arthritis at dosages over 10 mg/day, despite the FDA's findings that such usages were neither safe nor any more effective than dosages of 10 mg/day; for acute pain generally, even though that indication was reviewed and rejected by the FDA; and for other non-FDA approved uses, such as pre-operative and post-surgical pain, and for uses not approved by any compendia listed in the Medicaid reimbursement statute. Each will be considered in turn below.

69. As detailed below, pursuant to this strategy, Pfizer and Pharmacia used a variety of methods, including, inter alia, direct detailing using scripts and information provided to field sales representatives; disseminating articles concerning off-label uses of Bextra that were authored by Pfizer and Pharmacia employees; and, providing free samples of high dosage Bextra to physician specialities that did not treat primary dysmenorrhea, (the only approved indication

for 20 mg Bextra).

a. Pfizer and Pharmacia Improperly Promoted Bextra for Chronic Arthritis at Doses Greater than 10 mg/day

70. Pfizer and Pharmacia utilized their substantial field sales force to improperly promote excessive dosages of Bextra for chronic arthritis. In particular, Pfizer and Pharmacia developed sales "scripts" and marketing materials for sales representatives to use to encourage doctors to prescribe Bextra for chronic arthritis at dosages above 10 mg/day (either by prescribing 20 mg or more, or by prescribing 10 mg twice a day rather than once a day). These scripts and marketing materials were designed to convey several false impressions: (a) that doses of Bextra above 10 mg/day were more effective for chronic arthritis than doses of 10 mg/day; (b) that doses of Bextra above 10 mg/day were safe for long-term use for chronic arthritis, and (c) that Bextra is safer than Vioxx (its chief competitor) even though no head-to-head clinical trials had been conducted.

71. An example of such a script is provided as Exhibit 8. Among other things, the script creates the false and misleading impression that Bextra is safe and more effective for chronic arthritis at doses above 10 mg/day. It states:

> Bextra is more efficacious because it provides you greater flexibility in individualizing your patient's pain therapy to their individual pain needs. Bextra 10 mg once daily is extremely effective in your chronic daily osteo and rheumatoid arthritis sufferers. But, Bextra provides the added spectrum of efficacy in that 20 mg and 40 mg doses are approved for more acute nonarthritic pain. In fact I'll be leaving you this study comparing Bextra's efficacy with Tylox.

72. The script is misleading, inaccurate and improper in numerous ways. First, it suggests that Bextra may be used for chronic arthritis at doses above 10 mg/day. As detailed above, doses higher that 10 mg/day for chronic arthritis are not approved by the FDA nor are they indicated in any of the relevant compendia. Second, the script falsely suggests that Bextra is approved at doses of 20 mg and 40 mg/day for any acute nonarthritic pain. The FDA, however,

rejected a general acute pain indication, and approved Bextra only for primary dysmenorrhea. The only compendium to list another pain usage restricted off-label use to post-operative pain. Third, the script also promotes the use of Bextra for chronic arthritis pain at dosages higher than approved. It further invites the doctor also to review a study using higher doses for relieving acute post-operative pain. Fourth, the script promotes high Bextra dosages for arthritis pain (20 mg/day and 40 mg/day), that were found by the FDA to be unsafe for chronic arthritis pain, and to be no more effective than 10 mg/day. Finally, the script contends that Bextra is safer than Vioxx, even though there are no head-to-head clinical studies of Bextra versus Vioxx, and, thus, there is no scientific basis for the claim.

73. The script is also materially misleading in its promotion of Bextra's safety. It states:

> And Bextra provides this same great tolerability profile all along this outstanding range of efficacy [10 mg, 20 mg, and 40 mg doses].
>
> Which brings us to the third reason Bextra is more effective. Because it is safer than Vioxx. . . . Bextra . . . has been given a clean bill of health by the FDA across its 10-40 mg dosing spectrum in terms of both GI and cardiorenal safety.

These statements are false and improperly minimize the safety risks of Bextra. The FDA medical review clearly found problems with the safety of Bextra at long-term doses above 10 mg/day (see paragraphs 39-43 above), including edema (retained fluid) and hypertension (high blood pressure). These are clearly issues involving "cardiorenal safety" (kidney and circulatory system).

74. Scripts such as this were part of Pfizer's national scheme to promote off-label uses of Bextra. The above script was provided by an email from Matthew Lustig, a district sales manager, to his South Florida "Sharks" marketing team which included Relator John Kopchinski. See Exhibit 8. This email was, however, copied to Mark Brown, a national sales director for

Pfizer, who was involved in creating the script.

75. The strategy implemented in this script - mix and match information about chronic arthritis use of Bextra versus acute pain use of Bextra to confuse issues about safety and efficacy - was consistent with Pfizer overall marketing strategy, and is fully consistent with Pfizer's disturbing disregard for the safety of patients taking Bextra.

76. This strategy went beyond attempts to mislead and cause confusion into outright lies and misrepresentations. Exhibit 4, (discussed infra at ¶¶115-16), contains a slide (at 14) that references concerns about "the cardio-renal profile of Vioxx" and then states "Bextra offers impressive cardio-renal safety." Given the concerns of the FDA medical review regarding the safety of Bextra at doses above 10 mg/day in the long run, in connection with edema and hypertension, this statement is at worst a lie, at best seriously misleading.

77. The promotion of Bextra for chronic arthritis uses at more than the FDA-approved 10 mg/day came from high-level management. The attached Exhibit 1, dated February 19, 2002 (just prior to the Bextra "launch"), was distributed by Mark Brown, a national sales director, to district sales managers, and purportedly represents "a list of questions and answers from our Bextra meeting last week." On the third page, the answer to question 6 concerning "incidence of hypertension and edema" suggests that Bextra is safe in these regards at doses of 10, 20, and 40 mg for chronic arthritis use. Such a suggestion is contradicted by the prior findings on hypertension and edema in the FDA medical review, and the FDA's limited approval of Bextra for 10 mg/day only for chronic arthritis. Further, the last two pages of Exhibit 1 contains a list of questions without answers, which include the following suggestive questions promoting Bextra for chronic arthritis at doses above 10 mg/day:

> 3. Since the 10 mg and 20 mg are the same price, with similar side effect profiles, why not start with 20 mg? As we learned from Celebrex, efficacy

is most important.

4. What will be the Ortho dosing for Bextra? Will we recommend 20 mg BIDPRN [twice a day as needed] to start?

5. The slide comparing Bextra 10 mg/20 mg in arm stiffness. Why does 20 mg drop off; should it not be at least equal?

78. There were several clear answers to these questions. First, the FDA did not approve Bextra for 20 mg dosing for chronic arthritis. Second, the FDA medical review found that 20 mg was no more effective than 10 mg for chronic arthritis. And, third, the FDA medical review expressed concerns over the safety of Bextra for chronic use at over 10 mg/day. Nevertheless, Mr. Brown chose to disseminate these questions to sales managers and representatives without providing those simple answers.

79. Because the FDA limiting Bextra's approval to 10 mg/day for chronic arthritis, some pharmacists and insurers resisted filling 20 mg prescriptions for Bextra. In these situations, sales representatives such as Relator Mr. Kopchinski were instructed to advise the doctor to write the prescriptions for 10 mg/twice a day, rather than 20 mg/once a day. Since 10 mg was a dosage approved for chronic arthritis, this strategy was intended to bypass the pharmacy, HMO, and insurer systems designed to prevent the filling of prescriptions for unapproved uses of drugs.

b. Pfizer and Pharmacia Improperly Promoted Bextra for General Acute Pain - An Indication that was Rejected by the FDA

80. As mentioned above, the FDA rejected a general acute pain indication for Bextra. Rather, Bextra's only acute pain indication was extremely restricted and limited to primary dysmenorrhea.

81. Pfizer, however, disregarded these federal limitations and aggressively promoted Bextra for general acute pain relief. As one example only, Relator John Kopchinski and other

sales representatives received voicemails advising them that Bextra at 80 mg was effective for migraine pain. Even though this was not a medically approved use of Bextra, Pfizer expected its sales representatives to mention this potential use to physicians.

82. A central component of this strategy was to mix and match the terms "acute pain" with discussions about the FDA-approved usage of Bextra for primary dysmenorrhea, or with discussions about the use for post-surgical pain. The clear intent of this mixing and matching was to promote the usage of Bextra for acute pain generally.

83. An example of this strategy is the attached Exhibit 8, an email from South Florida district sales manager Matthew Lustig transmitting a "Bextra v. Vioxx" selling point script. This script contains the sentence "Bextra provides the added spectrum of efficacy in that 20 mg and 40 mg doses are approved for more acute non-arthritic pain." In other words, rather than admit the limitation of the FDA approval of 20 mg and 40 mg doses to dysmenorrhea, this script creates the false impression that Bextra is generally approved for any type of acute pain.

84. Another example is a "January 2003 POA Resource Guide," (Exhibit 9), which advises sales representatives how to "detail" [market] Bextra and Celebrex to doctors. In discussing pages 8-9 of the detailing materials, the Guide suggests (in connection with a graph about the onset of pain relief for dysmenorrhea) that sales representatives state "Bextra provides onset of action and pain relief comparable to the efficacy of naproxen sodium SR in an acute pain condition." See Exhibit 9 at 10 (emphasis supplied). Once again, this material improperly created the false impression that Bextra was generally approved for acute pain relief.

85. Another example of promoting Bextra off-label for general acute pain use is the February 19, 2002 list of questions and answers distributed by Mark Brown, a national sales director, to his district sales managers. See Exhibit 1 at 4. That document identifies "Bextra

Acute Pain" and states that "Bextra had outstanding efficacy and safety in a large # of acute pain studies." Further, on the last two pages of the exhibit, which lists questions without answers, the following questions are listed:

> **Acute Pain Indication**
>
> 1. What is the timeline for the pain indication?
>
> 2. What approach/strategy should the sales force take when telling to RX Bextra over VIOXX for acute pain when Bextra doesn't have this indication[?]
>
> 3. For acute pain patients not responding to Celebrex how can we position Bextra with no acute pain indication, to beat VIOXX?

86. The very simple answer to questions 2 and 3 is that marketing Bextra for general acute pain without an FDA indication for general acute pain is illegal. Nevertheless, Mr. Brown - a high level national manager at Pfizer - chose to disseminate this document to sales representatives and sales managers without providing this very simple and true answer.

c. Pfizer and Pharmacia Improperly Promoted Bextra for Pre-Surgical Protocols

87. As part of its national scheme to promote Bextra for non-approved usages, Pfizer encouraged sales representatives to convince physicians to include Bextra on their form "protocols" for certain surgical procedures. An example, attached at Exhibit 10, is an email from Matthew Lustig, a South Florida district manager, to his "Sharks" in which he asks "where are our protocols," and incorporates a prior email from Mark Brown, (a national sales director (also copied to Christopher Dowd, vice president of sales)), which references "another example of a surgery protocol." It relates:

> a "protocall [sic] for Bextra with Dr. McIlwain in Tri-Cities that Roger Catlett [a sales representative] helped develop. Roger has done a great job implementing this strategy we talked about at POA-2 and will definitely reap the benefits of this

protocall [sic]. Great job Roger! 5000 Ace Points [about $50.00] on the way." The protocol, referencing "Bextra 3 days before" surgery is attached as the second page of the email.

88. This example illustrates how Pfizer discussed the development of form protocols for doctors at sales meetings, encouraged its marketing sales representatives to develop such protocols with physicians, and rewarded its marketing sales representatives with monetary incentives to develop such protocols. All of this was for uses of Bextra, in pre- and post-surgical pain, that were not FDA-approved.

89. Indeed, this protocol was not even in compliance with the single compendium that included a "medically approved," albeit off-label, use of Bextra for post-surgical pain. This protocol sets forth a use of Bextra for a full 3 days prior to surgery. The current DrugDex compendium entry, (see Exhibit 11), only lists a usage of Bextra for "post-operative pain." The discussion of that potential usage references only the pre-operative usage of Bextra beginning "within 75 minutes of surgery" for oral surgery or orthopedic foot surgery, and beginning "1 to 3 hours before surgery" for hip surgery. Nothing in this compendium entry indicates that taking Bextra beginning three days before surgery has been determined to be safe or effective. Likewise, there is no indication that taking Bextra three days before surgery provides any advantage in the relief of postoperative pain over taking Bextra beginning 1 to 3 hours before surgery.

90. The development of drug protocols for surgical procedures was an essential and formal component of Pfizer promotional efforts for Bextra. In the "January 2003 POA Resource Guide", (Exhibit 9), sales representatives are advised on "how to identify opportunities for introducing and/or updating protocols and standing orders," and "how to successfully implement new protocols and standing orders." (See section titled "Portfolio Resources," including

document titled "Pain Management Protocols and Standing Orders Management Tool".)

d. Pfizer and Pharmacia Improperly Promoted Bextra Off-Label for Post-Surgical Pain

91. Pfizer and Pharmacia actively promoted the use of Bextra for post-surgical pain, a use not approved by the FDA. This promotion was carried out through various means, including:

(a) defendant-sponsored research into the use of Bextra for post-surgical pain;

(b) Pfizer and Pharmacia employees co-authoring articles concerning the use of Bextra for post-surgical pain;

(c) Pfizer and Pharmacia encouraged their sales representatives to solicit doctors to "request" medical information, and in response, provided medical articles on the use of Bextra for post-surgical pain. The sales representatives were further encouraged to fold down the top page of the article reprints thereby concealing statements that the FDA had not approved Bextra for the general management of acute pain.

(d) Pfizer, as discussed infra, encouraged and rewarded sales representatives who developed form surgical protocols that listed Bextra as a standard part of a physician's routine surgical procedures and orders.

92. In addition, Pfizer and Pharmacia disseminated information and marketing scripts to their sales representatives advising them how to sell Bextra for the non-FDA-approved usage of post-surgical pain relief. For example, Matthew Lustig (South Florida sales manager), forwarded to his sales representatives information regarding a purported advantage of Bextra in managing orthopedic surgical pain, in the area of sleep apnea. (See Exhibit 12.) Sales representatives were encouraged, in this off-label context, to "freeze" an "Orthopod [orthopedic surgeon]" by asking "Doctor, do you make any therapeutic changes for patients receiving surgery and [who] have sleep apnea"? The purpose of this question was to initiate a discussion with the

physician in which the sales representative could present Bextra's purported advantage for post-surgical pain relief (a non-FDA approved use) for patients with sleep apnea.

93. Another example is the email attached at Exhibit 13, in which Matthew Lustig, a South Florida district sales manager, forwards to his "Shark" team sales representatives an email from Mark Brown, national sales director. While the Mark Brown email seeks to maintain the pretense that such information is not for use in marketing, by adding the tag "NOT FOR USE SELLING - REFERENCE AND TRAINING ONLY," it advises that "an easy to follow review of the Oral Surgery Study with Bextra [was attached]. This is the study that Medical Inquiry sends out upon request." In other words, it advised sales representatives - "Get your doctors to request medical information, and this is the medical information that we will send to them." By attaching the description of the article, it further advised the sales representatives that the information provided would help them in promoting Bextra. It was further common knowledge among Pfizer representatives that such "NOT FOR USE SELLING" tag lines were designed to maintain the pretense of plausible deniability, and that it was fully intended and expected that Pfizer representatives would use the referenced information to promote Bextra.

94. The pretense that the email attached hereto as Exhibit 13 was not intended for selling is undermined by a review of the attached article summary. After a "Synopsis" of the article, the summary then proceeds directly to a section titled "Sales Strategy (Make a point of how this study can help or hinder our sales efforts)," with five bullet points on sales points to be made from the article. See Exhibit 13, attached article summary, section titled "Sales Strategy."

95. Another example of the off-label promotion of Bextra for post-surgical pain is an October 7, 2002 email from Matthew Lustig, South Florida district sales manager, to his "Sharks" sales team, attaching what Mr. Lustig describes as a "great comparison for your orthopods and Pain Management docs." (See Exhibit 14.) The attached comparison is between Bextra and Toradol for the management of acute post-surgical pain. Nowhere does the comparison indicate that Bextra was not FDA-approved for such use.

3. Pfizer And Pharmacia Fraudulently Promoted Bextra Through Misleading Articles And Free Sample Programs

a. Pfizer and Pharmacia Disseminated Misleading Articles Regarding Bextra's Off-Label Uses

96. Although federal regulations prohibit Pfizer and Pharmacia from promoting Bextra for non-FDA approved uses, it is permitted to distribute publications created by third parties that describe results of off-label use of Bextra, provided such material was only distributed in response to non-solicited requests from physicians. Pfizer and Pharmacia circumvented this narrow exception by encouraging sales representatives to solicit physicians to "request" medical information regarding Bextra, and then either leaving with physicians such medical articles, or having such medical articles mailed to the physician. In many instances these materials were mailed or delivered to physicians even without the pretext of a request from the physician.

97. In Mr. Kopchinski's sales district, for example, there was an employee paid by Pfizer, as a so-called "meeting coordinator," who was responsible for sending one unsolicited article per month to 20 physicians, for each of the nine sales representatives in Mr. Kopchinski's district, for a total of 180 unsolicited articles per month. The sales representatives would be sent a copy of the article distributed so they would know what information had been disseminated to

the doctors. While sometimes these articles would relate to approved usages of Bextra, more frequently than not they would relate to unapproved usages of Bextra. In addition, Mr. Kopchinski and his fellow sales representatives were provided with article reprints (see details below) about unapproved uses of Bextra and instructed to disseminate such articles, whether the physicians requested them or not.

98. The medical information left with or mailed to the physicians consisted of carefully selected medical articles regarding the use of Bextra for postoperative pain. This information was misleading and/or intentionally incomplete in the following respects: (a) Pfizer did not disseminate information concerning the FDA's medical review findings showing that Bextra was not safe or effective for chronic arthritis at doses over 10 mg/day, nor for general acute pain relief; (b) rather, Pfizer disseminated information regarding only the use of Bextra for short-term post-operative acute pain usage, as these studies found that doses of Bextra higher than 10 mg/day were more effective for such short-term acute pain relief, and as such studies did not have to address the long-term safety effects of higher doses for chronic pain or for longer-term acute pain usage. By presenting such incomplete information, Pfizer's purpose was to create the misleading impression among the doctors that received such information, that Bextra was generally safe and effective for any purpose at doses above 10 mg/day.

99. Examples of such "medical information" are attached as Exhibit 15 (an article regarding the use of Bextra as an analgesic for hip surgery) and Exhibit 16 (an article regarding use of Bextra as an analgesic for oral surgery).

100. Exhibit 15, the hip surgery article, was based on work sponsored entirely by Pharmacia Corporation and Pfizer Inc. See Exhibit 15 at 49, Acknowledgement. Three of the four authors work for Pharmacia Corporation or for its affiliate Pharmacia Europe Ltd. See

Exhibit 15, title page, authors' names and associated footnotes.

101. Exhibit 16, the oral surgery article, was based on work sponsored by Pharmacia Corp. and Pfizer Inc. Three of the five authors work for Pharmacia Corp. See Exhibit 16 at 621.

102. Both articles were prepared in "reprint" form by Pharmacia Corp. and Pfizer Inc. See initial pages to Exhibit 15 and Exhibit 16. The initial pages to these reprints contained information about the FDA indicated usages of Bextra, and contained the following sentence "The following are important considerations for the reader; Bextra (valdecoxib tablets) is not indicated for the management of acute pain." However, Pfizer sales representatives were instructed, when leaving these reprints with doctors, to fold this first page over, so that it became the last page, not the first page, of the reprint as it was presented to the physicians. The intent of this practice was to reduce the chance that the physician would notice the warnings on the initial page showing that Bextra was not FDA approved for the acute pain usages described in the articles.

103. The dissemination of such articles was a cornerstone of Pfizer's marketing strategy. For example, on January 8, 2003, Pfizer sent out to its representatives a copy of a mailing envelope that would be used to send medical articles to doctors. The letter accompanying this mailing envelope sample is attached hereto as Exhibit 17. The letter states:

> The purpose of this communication is to provide you with a sample of the newly designed mailing envelope being utilized by U.S. Medical Information [section within Pfizer].

The letter then encourages the sales representatives to show the envelope to doctor's staffs so that they will not construe the envelope as marketing material to be thrown away:

> We suggest that you show this envelope to your physicians' office staff and inform them that it is used by Pfizer Medical Information to provide information requested by their physicians. It will not contain advertising or other promotional materials. By instructing the office staff about our mailing envelopes, we hope to

> assure that your healthcare professionals receive the full value of Pfizer Medical Information and to minimize the risk of our responses being discarded by the office staff before reaching the physician.

The middle paragraph of the letter, however, reveals that this dissemination of medical information is actually a crucial component of Pfizer's marketing efforts:

> In discussions with various representatives from the sales divisions, we have experimented with several design concepts. Our goal was to create a design that would stand out in the physician's office, yet maintain the image of a medical information communications sent in response to the physician's request. (Emphasis added).

In other words, "we're having to be more clever about how we send these articles, because some of the doctor's staff are beginning to figure out that we just send these articles to market our products."

104. In conjunction with the dissemination of these envelopes, sales representatives were encouraged to suggest to doctors that they request such medical information. The sales representatives were well aware what medical information would be sent, and that such medical information would not include the medical information from the FDA medical review showing concerns about the long-term use of Bextra over 10 mg/day for chronic arthritis pain.

105. Sales representatives of Pfizer were provided with copies of such articles, and were expected to use such articles in their marketing efforts. For example, the attached Exhibit 18 is a March 7, 2002 email from Matthew Lustig, South Florida sales director, to his "Sharks" marketing team. It attaches a medical letter and states "This is not approved for detailing. This is what doctors are sent to address Bextra v. Vioxx for acute pain." The attached letter describes the use of Bextra for post-oral-surgery pain. The purpose of this email was to let the sales representatives know that, if they convinced doctors to request additional information, the doctors would be provided with "information" on Bextra that would assist the sales

representatives in their selling efforts.

106. In further example, Exhibit 19 is a copy of a May 2002 memorandum from Pharmacia Corp. to "Pharmacia and Pfizer Sales representatives and Account Managers," which shows that sales representatives were encouraged to leave reprints of medical articles about non-FDA-approved uses of Bextra with doctors. Exhibit 19 summarizes and attaches the oral surgery study attached hereto as Exhibit 13. The memorandum is labeled "This memo is for your information only. Not to be shown to healthcare providers." See Exhibit 19 at 1-2. It also states "this article contains information that differs from the approved product labeling." However, the memorandum then tells the sales representatives that "this reprint can be left with physicians." (Emphasis added.) See Exhibit 19 at 1, boxed section titled "Instructions for use of this reprint." The memorandum then provides a summary of the survey results, with "selling points" to be used to promote Bextra over the other analgesics tested in the oral surgery study. Pfizer and Pharmacia sales representatives were well aware, despite the cautionary legends listed on this memorandum, that the information was actually provided to them to be used in their marketing efforts.

107. This strategy was not an isolated strategy employed by South Florida sales manager Matthew Lustig only, but was pervasive throughout Pfizer and Pharmacia. For example, Exhibit 20 contains a May 31, 2002 email from Jim Bezila, a regional sales manager for the Southeastern United States, to the sales managers and sales representatives in his region, stating "Attached is an excellent review of the Bextra v. Vioxx pain study [for post-oral-surgery pain] by Memphis PHR ["professional health care representative," meaning a marketing representative] Cindy Parolli. While it is not for detailing [meaning not to be used in sales presentations with doctors], it is available through a medical information request and can be sent

to a physician if he/she requests comparative data of Bextra vs. Vioxx." Thus, once again this email demonstrates a pro forma adherence to the principle that Pfizer and Pharmacia could not actively promote such use of Bextra, as the email states the information is "not for detailing." Once again, however, the attached review belies that notion that it is not intended to be used for marketing purposes, as it ends with a series of "Selling Points."

108. Exhibit 21 is yet another example of how Pfizer and Pharmacia provided their sales representatives with information regarding the type of materials that would be sent to doctors if they convinced the doctors to "request" medical information on Bextra. This exhibit contains an August 27, 2002 email from Matthew Lustig, a South Florida sales manager, to his South Florida "Sharks" marketing team, stating "Importance: High", and stating "attached are a copy of all the current Bextra Medical Inquiry letters available through HQ [headquarters]." Exhibits 22, 23, and 24 are three of the "Medical Inquiry Letters" referenced in this email, and all include information about the non-FDA-approved use of Bextra for acute pain. While each includes information regarding research findings that Bextra is purportedly safe at doses above 10 mg/day for acute pain use, each is written to hide or minimize the FDA medical review conclusions that Bextra is not safe when used for chronic arthritis at doses above 10 mg/day. Again, this information was provided to sales representatives to let them know the type of favorable information about Bextra that would be provided to doctors, if the sales representatives convinced the doctors to request additional information.

109. This publication strategy was not limited to certain departments or regions of Pharmacia and Pfizer. The attached Exhibit 25 shows the dissemination by Rick Burch, marketing senior vice president overseeing about 4000 Pfizer marketing representatives, to all Pfizer sales managers responsible for Bextra, of an informational letter regarding the strategy for

distribution of Bextra. This letter, to "Dear Field Sales Colleagues," and written and disseminated in February 2002, before Bextra was released for distribution, clearly shows that the publication of articles in academic journals, and the dissemination of such articles to physicians, was a cornerstone of the Pharmacia/Pfizer marketing strategy:

> The launch of BEXTRA, the second COX-2 specific inhibitor to emerge from the Pharmacia/Pfizer Alliance, is being supported by a comprehensive clinical program. To help generate awareness and excitement surrounding our important addition to the analgesic/anti-inflammatory market, we have submitted many studies to key, peer-reviewed journals.

110. The memorandum then proceeds to summarize various articles, including articles about non-FDA-approved uses for post-surgical pain. See Exhibit 25 at 4-6. Again, while this memorandum includes the typical disclaimer concerning marketing purposes, Pfizer representatives were well aware that this information was being provided to them for use in their marketing efforts.

b. Pfizer and Pharmacia Provided Generous Free Samples to Specialists Who Did Not Treat Primary Dysmenorrhea - The Only "On- Label" Indication For High Dose Bextra

111. The only FDA-approved use of 20 mg doses of Bextra is for the treatment of primary dysmenorrhea (painful menstruation). Accordingly, the only physicians who would have any "on-label" use for 20 mg samples of Bextra would in virtually all instances be gynecologists and primary care physicians treating female patients.

112. Despite this, Pfizer provided all of their sales representatives with 20 mg samples and instructed them to leave them with all doctors, regardless of whether such physicians treated female patients for dysmenorrhea. The purpose of this policy and practice was to promote the usage of Bextra for non-FDA-approved uses, including: (a) usage for chronic arthritis at 20 mg; (b) usages of 20 mg tablets for acute pain other than dysmenorrhea.

113. This practice was also designed to promote the use of Bextra for other indications not included in any Medicaid-referenced compendia. The only off-label use identified in any of the compendia referenced in the Medicaid drug reimbursement statute was for post-operative pain following dental surgery or orthopedic (hip replacement) surgery. Thus, while this use was non-FDA approved, it was, after the publication of this compendium entry, eligible for Medicaid reimbursement. However, even though such uses would be limited to dentists and orthopedic surgeons, Pfizer instructed its sales representatives to leave 20 mg samples of Bextra with all types of doctors. This included doctors, such as rheumatologists, whose use for Bextra would be to treat chronic arthritis pain - the type of use that the FDA medical review had specifically determined that Bextra was neither safe, nor more effective, at doses over 10 mg/day, and as to which no compendium referenced in the Medicaid drug reimbursement statute had approved doses greater than 10 mg/day.

c. Pfizer and Pharmacia Promoted Off-Label Uses of Bextra Through "Clinical Seminars"

114. So-called "clinical seminars" were another essential component of Pfizer and Pharmacia's Bextra off-label marketing strategy. At these seminars, which were presented by doctors paid by Pfizer and Pharmacia as medical consultants, attending doctors (who were frequently paid money to attend on the pretense that they would provide "consulting" information to Pfizer and Pharmacia (see Part B(1), infra), or at the very least were provided with a free meals, accommodations and/or travel expenses), physicians would be immersed in information about Bextra's use for the management of post-surgical pain and other acute pain at doses above 10 mg/day. Such seminars would not disseminate information regarding the FDA medical review's findings that Bextra was neither safe nor more effective for chronic arthritis pain at doses above 10 mg/day.

115. For example, Exhibit 26 is the announcement and invitation for a February 11, 2003 seminar on "Current Clinical Trends: Cox-2 Inhibition and Pain Management," presented by Jeffrey A. Gudin, M.D., in Ft. Lauderdale, Florida." Exhibit 27 is a copy of the slides for the presentation given at that meeting. These slides prominently mention the use of Bextra ("valdecoxib") at doses of 20 mg and 40 mg twice daily for post-surgical pain, see Exhibit 27 at 3, 5. Although one slide lists the FDA-approved usages of osteoarthritis, rheumatoid arthritis, and primary dysmenorrhea, it identifies them only as usages for which "efficacy and clinical utility of BEXTRA have been demonstrated," rather than as the FDA-approved uses. See Exhibit 27 at 5 top right slide. The slides fail to indicate the FDA's concerns about the use of Bextra for chronic arthritis pain at dosages above 10 mg/day. Rather, immediately following the slide regarding the use of Bextra for chronic arthritis pain, for which no suggested dosage is indicated, the next slide discussed the use of Bextra (valdecoxib) at doses of 40 mg for post-operative oral surgery pain. See Exhibit 27 at 5, cf., top right slide with middle left slide.

4. Pfizer And Pharmacia Improperly Minimized And Disregarded Bextra's Serious Health Risks

116. In promoting Bextra, Pfizer and Pharmacia disregarded patient safety, and improperly minimized or misrepresented health risks. Examples of this disregard for patient safety abound throughout this Complaint, but the following examples are particularly illustrative.

117. Pfizer affirmatively misrepresented Bextra's side effects to prescribers. The attached Exhibit 4 is a printout of PowerPoint slides from a January 27, 2003 presentation to Pfizer sales personnel. The middle slide on page 9 explicitly instructs sales personnel to provide misleading information about safety. This slide states "Safety Data: GI [gastro-intestinal]¢Only in Celebrex Section, CV [cardiovascular]¢Only in Bextra Section. . . Rationale . . . Halo Effect!

Physicians assume data apply to both products."

118. In other words, in Exhibit 4, the sales personnel were told to discuss only Celebrex safety for the issues where Celebrex was purportedly better than Bextra, and to discuss only Bextra safety for the issue where Bextra was purportedly better than Celebrex. They were explicitly told that the purpose of this was to mislead the doctors into thinking that the favorable safety information presented applied to both drugs (the "Halo Effect"), when in fact it clearly did not. This clearly demonstrates Pfizer's plan to promote the sale of Bextra through the dissemination of intentionally confusing data and information, and by withholding from physicians information regarding potential safety issues with the use of Bextra.

119. Likewise, Pfizer also actively minimized known health risks of Bextra. For example, on October 2, 2002, Rick Burch, a senior vice-president of sales at Pfizer, sent an email (see Exhibit 3, including attachments to the email) to Pfizer regional and district sales managers. This email provided a copy of an important safety announcement that the FDA made Pfizer send to healthcare professionals advising of reports of serious and life-threatening allergic and skin reactions occurring with some persons taking Bextra. The real purpose of the email, however, was to transmit the other attachment to the email - the "Backgrounder: Dear Healthcare letter on BEXTRA Safety Information." While labeled "Do Not Detail," meaning do not share with physicians, that label was placed solely to maintain plausible deniability. This "backgrounder" was actually intended to provide Pfizer sales representatives with sales points designed to minimize the marketing damage that the notice of adverse reactions could cause - sales points such as "no deaths reported in relation to those incidents," "small number of cases," and similar reactions occurring in competing drug products.

120. That Mr. Burch's October 2, 2002 email was motivated by sales concerns, rather

than a concern over adequately informing doctors about a potential danger from Bextra, is abundantly clear from the last lines of the email:

> We should also take this opportunity to reinforce our POA3 [marketing] messages.
>
> The most recent NRx share as of September 20th is 8%!
>
> - Bextra Provides Rapid and Powerful Relief
> - Bextra Provides Superior Effectiveness because it works in **Tough Pain** with **Fast Onset** and **Once a Day Dosing**.
> - Bextra has achieved very high patient and physician satisfaction with more than 800,000 patients treated and 2.3 million prescriptions written in a very short time period.

121. Finally, the attached Exhibit 5 contains a message from "Mark," meaning national sales director Mark Brown, to the "Agents of Change," which were the district sales managers in charge of promoting Bextra. The message discusses a study showing that Vioxx, another pain reliever that is in the same "COX-2" class as Celebrex and Bextra, had potential cardiac safety issues. Mr. Brown makes the following comment:

> It is not approved [for providing to doctors] but every representative should know of its contents. Representatives should not run out blitzing this information. Since negative information on any COX II sometimes hurts all COX II's it should be mentioned or discussed only after careful consideration of the impact it may have with that specific doctor."

The message was clear: if a representative was concerned that sharing this safety information about a related COX-2 drug might reduce a doctor's likelihood to prescribe any COX-2 drug, including Celebrex and Bextra, the representative was instructed not to share this safety information with the doctor. However, if the representative believed that sharing this safety information about Vioxx might convince a doctor to prescribe Celebrex and Bextra instead of Vioxx, the representative was instructed to share the information.

122. These are just a few examples of Pfizer and Pharmacia's disregard for patient

safety. As set forth above, Pfizer and Pharmacia aggressively promoted Bextra for uses and dosages that were not found to be safe by the FDA.

B. Pfizer And Pharmacia Paid Substantial Financial Inducements To Influence Physicians' On-Label And Off-Label Prescriptions Of Bextra

1. Pfizer and Pharmacia Improperly Paid Prescribers To Attend Promotional Meetings

123. Pfizer and Pharmacia utilized paid "consultant meetings" to improperly disseminate their promotional messages about Bextra. Although the meetings were purportedly for the purpose of providing independent advice on Bextra, in fact, the consultant meetings were little more than promotional events coupled with financial inducements for prescribing physicians.

124. Physicians invited to the meetings were not asked for advice or expert consultation. Instead, Pfizer and Pharmacia invited and paid high-prescribing - and potentially high-prescribing - physicians to listen to both off-label and on-label promotion to influence their prescribing practices. Hundreds of consultant meetings were conducted across the country. Typically, between 50 to 150 physicians would attend as paid consultants," although on occasion as many as several hundred prescribers would attend.

125. Pfizer and Pharmacia typically paid the physician participants between $250 and $1,500 each to simply attend a single consultant meeting. The doctors also received travel expenses, accommodations at luxury hotels and meals. The "honorarium" payments did not reflect the value of services provided. The physician was not required to do anything but show up to receive his or her payment. In addition, Pfizer and Pharmacia had no legitimate business reason to hire hundreds, if not thousands, of "consultants" - who were also high or potentially high prescribers - to "consult" with Pfizer and Pharmacia about a single drug. Each of these

payments constituted a reward or kickback for the purpose of influencing the prescribing practices.

126. In most cases, the physician participants were selected to attend the "consultant meetings" based on the strength and history of their Bextra prescriptions and the potential to grow their market, rather than on their leadership or distinction in professional practice. Pfizer and Pharmacia targeted physicians with "high decile" prescribing activity, or the potential for high prescribing activity. Pfizer and Pharmacia invited such physicians to participate in the consultant meetings in order to influence and increase their future prescribing activity.

127. The "consultant meetings" included presentations by doctors paid by Pfizer as medical consultants, and attending doctors (who were paid money to attend, in the pretense that they would provide "consulting" information to Pfizer and Pharmacia, and or at the very least were provided with a free meals, accommodations and travel expenses), physicians would be provided information about Bextra's usage for the management of post-surgical pain and other acute pain at doses above 10 mg/day. Such meetings would not disseminate information regarding the FDA medical review's findings that Bextra was not safe or more effective for chronic arthritis pain at doses above 10 mg/day.

128. Pfizer and Pharmacia's sales representatives were involved to assure that the doctors that they marketed to in fact attended such programs. For example, the attached Exhibit 28 is a copy of emails concerning orthopedic surgeons invited to attend "Fall Cox-2 [Bextra and Celebrex] programs." It is sent by Nicole Parker, assistant to the Pfizer "Rheum[atology]/Ortho[pedics]/Neuro[logy] East Sales Director," who is Mark Brown. The email was forwarded by Matthew Lustig, South Florida district sales manager for RON, to his "Sharks" marketing team asking them to "Please follow-up with our docs (in red) making sure

they get their invites in." The sales representatives were well aware of the following facts: (a) at these programs non-FDA-approved uses of Bextra would be presented; (b) attending physicians were paid fees, allegedly for "consulting," to attend these programs, up to $1,500; and (c) attending physicians who began writing more Celebrex and Bextra prescriptions after attending such programs would be invited back to attend more programs and receive more "consulting" fees and other perks, while physicians who did not do so would not be invited back and would receive no further "consulting" fees. Thus, while these programs were disguised as "consulting" arrangements, in actual operation these programs provided financial incentives to doctors to prescribe Bextra more frequently.

129. Similarly, the attached Exhibit 29 shows that Nicole Parker forwarded information to Matthew Lustig regarding a Pain Management Consultants' Meeting taking place April 26-28, 2002, in Miami, Florida. Matthew Lustig forwarded this information to his "Sharks' marketing team. The marketing purpose of this meeting is made clear by Mr. Lustig's statement: "We have a number of people [doctors] going to this meeting. If any of them want to golf let me know, I will be there." Thus, Mr. Lustig was asking his representatives to determine if their doctors were going, and whether those doctors would want to play golf with the district sales manager Mr. Lustig.

130. This strategy of promoting non-FDA-approved uses of Bextra began even before Bextra was available for distribution. The attached Exhibit 30 is a slide presentation (attached to an email showing its distribution throughout the country) that was presented at a "District Consultant's Initiative Orlando" in February 2002. This was a meeting of physicians ostensibly retained by Pfizer as "Consultants." This slide presentation provided information about non-approved used of Bextra - post-surgical pain relief for dental surgery and hip replacement

surgery. This slide presentation was not just presented in Orlando, but was widely disseminated to sales representatives throughout the country.

131. Other examples of slide presentations made to physicians, in which non-FDA-approved uses of Bextra were promoted, are Exhibit 31 ("Introducing: A New Cox-2 Specific Inhibitor" and "Pain Considerations: Surgery and Acute Injuries"). Both presentations blatantly promote Bextra for the use of acute pain, and fail to advise doctors of the serious safety concerns in the FDA medical review about the use of Bextra at dosages above 10 mg/day for chronic arthritis pain.

132. The "consultants' meetings" were a critical component of Pfizer and Pharmacia's marketing efforts for Bextra. The attached Exhibit 9 is a "January 2003 POA Resource Guide" which advises sales representatives how to market Bextra and Celebrex. Included within this guide is a section titled "Medical Education Resources" which references the following program referenced as a "Promotional Program" - a "National Cox-2 Speaker Development" program consisting of "a total of 4 meetings to train approximately 300 physicians on the latest data on Celebrex and Bextra in order for them to serve as primary regional and district speakers in 2003." See Exhibit 9 at 32. Relator John Kopchinski has personal knowledge that these programs included information on non-approved usages of Bextra, and that it was fully intended that these physicians would disseminate that information to other physicians.

2. Pfizer Used Paid "Clinical Paper Reviews," "Preceptorships," "Journal Clubs." And Speaking Events To Induce Physicians To Prescribe Bextra

a. Pfizer Paid Physicians For Clinical Paper Reviews

133. Pfizer also offered physicians kickbacks in the form of payments for reviewing clinical papers selected by Pfizer. The clinical paper reviews were putatively for sales

representatives' training and education. Providers were given reprints to review and discuss for 20 or 30 minutes with a sales representative. Although the training was supposedly for the Pfizer and Pharmacia sales representatives, in fact, the sales force was already familiar with the materials being reviewed.

134. Pfizer typically paid providers an average of $500, (usually from $250 to $1,000), to read and review the reprint material with a sales representative. That meeting usually took about half an hour or less to complete.

135. Material that was eligible for "clinical reprint reviews" included articles covering both on-label and off-label uses of Bextra. With respect to the "on label" materials, sales representatives were already well-versed in their content. Review of such materials was not intended to train Pfizer sales representatives. Rather, it was an opportunity for Pfizer to pay physicians for listening to product promotion.

136. The "off-label" reprints are permitted to be discussed only in response to providers' unsolicited questions. "Training" on such materials subverted this restriction by providing off-label information directly to the physician for discussion with the Pfizer sales representative.

137. In many cases, Pfizer sales representatives had already received training on the reprints at sales meetings. Indeed, in many instances, the sales representative "trained" on the same reprint multiple times. Thus, the educational value of such training to the representatives was low to nonexistent. However, it was extremely beneficial commercially for Pfizer and Pharmacia because it purchased guaranteed physician exposure to both on-label and off-label uses of Bextra.

138. Many of the physicians who participated in the paid clinical reprint reviews did so

repeatedly, and often also participated in numerous other paid events, including "consultants' meetings," speaker's training, and preceptorships. Such repeated opportunities to participate in paid events were offered as financial inducements to influence the physicians' prescribing practices and to ensure product loyalty.

b. Pfizer's "Preceptorships" Compensated Physicians Generously For Sales Representatives "Shadowing" Them

139. Pfizer also conducted a "preceptorship" program in which physicians were paid as much as $1,000, to be "shadowed" by a Pfizer sales representative for part of the work day. By "pairing up" with the physician, the sales representative was able to promote over a period of many hours, without the usual problems of gaining access to prescribing physicians.

140. Preceptorships were an important means by which off-label and on-label promotion of Bextra was conducted. In essence, the "preceptorships" amounted to Pfizer buying access to prescribing physicians.

141. Preceptorship payments were offered to high prescribing physicians, and physicians whose prescribing patterns could be developed, shifted or strengthened. They were extended both to convey promotional on-label and off-label information, and to influence prescribing behavior with cash payments.

142. The top Bextra prescribers (or prescribers with the market potential to become top prescribers) were targeted by Pfizer for paid preceptorships. Indeed, top prescribers received multiple paid preceptorships, in some cases six or more a year. As mentioned above, these top prescribers also received additional payments for speaking, clinical reprint reviews and other paid promotional programs.

c. Pfizer Paid Physicians To Participate In "Journal Clubs," And Speaker "Roundtables"

143. Pfizer also paid $250 to $1,000 honoraria to physicians who attended and moderated "journal clubs." Typically, the "journal club" would involve 3 or 4 participants - usually rheumatologists - who once a month convened to discuss a clinical paper.

144. Each "club" meeting was moderated by a physician who was paid a generous honorarium by Pfizer. The moderator position rotated every month among the club members.

145. The clinical paper discussed at the roundtable was selected by Pfizer - not the participants - on the basis of its promotional value.

146. Again, physicians were invited to join the "journal club" based on their status as a top prescriber, or a potential top prescriber, rather than based on their professional distinction.

147. Similarly, top prescribers were also rewarded with speaking programs - generally, small roundtables with a few physicians. In most instances, roundtable talks covered Bextra's unapproved uses, as discussed above.

148. Physician speakers were paid $250 to $1,000 honoraria to make a roundtable presentation. In the case of some top prescribing physicians that it wanted to particularly reward and induce, Pfizer cut two separate honoraria checks for a single roundtable presentation.

149. In advance of the presentation, Pfizer sales representatives met with the paid physician-speakers and gave them the informational points that Pfizer wanted covered at the roundtable. The payments for and the contents of the roundtables were designed to influence physician prescribing practices, as well as to promote expansive and unapproved uses of Bextra.

150. "High decile" physicians targeted for Pfizer's various kickback programs also were invited to attend "speaker training" programs at luxury resort destinations, such as the Caribbean. In addition to airfare, luxury hotel accommodations and meals, invited physicians also received at least $1,000 to attend.

151. The speaker training trips were regarded as "rewards" for top prescribers, rather than true "training" sessions. Physicians who were not necessarily promising speaker prospects were invited to attend simply because of their high prescribing potential.

152. Pfizer's payments to physicians to participate in consultant meetings, clinical article reviews, journal clubs, preceptorships, speaker training and speaker roundtables, constitute rewards or kickbacks to influence the physicians' prescribing practices.

C. Pfizer And Pharmacia Caused The Submission of False or Fraudulent Claims to Federal And State Health Insurance Programs

153. As described below, Pfizer and Pharmacia between late 2001 to the present, knowingly violated the regulatory schemes described above in their marketing of Bextra. When they intentionally decided to employ these improper marketing practices and kickbacks to promote Bextra, Pfizer and Pharmacia knew or should have known that pharmacists and physicians would routinely and necessarily file false and fraudulent claims with the federal government when they sought federal and state reimbursement for Bextra prescriptions. But for Pfizer and Pharmacia's actions most, if not all, of the false claims for the prescription of Bextra would never have been filed. Pfizer and Pharmacia substantially benefited from all of the false and fraudulent claims described herein.

154. Indeed, Pfizer actively promoted sales to Medicaid patients. For example, a June 4, 2002 email from Matthew Lustig, a South Florida district sales manager (with a copy to national sales director Mark Brown) advise how to "get Bextra and Celebrex approved with United Health Care." The attachments to the email show that United Health Care's enrollees included many "Medicaid Lives," including 32,809 in Orlando, Florida, and that such lives were being "targeted" by Pfizer.

155. Pfizer and Pharmacia were aware that the off-label marketing practices caused the submission of claims for usages of Bextra that were not approved by the FDA nor approved for reimbursement under Medicaid, and thus were illegal false claims under Medicaid. As part of their routine marketing efforts, Pfizer and Pharmacia prepared charts for their sales representatives showing the percentages of market share for various drugs.

156. An example of such a chart is the attached Exhibit 32. This chart was prepared by Pfizer for the Relator John Kopchinski. The "RON" indication in the top indicates that Mr. Kopchinski was a representative marketing to rheumatologists ("R"), Orthopedists ("O"), and Neurologists ("N") - thus, Mr. Kopchinski did not market to any doctors who would treat primary dysmenorrhea, the one condition for which 20 mg dosages were FDA-approved. The therapeutic class at issue in this sales report was the "ARTHRITIS" market - i.e., the condition for which FDA approval was strictly limited to 10 mg/day; for which no compendia listed in the Medicaid drug reimbursement statute listed an approved usage for over 10 mg/day; and for which the FDA medical review expressed serious concerns about the safety and effectiveness of dosages over 10 mg/day.

157. A consideration of the relative sales percentages of Bextra 10 mg/day versus 20 mg/day in this sales report shows how successful Pfizer's and Pharmacia's scheme to promote the off-label usage of Bextra was. For the arthritis market, 10 mg/day was the only FDA-approved usage - thus, no 20 mg tablets should be prescribed. On the Medicaid side, some limited usage of 20 mg tablets might be expected, for doctors who perform orthopedic surgery, for the non-FDA-approved, but at some point compendium-approved, limited usage for post-surgical pain. This usage, however, would be only a very small percentage of any such market.

158. However, the sales table shows a steady increase in the relative percentage of 20

mg tablets versus 10 mg tablets in the "arthritis" market. In April of 2002, 10 mg had a 0.5 percent market share, 20 mg a 0 percent market share. By January of 2003, however, 20 mg tablets were 8.2 percent of the market, compared with 8.0 percent for 10 mg tablets. Based on Mr. Kopchinski's personal knowledge gained from his marketing experience with Bextra, only a small amount of the use of 20 mg tablets, 5 percent or less, can be accounted for as compendium-approved post-surgical pain- the remaining amounts represent usage of Bextra 20 mg tablets for chronic arthritis pain, or for other acute or chronic pain for which there was no FDA or Medicaid compendia approval.

159. Pfizer's illegal marketing and kickbacks practices caused the submission of false or fraudulent claims to federal and state health insurance programs. In the case of Medicaid, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, all states require the prospective Medicaid provider to agree that he/she will comply with all Medicaid requirements, including the fraud and abuse provisions. Some states, such as Florida, have provider agreements that expressly provide that the submission of a Medicaid claim is an express certification that the provider has complied with all Medicaid requirements. In other states, such as Massachusetts, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the state Medicaid program, including compliance with Federal Regulations. In these states, submission of a Medicaid claim is an express certification by the provider that the services for which reimbursement are sought are eligible for Medicaid reimbursement and that the provider has complied with all Medicaid requirements.

160. Even in those states in which submission of a Medicaid claim does not constitute an express certification, the Medicaid Provider Agreement conditions participation in the

Medicaid Program with compliance with all state and federal Medicaid statutes and regulations. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicaid patients. By submitting a claim for Medicaid reimbursement in these states, the provider implicitly certifies that the submitted claim is eligible for Medicaid reimbursement and that the provider is in compliance with all state and federal Medicaid requirements.

161. To summarize, pursuant to the terms of each state's provider agreements or the claim forms used to submit claims, all pharmacists and physicians expressly or impliedly certify that the claims they have submitted are eligible for Medicaid payment and that the providers have complied with the statutes and regulations relating to Medicaid.

162. Medicaid claims for the payment of off-label Bextra prescriptions or for Bextra prescriptions induced by illegal kickbacks, are filed with the states by the pharmacists who fill the Medicaid patients' prescriptions. In most cases, the pharmacist will not know whether the prescription is on-label or off-label (prescriptions are not required to state the patient's diagnosis), and consequently, does not know whether the prescription is for a medically acceptable use, and consequently, a covered out-patient drug under Medicaid. Likewise, the pharmacist does not know whether the prescription has been induced by a kickback. Nonetheless, because such prescriptions are not eligible for federal or state reimbursement, submission of such a claim for reimbursement constitutes a false or fraudulent claim under the federal False Claims Act, 31 U.S.C. §3729, and the States' analogous false claims statutes. And, those who knowingly cause such false or fraudulent claims to be filed, as Pfizer and Pharmacia has through its fraudulent practices, are liable under the federal False Claims Act, 31 U.S.C. §3729, and the States' analogous false claims statutes

163. Pfizer and Pharmacia knew that off-label and kickback-induced prescriptions of Bextra were not eligible for federal and state health care program reimbursement. Notwithstanding their knowledge that Bextra prescriptions induced by kickbacks or manufacturer off-label promotion were not eligible for federal and state reimbursement, Pfizer and Pharmacia knowingly undertook such practices to increase both off-label and on-label Bextra prescriptions. But for their illegal promotion and kickback practices, most of the ineligible claims for payment of Bextra prescriptions would have never been filed. Every Bextra prescription caused by Pfizer and Pharmacia's off-label promotion of Bextra and financial inducements is a false or fraudulent claim for payment under 31 U.S.C. §3729, and the States' analogous false claims statutes.

164. All conditions precedent to the initiation or maintenance of this action have been performed or have occurred.

165. The Relator has retained the undersigned attorneys to represent him in this action and is obligated to pay them a reasonable fee for their services.

Count I
False Claims Act 31 U.S.C. §§3729(a)(1) and (a)(2)

166. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

167. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

168. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

169. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts,

to induce the Government to approve and pay such false or fraudulent claims.

170. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

171. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across the United States. Relator has no control over or dealings with such entities and has no access to the records in their possession.

172. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by defendants paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

173. By reason of defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by defendants.

Count II
False Claims Act 31 U.S.C. §3730(h)

174. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

175. Beginning in January 2003, and continuing to the date of filing this Complaint, Relator has taken actions to investigate the allegations set forth herein; to set the stage for the initiation of this lawsuit; and to assist undersigned counsel in the preparation of the instant Complaint, and in preparing to disclose Pfizer's and Pharmacia's fraudulent scheme to the

appropriate governmental officials.

176. These actions were fully lawful, and are protected actions of Relator pursuant to 31 U.S.C. § 3730(h), the federal False Claim Act's anti-retaliation action.

177. On Friday, March 7, 2003, Relator was terminated without cause from his position as a marketing representative of Pfizer. While Pfizer informed Relator that he was terminated for allegedly participating in his supervisor's theft of medications (including controlled substances) from Pfizer and from a doctor's office, this is wholly a pretense. Relator is the person who, at great risk to his career, reported his supervisor's misconduct. Further, Relator suffered wholly improper and illegal retaliation for reporting that misconduct.

178. On information and belief, Relator was fired, in whole or in part, because Pfizer learned of his federally protected efforts with respect to the instant Complaint, False Claims Act lawsuit, and disclosure to the appropriate governmental officials.

Count III
California False Claims Act
Cal Govt Code §12651(a)(1) and (2)

179. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

180. This is a claim for treble damages and penalties under the California False Claims Act.

181. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

182. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

California State Government to approve and pay such false and fraudulent claims.

183. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

184. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across California. Relator has no control over or dealings with such entities and has no access to the records in their possession.

185. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

186. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

187. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count IV
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1) and (2)

188. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

189. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

190. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

191. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

192. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

193. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Delaware. Relator has no control over or dealings with such entities and has no access to the records in their possession.

194. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

195. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

196. The State of Delaware is entitled to the maximum penalty of $11,000 for each and

every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count V
Georgia False Medicaid Claims Act
Ga. Code Ann. §49-4-168

197. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

198. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

199. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

200. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

201. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

202. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Georgia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

203. The Georgia State Government, unaware of the falsity of the records, statements

and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

204. By reason of the defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

205. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VI
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

206. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

207. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

208. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

209. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

210. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance

program represents a false or fraudulent claim for payment.

211. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Hawaii. Relator has no control over or dealings with such entities and has no access to the records in their possession.

212. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

213. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

214. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VII
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1), (2)

215. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

216. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

217. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

218. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

219. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

220. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Illinois. Relator has no control over or dealings with such entities and has no access to the records in their possession.

221. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

222. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

220. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VIII
Indiana False Claims and Whistleblower Protection Act
Ind. Code Ann. §5-11-5.5-1

223. Relator realleges and incorporates by reference the allegations contained in

paragraphs 1 through 165 of this Complaint.

224. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

225. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

226. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

227. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

228. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Indiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

229. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

230. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

231. The State of Indiana is entitled to the maximum penalty of $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count IX
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1), (2)

232. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

233. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

234. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

235. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

236. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

237. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Massachusetts. Relator has no control over or dealings with such entities and has no access to the records in their possession.

238. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

239. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

240. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count X
Michigan Medicaid False Claims Act
Mich. Comp. Laws. §§400.601 et seq.

241. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 165 above as though fully set forth herein.

242 This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

243. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

244. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

245. Each prescription that was written as a result of defendants' illegal marketing

practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

246. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Michigan. Relator has no control over or dealings with such entities and has no access to the records in their possession.

247. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

248. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

249. Additionally, the Michigan State Government is entitled to the maximum civil penalties for each and every violation alleged herein.

Count XI
Montana False Claims Act
Mont. Code Ann. §17-8-401

250. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

251. This is a claim for treble damages and penalties under the Montana False Claims Act.

252. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or

approval.

253. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

254. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

255. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Montana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

256. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

257. By reason of the defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

258. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XII
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a), (b)

259. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

260. This is a claim for treble damages and penalties under the Nevada False Claims Act.

261. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

262. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

263. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

264. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Nevada. Relator has no control over or dealings with such entities and has no access to the records in their possession.

265. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

266. By reason of the defendants' acts, the State of Nevada has been damaged, and

continues to be damaged, in substantial amount to be determined at trial.

267. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIII
New Hampshire False Claims Acts
N.H. Rev. Stat. Ann. §167.61

268. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

269. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

270. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

271. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

272. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

273. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous entities across New Hampshire. Relator has no control over or dealings with such entities and

has no access to the records in their possession.

274. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

275. By reason of the defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

276. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIV
New Jersey False Claims Act
N.J. Stat. §§2A:32C-3(a), (b) and (g)

277. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 165 above as though fully set forth herein.

278. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

279. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

280. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

281. Each prescription that was written as a result of defendants' illegal marketing

practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

282. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across NewJersey. Relator has no control over or dealings with such entities and has no access to the records in their possession.

283. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

284. By reason of the defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

285. Additionally, the New Jersey State Government is entitled the maximum civil penalty of $11,000 for each and every violation alleged herein.

Count XV
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. §27-2F-1

286. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

287. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

288. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or

approval.

289. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

290. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

291. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across New Mexico. Relator has no control over or dealings with such entities and has no access to the records in their possession.

292. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

293. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

294. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVI
New York False Claims Act
N.Y. State Fin. §187

295. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

296. This is a claim for treble damages and penalties under the New York False Claims Act.

297. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

298. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

299. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

300. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across New York. Relator has no control over or dealings with such entities and has no access to the records in their possession.

301. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

302. By reason of the defendants' acts, the State of New York has been damaged, and

continues to be damaged, in substantial amount to be determined at trial.

303. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVII
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 §5053

304. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

305. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

306. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

307. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

308. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

309. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Oklahoma. Relator has no control over or dealings with such entities and

has no access to the records in their possession.

310. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

311. By reason of the defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

312. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVIII
Rhode Island False Claims Act
R.I. Gen. Laws §9-1.1-3(a)(1), (2), and (7)

313. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 165 above as though fully set forth herein.

314. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

315. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

316. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

317. Each prescription that was written as a result of defendants' illegal marketing

practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

318. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Rhode Island. Relator has no control over or dealings with such entities and has no access to the records in their possession.

319. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

320. By reason of the defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

321. Additionally, the Rhode Island State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIX
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

322. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

323. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

324. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or

approval.

325. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

326. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

327. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Tennessee. Relator has no control over or dealings with such entities and has no access to the records in their possession.

328. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

329. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

330. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XX
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

331. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

332. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

333. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

334. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

335. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

336. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Texas. Relator has no control over or dealings with such entities and has no access to the records in their possession.

338. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used defendants' illegal off-label marketing practices and/or illegal inducements.

339. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

340. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XXI
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1), (2)

341. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

342. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

343. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

344. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

345. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

346. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Virginia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

347. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

348. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

349. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XXII
Wisconsin False Claims for Medical Assistance Act
Wis. Stat §§20.931(2)(a), (b), and (g)

350. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 165 above as though fully set forth herein.

351. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.

352. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

353. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

354. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And,

each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

355. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across Wisconsin. Relator has no control over or dealings with such entities and has no access to the records in their possession.

356. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used defendants' illegal off-label marketing practices and/or illegal inducements.

357. By reason of the defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

358. Additionally, the Wisconsin State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXIII
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §1-1188.14(a)(1), (2)

359. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 165 of this Complaint.

360. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

361. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

362. By virtue of the acts described above, defendants knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims. .

363. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

364. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the District of Columbia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

365. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and/or illegal inducements.

366. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

367. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Prayer

WHEREFORE, Relator prays for judgment against the defendants as follows:

1. that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the state statutes set forth above;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the States and the District of Columbia's statutes set forth above;

4. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt Code §12651(a);

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. §49-4-168.1(a);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

9. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus a civil penalty of $5,000 for each violation of Ind. Code Ann. §5-11-5.5-2(b);

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mich. Comp. Laws §400.601;

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1)(a), (b);

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of N.J. Stat. § 2A:32C-3;

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. §167.61-b(I);

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §189(1);

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63 §5053.1(B);

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws §9-1.1-3(a).

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §71-5-182(a)(1);

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

22. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a)(1), (2);

23. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat §20.931(2);

24. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §1-1188.14(a)(1), (2);

25. that Relator be awarded double back pay, front pay, and any special damages caused by his firing pursuant to §3730(h) of the federal False Claims Act;

26. that Relator be reinstated to the same seniority status he would have held but for his unlawful firing;

27. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the federal False Claims Act, and the equivalent provisions of the state statutes set forth above;

28. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

29. that Relator recover such other relief as the Court deems just and proper, or that is necessary to make Relator whole.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

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