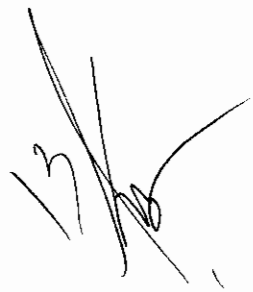
UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA EX REL. [UNDER SEAL]	)	C.A. No. 03-60494 (J. Hurley)
Plaintiffs,	)	
v.	)	FIRST AMENDED COMPLAINT
[UNDER SEAL]	)	
Defendant	)	

FILED IN CAMERA AND UNDER SEAL



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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA EX REL. JOHN KOPCHINSKI Plaintiffs, v. PFIZER, INC. and PHARMACIA CORP. Defendants	C.A. No. 03-60494 (J. Hurley) FIRST 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]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 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]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [H.B. 468, 46th Legisl., 2nd Sess. (New Mexico 2004) (enacted, not yet codified)]; 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.]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.13 et seq.] FILED IN CAMERA AND UNDER SEAL JURY TRIAL DEMANDED

Plaintiff John Kopchinski, through his attorneys Phillips & Cohen LLP and Ausley & McMullen PA, on behalf of the United States of America, the State of California, the State of Delaware, the State of Hawaii, the State of Illinois, the State of Massachusetts, the State of Nevada, the State of New Mexico, the State of Tennessee, the State of Texas, the State of Virginia 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 Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, HCw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Mexico Medicaid False Claims Act, H.B. 468, 46th Legisl., 2nd Sess. (New Mexico 2004) (enacted, not yet codified); 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.; 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]

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

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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.

found in, reside, or transact or have transacted business in the Southern District of Florida.

16. Venue is proper in the Southern District of Florida 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.

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 7, 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 8. 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 8) 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 8 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 10mg/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 8 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 8 at 7 ¶6 "Dosing." Using less technical terms, the FDA concluded that Bextra, when used for long periods of time at doses over 10mg 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 10mg/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 8 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 8 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 8 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 20mg/day."

Exhibit 8 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