IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION
CASE NUMBER:_____

UNITED STATES OF AMERICA ex rel. JOHN KOPCHINSKI,	)
Plaintiff,	)
v.	)
PFIZER, INC., and PHARMACIA CORPORATION,	)
Defendants .	)

COMPLAINT

(QUI TAM COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. 3730(b)(2))

SYNOPSIS

1. This is an action pursuant to the Federal False Claims Act, 31 U.S.C. §§3729 *et seq.*. This action arises from the causation of thousands of false claims to Medicaid by Defendants Pfizer, Inc. ("Pfizer") and Pharmacia Corporation ("Pharmacia"). As set forth more fully below, Pfizer and Pharmacia engaged in a systematic course of fraudulent conduct designed to cause the submission of false Medicaid claims by physicians and pharmacists for unapproved uses of Pfizer and Pharmacia's new patented drug **Bextra**. 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.

2. Pfizer and Pharmacia's fraudulent scheme involved deliberate disregard of federal Food and Drug Administration ("FDA") regulations concerning off-label promotion and conduct

designed to hide such disregard from the regulatory authorities; deliberate misrepresentations to physicians of the evidence regarding the safety and efficacy of off-label usage of Bextra; deliberate creation of publications designed to appear to be written by neutral independent researchers, when in fact such publications were created and written by Pfizer and Pharmacia and their agents; dissemination of such publications to physicians, supposedly in response to independent requests from such physicians, but in fact based upon "requests" solicited by marketing representatives, or sent with no actual physician "request" at all; medical seminars ostensibly for "consulting" but actually designed to promote off-label use of Bextra to physicians; promotion of usages of Bextra at dosages that were neither effective nor safe, through the provision of misleading articles and information by sales representatives to physicians; and other methods designed to promote the use of Bextra for off-label, unsafe, unapproved, and ineffective usages, all for the purpose of significantly increasing the sales of Bextra.

PARTIES

3. Relator John Kopchinski ("Kopchinski" or "Relator") is a resident of the State of Florida in Broward County, 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.

4. 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.

5. 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.

6. Relator Kopchinski was hired directly out of the Army in January 1992 by the then Chief Executive Officer and Chairman of Pfizer, Inc., 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.

7. Defendant Pfizer, Inc. ("Pfizer") 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 Thirty Two Billion Dollars.

8. Pharmacia Corporation ("Pharmacia") 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 Fourteen Billion Dollars.

9. 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 are in the process of merging. As a result of the merger, the surviving corporation, which is anticipated to be Pfizer, will be responsible for the liabilities of both Pfizer and Pharmacia for the actions set forth herein.[1]

10. 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).

JURISDICTION AND VENUE

11. Jurisdiction is based on 31 U.S.C. §3730 and 28 U.S.C. § 1331.

12. At all times material hereto, Pfizer and Pharmacia regularly conducted substantial business within the Southern District of Florida, maintained permanent employees and offices in

[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, fifth page, "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, p. 3 ("Pfizer/Pharmacia Alliance"), p. 6 ("Co-promote territories (most major markets)"), p. 7 ("New Pfizer/Pharmacia Cox-2 Alliance Structure").

In any event, the currently occurring merger of Pfizer and Pharmacia will render this issue moot, as the surviving entity, which is expected to be Pfizer, will be responsible for the liabilities of both Pfizer and Pharmacia.

the Southern District of Florida, and made and are making significant sales within the Southern District of Florida. Accordingly, Pfizer and Pharmacia are subject to personal jurisdiction in the State of Florida.

13. Venue is appropriate in the Southern District of Florida pursuant to 28 U.S.C. §1391(b)(1) and (2).

FACTS

The Medicaid Program

14. More prescription drugs are purchased through the Medicaid program than through any other insurance program in the United States. The federal government provides most of the funds used to purchase these pharmaceuticals (depending on the state and its economic condition, between 50 to 83%). To try and prevent waste, fraud and abuse, the Medicaid program restricts the types and uses of drugs which may be paid for with federal funds. Additionally, federal regulations prohibit certain marketing practices which have a propensity to lead to the unnecessary and ineffective prescription of pharmaceuticals. These regulatory schemes are designed to insure that Medicaid only pays for drugs which are found to be safe and effective for their prescribed uses, and to insure that physicians who prescribe such drugs do not have ulterior motives for prescribing drugs that will be purchased with federal funds.

The Regulatory Scheme Limiting Reimbursement of Drugs Under Medicaid

15. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the pharmaceutical has proven to the Food and Drug Administration (FDA) that the drug is safe and effective for specific indications at specified dosages. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to prescribe approved drugs for

indications or at dosages different than those set forth in a drug's labeling, The Food Drug and Cosmetic Act prohibits drug companies from marketing or promoting approved drugs for uses other than those set forth in the drugs' approved labeling. This regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body.

16. The Medicaid program relies on the FDA's findings regarding what uses for approved drugs are safe and effective. In 1990, Congress passed the Omnibus Budget Reconciliation Act of 1990, which limited reimbursement for prescription drugs to "covered outpatient drugs." Covered outpatient drugs only include drugs used for "medically accepted indications." A medically accepted indication is a use which has been approved by the FDA or one which is supported by specific compendia set forth in the Medicaid statute. *See* 42 U.S.C. § 1396r-8(k)(b) and (g)(1)(B). To date, only one of the compendia referenced in the statute supports an off-label usage of Bextra, and that usage is for a significantly limited purpose—far more limited than the scope of Pfizer and Pharmacia's marketing of Bextra. Further, even with respect to this limited off-label usage, any prescriptions written for this off-label usage, prior to the publication of the edition of this compendium including this off-label usage, were not entitled to reimbursement under Medicaid.

17. Medicaid law prohibits billing Medicaid for a use of a drug that is neither FDA-approved nor listed as an approved medical usage in one of the compendia listed in the Medicaid drug reimbursement statute. Causing the submission of a claim to Medicaid for such a use of a drug is both fraudulent and illegal, and is a false claim pursuant to the Federal False Claims Act.

Pfizer and Pharmacia's Scheme to Defraud Medicaid

18. In this *qui tam* action Kopchinski reports that his employer, Pfizer, in conjunction with Pharmacia, knowingly and deliberately engaged in conduct they knew would lead to the violations of state and federal Medicaid statutes and regulations designed to restrict Medicaid reimbursement for one of Pfizer and Pharmacia's patented drugs, Bextra. Pfizer and Pharmacia did not directly provide Bextra to the Medicaid program or issue prescriptions for the drug. Instead, Pfizer and Pharmacia embarked on a course of unlawful conduct that they knew would lead to the submission by physicians and pharmacists of thousands of Medicaid claims for Bextra when such prescriptions were not eligible for Medicaid reimbursement. Although most of the physicians and pharmacists were unaware that their Medicaid claims were ineligible for reimbursement, Pfizer and Pharmacia knew their actions would inevitably cause these Medicaid providers to submit false claims to the federal government. Relator Kopchinski, in the name of the United States, seeks to hold Pfizer and Pharmacia liable for knowingly causing these false claims to be presented to the United States for payment in violation of 31 U.S.C. § 3729.

Pfizer and Pharmacia's Highly Aggressive Marketing Goals and Plans for Bextra

19. Bextra is Pfizer and Pharmacia'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 Pharmacia, and the competing drug Vioxx. The COX-2 class of drugs is designed to relieve various forms of pain and inflammation.

20. Pfizer and Pharmacia's highly 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." This presentation sets forth Pfizer

and Pharmacia's aggressive goal that Celebrex and Bextra combined would move from sales of $9 Billion in 2001, for Celebrex alone, to sales of $15 Billion or more by 2005, for Bextra and Celebrex combined. *See* Exhibit 2, p. 16. For Bextra alone, Pfizer and Pharmacia were shooting for sales of $350 Million in 2002, Bextra's first year on the market; and sales of $1 Billion for Bextra by 2004. *See* Exhibit 2, p. 21.

21. 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 and Pharmacia were not going to allow the federal Food and Drug Administration's ("FDA") limited approval of Bextra, discussed more fully below, to block these aggressive plans. The presentation acknowledges that, while the FDA only approved Bextra for chronic arthritis and menstrual pain,[2] Pfizer and Pharmacia 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, p. 13. Despite this, the presentation makes it clear that Pfizer and Pharmacia still intended to market Bextra for "perioperative pain," and were aggressively pursuing clinical trials on Bextra for many types of acute pain. *See* Exhibit 2, p. 12 (Bextra will pursue "perioperative pain"); pp. 42-44 (clinical trials on Bextra and acute pain).

22. As set forth more fully below, Pfizer and Pharmacia pursued their aggressive marketing goals for Bextra by promoting Bextra for uses and dosages that the FDA had found were not safe and not effective, and for uses and dosages that were not approved for reimbursement by Medicaid.

Pfizer and Pharmacia's Motivation to Circumvent the FDA's Limited Approval of Bextra

[2] OA, RA, and Dysmenorrhea, meaning osteoarthritis, rheumatoid arthritis, and menstrual pain.

23. In late 2001, Pfizer and Pharmacia obtained regulatory approval of the federal Food and Drug Administration ("FDA") for certain limited usages of Bextra. The FDA's limited approval—far more limited than the scope of the approval sought by Pfizer and Pharmacia—frustrated Pfizer and Pharmacia's overall intended marketing scheme for Bextra and resulted in their fraudulent marketing scheme to circumvent the FDA's limited approval.

24. As discussed above, Pfizer and Pharmacia's overarching business goal was to establish their prior drug Celebrex, in combination with their new drug Bextra, as the dominant products in the market for non-aspirin non-narcotic acute and chronic pain relief. To fulfill that goal, however, Pfizer and Pharmacia needed Bextra to be prescribed and dispensed for a broad range of chronic and acute pain conditions—far broader than the indications actually approved by the FDA.

25. The FDA's limited approval of Bextra seriously hampered Pfizer and Pharmacia's marketing plans. Pfizer and Pharmacia are prohibited from marketing their products for purposes not approved by the FDA. The proper procedure Pfizer and Pharmacia should have followed, to expand their marketing of Bextra beyond these boundaries, was to conduct additional research, submit such research to the FDA, and have the FDA evaluate and approve Bextra as safe and effective for the additional usages.

26. This FDA approval process, however, can take years, and is by no means guaranteed. Furthermore, in order 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 without loss of sales to competitors. After this period, other companies can market "generic" versions of the drug; and thus, the

company holding the original patent loses market share, and consequently sales to, generic competitors.

27. Thus, to maximize their profits during the effectiveness of the patent of Bextra, Pfizer and Pharmacia embarked on the fraudulent and illegal scheme described herein, designed to convince physicians to prescribe Bextra for non-approved usages. This scheme violated the FDA laws and regulations concerning marketing of drugs; violated the Medicaid drug reimbursement statutes and regulations; and is estimated to have already resulted in the submission of hundreds of thousands of false claims for Medicaid reimbursement, pursuant to the Federal False Claims Act.

Pfizer and Pharmacia's Disregard for Patient Safety

28. Throughout their marketing of Bextra, Pfizer and Pharmacia have displayed a disturbing disregard for the safety of the patients taking Bextra. Examples of this disregard for patient safety abound throughout this Complaint, but the following examples are particularly graphic.

29. 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 was forcing Pfizer and Pharmacia to 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.

30. 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.

31. Similarly, 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."

32. 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 and Pharmacia'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.

33. 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.

34. These are just a few glaring examples of Pfizer and Pharmacia's disregard for patient safety. As set forth below, Pfizer and Pharmacia aggressively promoted Bextra for uses and dosages that were not found to be safe by the FDA.

Pfizer and Pharmacia's Causation of False Claims to Medicaid

35. As described below, Pfizer and Pharmacia, between late 2001 to the present, knowingly and intentionally violated the regulatory schemes described above in their marketing of Bextra. When they intentionally decided to employ these improper marketing practices to

promote Bextra, Pfizer and Pharmacia knew or should have known that pharmacists and physicians would routinely and necessarily file false claims with the federal government when they sought federal 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 were the indirect beneficiaries of all of the false claims described herein.

36. Pfizer and Pharmacia actively promoted sales to Medicaid patients. For example, the attached Exhibit 6 contains a June 4, 2002 email from Matthew Lustig, a South Florida district sales manager (with a copy to national sales director Mark Brown) advising 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.

The FDA's Limited Approval of Bextra for Certain Purposes Only

37. In November 2001, the FDA approved Bextra for the following limited indications: (a) for treatment of osteoarthitis, 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")

38. 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.

The FDA's Determinations That Bextra Was Unsafe or Not Effective For Other Purposes or at Higher Dosages

39. Despite these deletions from the report, it is evident from the remaining portions of the report 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 10-80mg 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, p. 3 item 1B. Thus, and as set forth more fully below, it is clear from the non-deleted portions of the FDA medical report that the FDA'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.

40. For example, with respect to the approved use of Bextra with respect to chronic arthritis, the FDA medical review indicates significant concern about the safety of dosages higher than the approved dosage of 10 mg/day:

> 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, p. 3 ¶ 2(a).

> Valdecoxib [Bextra] should be limited to 10 mg/d[ay] in chronic use in OA and RA [chronic arthritis]. At this does 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, p. 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.

41. 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 80mg/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, paragraph spanning pages 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 obviously 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 20mg/twice a day.

42. In addition to the FDA's concerns about the safety of long-term use of Bextra at doses over 10mg/day, the FDA also concluded that long-term use of Bextra at dosages over 10mg/day were no more effective in relieving chronic arthritis pain than dosages of 10mg/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, p. 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, p. 6 "Arthritis" (emphasis added).

43. The FDA medical report shows that Pharmacia and Pfizer requested approval of Bextra for general use in acute pain. The report quotes the "sponsor'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, p. 4 section 3, "Overview of Clinical Program," "Analgesia." Thus, it is apparent from the report that the FDA specifically rejected the following proposed uses of Bextra: (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, and to use Bextra and Celebrex in combination to dominate the market for non-aspirin non-narcotic acute and chronic pain relief.

Pfizer and Pharmacia's Scheme to Promote Bextra for Non-FDA-Approved Usages

44. Despite the FDA's decision, Pfizer and Pharmacia decided to employ a strategy that would allow them to promote Bextra, for uses or dosages not approved by the FDA, by the following steps: (a) publish articles regarding the use of Bextra for non-FDA approved usages, and then disseminate these articles to doctors; (b) hold seminars with doctors, allegedly as "consultants" to the companies, which had as their actual purpose the promotion of Bextra for non-approved usages; (c) provide scripts and information to sales representatives to use in marketing Bextra for off-label usages; (d) through these methods, promote the use of Bextra 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; (e) through these methods promote the usage of Bextra for acute pain generally; and (f) through these methods, promote the usage of Bextra for non-FDA approved uses, and for uses not approved by any compendia listed in the Medicaid reimbursement statute.

Promotion of Bextra for Chronic Arthritis at Doses Greater Than 10mg/day

45. Pfizer and Pharmacia provided sales scripts and marketing materials to its sales representatives that were designed to encourage doctors to prescribe Bextra for chronic arthritis at dosages above 10mg/day (either by prescribing 20 mg or more, or by prescribing 10mg twice a day rather than once a day). These scripts and marketing materials were designed to convey two false impressions: (a) that doses of Bextra above 10 mg/day were more effective for chronic arthritis than a dose of 10mg/day; and (b) that doses of Bextra above 10 mg/day were safe for long-term use for chronic arthritis.

46. An example of such a script is provided as Exhibit 9. This script was materially misleading in the following respects:

a. The script begins by talking about the use of Bextra for arthritis pain:

> Doctor, today I'm going to ask you to do something different. I'm going to ask you to prescribe Bextra ahead of Vioxx in your patients suffering from arthritic pain.

b. The script ends by talking about the use of Bextra for arthritic pain:

> Today when you see a patient suffering from a painful arthritic condition, will you prescribe Bextra 10 mg ahead of Vioxx?

c. In the middle, however, the script mixes and matches information regarding chronic arthritis pain relief versus acute pain relief, to create the false and misleading impression that Bextra is safe and more effective for chronic arthritis at doses above 10 mg/day. For example:

> 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.

This discussion is misleading, inaccurate, and inappropriate because: (a) it suggests that Bextra may be used for chronic arthritis at doses above 10 mg/day—however, such doses for chronic arthritis are not approved by the FDA nor indicated in any of the relevant compendia; (b) it suggests that Bextra is approved at doses of 20 mg and 40 mg for any acute nonarthritic pain, whereas the FDA has only approved Bextra for acute pain of dysmenorrhea, and the only compendium to list another usage restricted that usage to postoperative pain; (c) in the context of a discussion about the use of Bextra for arthritis pain, it discusses dosages that

are not approved for arthritis pain, and invites the doctor to review a study using higher doses for relieving acute postoperative pain; and (d) in the context of a discussion of the use of Bextra for arthritis pain, it discusses the use of dosages (20 mg/day and 40mg/day) that were found by the FDA to be unsafe for chronic arthritis pain, and to be no more effective than 10 mg/day.

d. The script is also materially misleading in its discussion of the safety of Bextra. 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 flat out wrong. 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).

47. Scripts such as this were part of a national scheme by Pfizer and Pharmacia to promote such unapproved 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 9. This email was, however, copied to Mark Brown, a national sales director for Pfizer, who was involved in creating the script.

48. 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 and Pharmacia's overall marketing strategy, and is fully consistent with Pfizer and Pharmacia's disturbing disregard for the safety of patients taking Bextra, discussed in an above section.

49. This strategy went beyond attempts to mislead and cause confusion into outright lies and misrepresentations. Exhibit 4, already discussed above in the section on Pfizer and Pharmacia's disregard for patient safety, contains a middle slide on page 14 that references concerns about "the cardio-renal profile of Vioxx" and then states "Bextra offers impressive cardio-renal safety." Given the clear 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.

50. The strategy of promoting Bextra for chronic arthritis uses at more than the FDA-approved 10 mg/day came straight from the top. 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 40mg for chronic arthritis use—clearly at odds with 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 questions suggesting chronic arthritis use of Bextra at doses above 10mg/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?

There were several clear answers to these questions: (a) the FDA had not approved Bextra for 20 mg dosing for chronic arthritis; (b) the FDA medical review had found that 20 mg was no more effective than 10 mg for chronic arthritis; and (c) the FDA medical review had 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.

51. Because of the FDA indication limiting use to 10 mg/day for chronic arthritis, some pharmacists and insurers resisted filling 20 mg prescriptions of 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.

Promotion of Bextra for General Acute Pain Uses That Were Not Medically Approved

52. The only use of Bextra for acute pain that is FDA-approved is for primary dysmenorrhea. The only other use of Bextra for acute pain that is eligible for Medicaid reimbursement, at least currently, is the compendium-referenced use of Bextra for certain post-surgical pain.

53. Despite this, Pfizer and Pharmacia aggressively marketed Bextra as 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 and Pharmacia expected its sales representatives to mention this potential use to physicians.

54. 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.

55. An example of this strategy is the attached Exhibit 9, 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 attempts to create the impression that Bextra is generally approved for any type of acute pain.

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

57. Another example of promoting general acute pain use, and showing that it came from the very top, is the 2/19/2002 list of questions and answers distributed by Mark Brown, a national sales director, to his district sales managers. *See* Exhibit 1. The fourth page of that

document lists "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?

There is a very simple answer to questions 2 and 3: MARKETING BEXTRA FOR GENERAL ACUTE PAIN WITHOUT AN FDA INDICATION FOR GENERAL ACUTE PAIN IS ILLEGAL!!! Nevertheless, Mr. Brown chose to disseminate this document to sales representatives and sales managers without providing this very simple answer.

Promotion of Protocols for Non-FDA Approved Usages

58. As part of the scheme to promote Bextra for non-approved usages, Pfizer and Pharmacia encouraged its sales representatives to convince physicians to include Bextra on their form "protocols" for certain procedures. An example is Exhibit 11. This is an email from Matthew Lustig, a South Florida district manager, to his "Sharks" asking "where are our protocols?" It 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," which attached a prior email attaching 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," is attached as the second page of the email.

59. Thus, Exhibit 11 shows that Pfizer and Pharmacia discussed the development of form protocols for doctors at sales meetings, encouraged its marketing sales representatives to develop such protocols with physicians, and provided its marketing sales representatives with monetary incentives to develop such protocols. All of this was for usages of Bextra, in pre- and post-surgical pain, that were not FDA-approved.

60. Nor was this protocol in compliance with the one compendium which had indicated a "medically approved" 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, however, *see* Exhibit 12, 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. Nothing in this compendium entry indicates 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.

61. The development of drug protocols was an essential and formal component of Pfizer and Pharmacia's promotional efforts. The attached Exhibit 10 is a "January 2003 POA Resource Guide" which advises sales representatives how to market Celebrex and Bextra. In the section titled "Portfolio Resources," it includes a document titled "Pain Management Protocols and Standing Orders Management Tool," which is described as telling "how to identify opportunities for introducing and/or updating protocols and standing orders," and "how to successfully implement new protocols and standing orders."

Promotion of Bextra for the Non-FDA-Approved Use for Post-Surgical Pain

62. Pfizer and Pharmacia actively promoted the use of Bextra for post-surgical pain, a use not approved by the FDA. This promotion took the following forms:

a. As discussed below, Pfizer and Pharmacia sponsored research into the use of Bextra for post-surgical pain.

b. As discussed more fully below, Pfizer and Pharmacia employees co-authored articles regarding research into the use of Bextra for post-surgical pain.

c. As discussed more fully below, Pfizer and Pharmacia encouraged its sales representatives to convince doctors to "request" medical information, and in response to such solicited "requests" 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 clearly indicating that the FDA had not approved Bextra for the general management of acute pain.

d. As discussed above, Pfizer and Pharmacia encouraged and rewarded their sales representatives to develop form surgical protocols in which Bextra would be listed as a standard part of a physician's routine surgical procedures and orders.

63. In addition to the above, 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.

64. One example of such information was the email attached as Exhibit 13. In this email, 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. Sales representatives were encouraged, in this non-FDA-approved

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.

65. Another example is the email attached as Exhibit 14. In this email, 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 proceeds to advise that it attaches "an easy to follow review of the Oral Surgery Study with Bextra. This is the study that Medical Inquiry sends out upon request." In other words, it clearly advised marketing 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 clearly advised the sales representatives that the information provided would help them in promoting Bextra. It was further common knowledge among Pfizer and Pharmacia 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 and Pharmacia representatives would use the referenced information to promote Bextra.

66. The pretense that the email attached hereto as Exhibit 14 was not intended for selling is completely shattered 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 14, attached article summary, section titled "Sales Strategy."

67. Another example of the promotion of Bextra for the non-FDA-approved use of post-surgical pain is the attached Exhibit 15, 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." The attached comparison compares Bextra vs. Toradol for the management of acute post-surgical pain. Nowhere in this comparison is it indicated that Bextra has not been FDA-approved for such a usage.

The Dissemination of Misleading Articles Regarding Off-Label Usages of Bextra

68. Although federal regulations did not permit Pfizer and Pharmacia to promote non-FDA approved uses of Bextra, they were permitted to distribute publications created by third parties that described results of off–label use of Bextra, provided such material was only distributed in response to **non-solicited** requests from physicians. Pfizer and Pharmacia decided to exploit this narrow exception by encouraging their 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.

69. Mr. Kopchinski has personal knowledge of this sales practice. In his district, 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.

70. 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 and Pharmacia 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 and Pharmacia 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 and Pharmacia'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.

71. Examples of such "medical information" are attached as Exhibit 16 (an article regarding the use of Bextra as an analgesic for hip surgery) and Exhibit 17 (an article regarding use of Bextra as an analgesic for oral surgery).

72. Exhibit 16, the hip surgery article, was based on work sponsored entirely by Pharmacia and Pfizer. *See* Exhibit 16, p. 49, Acknowledgement. Three of the four authors work for Pharmacia Corporation or for its affiliate Pharmacia Europe Ltd. *See* Exhibit 16, title page, authors names and associated footnotes.

73. Exhibit 17, the oral surgery article, was based on work sponsored by Pharmacia and Pfizer. Three of the five authors work for Pharmacia. *See* Exhibit 17, p. 621.

74. Both articles were prepared in "reprint" form by Pharmacia and Pfizer. *See* initial pages to Exhibit 16 and Exhibit 17. 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 and Pharmacia 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.

75. The dissemination of such articles, while designed to be ostensibly only the dissemination of articles in response to unsolicited requests from physicians, was actually a cornerstone of Pfizer's and Pharmacia'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 18. 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 and Pharmacia'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."

76. 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.

77. Sales representatives of Pfizer and Pharmacia were provided with copies of such articles, and were expected to use such articles in their marketing efforts. For example, the attached Exhibit 19 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.

78. In further example, Exhibit 20 is a copy of a May 2002 memorandum from Pharmacia 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 20 summarizes and attaches the oral surgery study attached hereto as Exhibit 14. The memorandum is clearly labeled "This memo is for your information only. Not to be shown to healthcare providers." *See* Exhibit 20, bottom of page 1 and 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 20, page 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.

79. 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 21 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**."

80. Exhibit 22 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 23, 24, and 25 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.

81. This publication strategy was not limited to certain departments or regions of Pharmacia or Pfizer. The attached Exhibit 26 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.**

The memorandum then proceeds to summarize various articles, including articles about non-FDA-approved uses for post-surgical pain. *See* Exhibit 26, attached memo, pages 4-6. Again, while this memorandum includes the traditional statement about not being used for marketing purposes, Pfizer and Pharmacia representatives were well aware that this information was being provided to them for use in their marketing efforts.

Leaving Samples for Unapproved Uses

82. The only FDA-approved usages of Bextra for a 20 mg/dose was in the treatment of dysmenorrhea (painful menstruation). Therefore, the only physicians who would have any

use, with respect to FDA-approved usages of Bextra, for 20 mg samples of Bextra would be gynecologists and primary care physicians treating female patients.

83. Despite this, Pfizer and Pharmacia provided all of their sales representatives with 20 mg samples and instructed their sales representatives to leave such samples with all physicians, whether or not such physicians treated female patients for dysmenorrhea. The clear 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.

84. This practice was also designed to promote the usage of Bextra for uses not approved by any Medicaid-referenced compendia. The only non-FDA approved usage listed 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 usage was non-FDA approved, it was, **after** the publication of this compendium entry, eligible for Medicaid reimbursement. However, such uses would be limited to dentists and orthopedic surgeons, and Pfizer and Pharmacia 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 for the treatment of chronic arthritis pain—the type of usage for which the FDA medical review had specifically determined that Bextra was neither safe, nor more effective, at doses over 10 mg/day, and for which no compendium referenced in the Medicaid drug reimbursement statute had approved usage at more than 10 mg/day.

Promotion of Non-Approved Uses of Bextra Through "Clinical Seminars"

85. Another essential component of Pfizer's and Pharmacia's attempts to promote Bextra for non-FDA-approved medical usages were "clinical seminars." 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, in the pretense that they would provide "consulting" information to Pfizer and Pharmacia, or at the very least were provided with a free mail and/or 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 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.

86. For example, Exhibit 27 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 28 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 28 p. 3 and page 5. While one slide does list the FDA-approved usages of osteoarthritis, rheumatoid arthritis, and primary dysmenorrhea, it lists them not as the FDA-approved usages, but only as usages for which "efficacy and clinical utility of BEXTRA have been demonstrated." Nowhere do the slides indicate that those usages are the only FDA approved usages. *See* Exhibit 28, p. 5 top right slide. Nowhere do the slides 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 28, p.5, *cf.* top right slide with middle left slide.

87. 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

29 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 $1500.00; 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.

88. Similarly, the attached Exhibit 30 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.

89. This strategy of promoting non-FDA-approved uses of Bextra began even before Bextra was available for distribution. The attached Exhibit 31 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.

90. Other examples of slide presentations made to physicians, in which non-FDA-approved uses of Bextra were promoted, are Exhibit 32 ("Introducing: A New Cox-2 Specific Inhibitor") and Exhibit 33 ("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.

91. The clinical seminars were an essential and formal component of Pfizer and Pharmacia's marketing efforts for Bextra. The attached Exhibit 10 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 10, p. 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.

Pfizer's and Pharmacia's Knowledge That Their Marketing Practices Were Causing the Submission of Claims for Bextra for Non-Approved Usages

92. Pfizer and Pharmacia were well aware that their marketing practices were causing 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.

93. An example of such a chart is the attached Exhibit 34. 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.

94. 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 small percentage of any such use.

95. 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 .5 % market share, 20 mg 0% market share. By January of 2003, however, 20 mg tablets were 8.2% of the market, compared with 8.0% 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% 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.

Pfizer and Pharmacia's Causation of False Claims

96. Each physician and pharmacist that participates in Medicaid 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.

97. 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.

98. 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.

99. Medicaid claims for the payment of off-label Bextra prescriptions 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. Nonetheless, because such prescriptions are not eligible for Medicaid reimbursement, submission of such a claim for reimbursement constitutes a false claim for the purposes of 31 U.S.C. § 3729. A pharmacist who does not know the claim is ineligible has not knowingly submitted a false claim and is not liable to the United States pursuant to § 3729(a). However, a person who *knowingly causes* such a claim to be filed, as Pfizer and Pharmacia did through their fraudulent marketing efforts, is liable for causing a false claim pursuant to § 3729.

100. Pfizer and Pharmacia knew that off-label prescriptions of Bextra were not eligible for Medicaid reimbursement. Both were aware of the passage of 42 U.S.C. §1396r-8 and its limitations on Medicaid reimbursement for prescription drugs. Notwithstanding their knowledge that off-label prescriptions of Bextra were not medically accepted uses eligible for Medicaid reimbursement, Pfizer and Pharmacia knowingly and intentionally took steps to increase the number of off-label Bextra prescriptions submitted to Medicaid. But for their promotion of off-label uses, most of the ineligible claims for payment of Bextra prescriptions would have never been filed. Every off-label Bextra prescription caused by Pfizer and Pharmacia's off-label promotion of Bextra is a false claim caused by Pfizer and Pharmacia for the purposes of 31 U.S.C. § 729.

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

102. 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 CAUSED BY KNOWING PROMOTION OF PRESCRIPTION SALES INELIGIBLE FOR MEDICAID REIMBURSEMENT

103. Relator repeats and re-alleges each and every allegation contained in Paragraphs 1 through 102 as if fully set forth herein.

104. Although Bextra has been on the market less than a year, it is estimated that as of March 2003 Pfizer and Pharmacia have already caused the submission of hundreds of thousands of false claims by knowingly promoting to Medicaid providers sales of Bextra for off-label uses not eligible for Medicaid reimbursement.

105. Every prescription for Bextra which was not written for a medically acceptable use, and that was submitted to Medicaid, constitutes a false claim. Pfizer and Pharmacia are liable, pursuant to 31 U.S.C. § 3729, for each of those false claims which would not have been written but for their off-label promotion of Bextra. At the time they engaged in such unlawful promotional activities, Pfizer and Pharmacia knew that off-label prescriptions for Bextra were ineligible for Medicaid reimbursement and that their activities would, in fact cause numerous ineligible prescriptions to be submitted to Medicaid. Had Pfizer and Pharmacia not engaged in such promotions, state and federal funds would not have been used to pay for prescriptions that were not qualified to be reimbursed by Medicaid.

106. In order to cause ineligible claims to be submitted to Medicaid, Pfizer and Pharmacia engaged in a systematic and extensive course of fraudulent conduct. This conduct included deliberate disregard of FDA regulations concerning off-label promotion and conduct designed to hide such disregard from the regulatory authorities, deliberate misrepresentations to physicians of the evidence regarding the safety and efficacy of off-label usage of Bextra; deliberate creation of publications designed to appear to be written by neutral independent researchers, when in fact such publications were created and written by Pfizer and Pharmacia and their agents; dissemination of such publications to physicians, supposedly in response to independent requests from such physicians, but in fact based upon "requests" solicited by marketing representatives; and medical seminars promoting off-label use of Bextra to physicians.

107. Relator cannot identify at this time all of the false claims which were caused by Pfizer and Pharmacia's conduct. The false claims were submitted by pharmacists with whom the Relator has had no dealings and the records of the false claims are not within the Relator's control. Indeed, specification of the vast number of false claims would be burdensome to the

Court and the parties. Given the vast number of false claims, their scope and complexity, Realtor is excused from the requirement of specifying each false claim. The time period of the false claims, however, was from the introduction of Bextra in March 2002 through to the present. Such claims were made and are being made across the entire United States.

108. As a result of Pfizer and Pharmacia's actions, the United States has paid directly or indirectly hundreds of thousands of false claims and spent hundreds of millions of dollars on prescriptions for Bextra for uses that have not been proved to be safe or effective. Congress, the federal government, and the individual states never intended to make such payments and would have never made such payments but for the conduct of Pfizer and Pharmacia. Although Pfizer and Pharmacia did not submit the claims and did not directly receive the payments from the states and the United States, they have been the greatest beneficiary from this pattern of unlawful conduct, filling hundreds of thousands of prescriptions for Bextra which would have never been placed but for their unlawful conduct.

WHEREFORE, the Plaintiff demands judgment on behalf of the United States, pursuant to 31 U.S.C. § 3729(a) and 28 CFR § 85.3(9), for:

(a) three times the damages caused to the Medicaid Program through the payment of claims for uses of Bextra not eligible for Medicaid reimbursement;

(b) civil penalties of $ 11,000.00 for each Medicaid prescription reimbursed for uses of Bextra not eligible for Medicaid reimbursement;

(c) all attorney's fees and costs reasonably incurred by the United States in connection with this action;

(d) prejudgment interest; and

(d) all other relief to which the United States may be entitled.

The Relator also demands judgment for himself personally, pursuant to 31 U.S.C. § 3730(d), for:

(a) thirty percent (30%) of the amount recovered;

(b) an award of reasonable attorney's fees and costs incurred by the Relator;

(c) prejudgment interest;

(d) all other relief to which the Relator may be personally entitled.

COUNT II

UNLAWFUL RETALIATION AGAINST RELATOR IN VIOLATION OF THE FEDERAL FALSE CLAIMS ACT

109. Relator incorporates the allegations of paragraphs 1 through 102 as if fully set forth herein.

110. 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.

111. 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.

112. 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.

113. 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.

WHEREFORE, Relator demands judgment against Pfizer for all damages authorized by 31 U.S.C. § 3730(h), including but not limited to: (a) reinstatement to the same seniority status he would have held but for his unlawful firing; (b) double the amount of back pay; (c) interest on back pay; (d) front pay; (e) any special damages caused by his firing; (f) reasonable attorney's fees and costs; and (g) any other relief necessary to make Relator whole.

PLAINTIFF DEMANDS A TRIAL BY JURY ON ALL CLAIMS.

Dated this _____ day of March, 2003.

KATZ, KUTTER, ALDERMAN AND BRYANT, P.A.

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RALPH C. LOSEY (Florida Bar No. 0296414)
ALAN HARRISON BRENTS (Florida Bar No. 0949639)
111 North Orange Avenue, Suite 1400 (32801)
Post Office Box 4950, Orlando, Florida 32802-4950
Telephone: (407) 841-7100
Facsimile: (407) 648-0660

and

PATRICIA IRELAND (Florida Bar No. 0200018)
801 Pennsylvania Avenue, N.W., Suite 750
Washington, D.C. 20004
Telephone: (202) 393-6222
Facsimile: (202) 393-5959
Attorneys for Plaintiff, United States of America ex rel. John Kopchinski