

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

LINDA A. WATTERS, COMMISSIONER,
OFFICES OF FINANCIAL AND
INSURANCE SERVICES FOR THE STATE
OF MICHIGAN IN HER CAPACITY AS
REHABILITATOR OF THE WELLNESS
PLAN AND IN HER CAPACITY AS
LIQUIDATOR OF MICHIGAN HEALTH
MAINTENANCE ORGANIZATION PLANS,
INC., FORMERLY KNOWN AS
OMNICARE HEALTH PLAN, INC.,
FRANKENMUTH FINANCIAL GROUP,
INC., INDIVIDUALLY AND ON BEHALF
OF ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

PFIZER INC., PHARMACIA CORP., and
G.D. SEARLE, LLC.

Defendants.

JUDGE : Cleland, Robert H.
DECK : S. Division Civil Deck
DATE : 04/12/2005 @ 16:35:43
CASE NUMBER : 2:05CV71434
CMP WATTERS V. PFIZER (KC)

CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

MAGISTRATE JUDGE KOMPALL

PRELIMINARY STATEMENT

1. Plaintiffs bring this action on behalf of themselves and all other similarly situated entities nationwide ("Third Party Payors") who paid for the drug Bextra (the "Class"), manufactured by Defendants Pfizer, Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle, LLC. ("Searle").

2. Non-steroidal anti-inflammatory drugs (“NSAIDs”) have been widely used to treat arthritis, acute pain, and chronic pain for nearly forty years. Although they relieve symptoms in certain patients, such relief comes at the expense of important adverse effects, most notably upper gastrointestinal toxicity. Use of NSAIDs leads to hospital admission for ulcer complications (bleeding and perforation) in approximately 1% of users annually and results in thousands of deaths every year.

3. The emergence of NSAIDs that selectively inhibit the cyclo-oxygenase 2 (“COX-2”) isoform, which is inducible and expressed at sites of inflammation, while sparing cyclo-oxygenase 1 (“COX-1”), associated with gastroprotection, was an apparent pharmacological breakthrough promising hope of a better future for NSAIDs.

4. Bextra was one of the new COX-2 inhibitors, as were Celebrex and Vioxx. Defendants believed that Bextra had the potential to be a new blockbuster drug with yearly sales in the billions of dollars, following on the heels of Celebrex and Vioxx, and thus promoted the drug as a panacea, offering all the benefits of less expensive NSAIDs with none of the drawbacks.

5. As part of the unlawful scheme set forth below, Defendants embarked on a significant marketing campaign directed to both doctors and consumers to accomplish this objective. Promotional materials, as well as sponsored studies and planted articles, gave the impression that Bextra was a “breakthrough” drug far superior to older and much less expensive NSAIDs.

6. Defendants’ marketing and promotion of Bextra was part of a scheme to create the impression of, and demand for, Bextra as a wide-ranging pain reliever, particularly for the treatment of arthritis pain. The scheme was accomplished by unlawful means including, but not limited to, the (i) suppression of data showing cardiovascular risks associated with the use of Bextra, (ii) suppression of data showing risks of serious and potentially life-threatening skin reactions, (iii) manipulation of data to give the

appearance of superiority over other NSAIDs when such superiority did not exist, (iv) false promotional materials directed to doctors and consumers, and (v) use of reprinted articles from prestigious medical journals that falsely claimed Bextra was proven to be safer than other NSAIDs.

7. As a result of Defendants' scheme, they were able to sell Bextra at a premium price over other NSAIDs and have it become a standard treatment option as opposed to less expensive NSAIDs. In 2004, Defendants reported sales of Bextra totaling more than \$1.2 billion.

8. The success of Defendants' scheme was recently documented in a study released on January 24, 2005, in the ARCHIVES OF INTERNAL MEDICINE, Volume 165, entitled *National Trends in Cyclooxygenase-2 Inhibitor Use Since Market Release*. The authors of that study concluded that "aggressive marketing techniques to patients and physicians" caused a growth not only in the use of COX-2 inhibitors, but also in overall market demand, resulting in the use of such drugs by patients who did not need them. In fact, Bextra has been promoted as a superior pain reliever when, for most patients, it has no proven superiority over other NSAIDs.

9. Bextra sells for between \$2.60 and \$5.80 per pill depending upon the dose, while other NSAIDs such as naproxen and ibuprofen sell for approximately \$0.06 to \$0.31 per pill. Billions of dollars have thus been wasted, as Plaintiffs and Class members have paid a premium price for a drug that is neither a premium nor a superior product. Had the truth been told about its safety and efficacy, Bextra would have sold at a price similar to that of other NSAIDs and would not have become a standard in the treatment of arthritis and other forms of pain relief. The study in the ARCHIVES OF INTERNAL MEDICINE found that 63% of patients who received COX-2 inhibitors were at a low risk for developing the ulcers and gastrointestinal problems that the COX-2 inhibitors were aimed

at preventing, and that Defendants' marketing scheme played a significant role in overuse of COX-2 inhibitors for this type of patient.

10. Defendants' promotional campaign targeted a broad spectrum of patients and resulted in increased use by patients with low GI risk, for whom other NSAIDs were a cheaper and equally effective option. Given the rising cost of health care for these patients, there is no reason, other than Defendants' financial interests, for so many to use Bextra.

11. In this action, Plaintiffs seek damages arising from the overpayments made by the Class on purchases of Bextra resulting from Defendants' illegal scheme.

PARTIES

12. Plaintiff Linda A. Watters, Commissioner, Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc. is a Michigan official whose function is to collect and liquidate all assets and liabilities of the former private third party payers Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness Plan and OmniCare were private third party payers whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. During times relevant to this lawsuit, Wellness Plan and OmniCare paid for prescriptions of valdecoxib (bextra). Plaintiff Frankenmuth Financial Group, Inc., is a Michigan Corporation headquartered in Saginaw County, Michigan. At all times relevant to this Complaint, Frankenmuth Financial group, Inc., was a third party payer whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. During times relevant to this lawsuit, Frankenmuth Financial Inc. paid for prescriptions for valdecoxib (bextra).

13. Defendant Pharmacia is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia has been engaged in the business of marketing and selling Bextra nationwide and in Michigan.

14. Defendant Pfizer is a Delaware corporation with its principal place of business in New York. In 2003, Pfizer acquired Pharmacia for nearly \$60 billion. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Bextra nationwide and in Michigan.

15. Defendant Searle is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Bextra nationwide and in Michigan.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961-1968.

17. This Court also has subject matter jurisdiction under the Class Action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a new subsection (d) and confers federal jurisdiction over class actions where, as here, “any member of a class of Plaintiffs are citizens of a State different from any defendant” and the aggregated amount in controversy exceeds five million dollars (\$5,000,000). See 28 U.S.C. § 1332(d)(2) and (6).

18. This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and because Defendants systematically and continually conduct business throughout the State of Michigan, including marketing, advertising, and sales directed to Michigan residents.

19. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, and Plaintiffs may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391 and 18 U.S.C. § 1965. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through providers and sales representatives who reside or transact business in this District, and thereby affected Class Members who similarly reside or transact business in this District.

FACTUAL BACKGROUND

Development of Bextra

20. Bextra is one of the new entries in a class of pain medications called non-steroidal anti-inflammatory drugs (“NSAIDs”). Aspirin, naproxen, and ibuprofen are examples of well-known NSAIDs.

21. NSAIDs reduce pain by blocking the body’s production of pain transmission enzymes called cyclo-oxygenase or “COX.” There are two forms of COX enzymes—COX-1 and COX-2.

22. In addition to transmitting pain sensations, COX-1 is involved in maintaining and repairing gastrointestinal tissue.

23. In addition to transmitting pain sensations, COX-2 is involved in the production of prostacyclin, a substance responsible for preventing the formation of blood clots.

24. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body’s ability to repair gastric tissue and causes harmful gastrointestinal side effects, including stomach ulceration and bleeding.

25. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related

cardiovascular events, including heart attack, stroke, unstable angina, cardiac clotting, and hypertension.

26. Traditional NSAIDs like aspirin reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs cause ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but actually reduce the risk of clots and help protect heart function.

27. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs.

28. Defendants set out to remedy this problem by developing “selective” inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing pain sensations.

29. In making this decision, Defendants either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels, causes blood clots, and gives rise to various clot-related cardiovascular events, including heart attack, stroke, unstable angina, cardiac clotting, and hypertension.

30. Defendants launched Celebrex, the first of the three major selective COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of the new “blockbuster” drug over less expensive NSAIDs. Merck & Co., Inc. (“Merck”) launched Vioxx shortly thereafter and engaged in similarly deceptive advertising and marketing of its new COX-2 inhibitor.

31. Fearing loss of market share, Defendants sought approval of a second generation COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for

the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

32. In its pre-approval marketing plans, Defendants assumed that Bextra would be approved and that such approval would include an indication that it was safer than other NSAIDs in protecting against GI complications. The treatment of pain with reduced GI complications was the single most important attribute to the planned marketing and promotion of Bextra and its place as a new blockbuster drug.

33. Pre-approval marketing plans were to stress that Bextra was superior to other NSAIDs in terms of both science and safety, offering a significant reduction in GI complications.

34. The FDA granted approval of the new drug on November 16, 2001 for two particular uses: treatment of primary dysmenorrhea and relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

35. However, the agency did not grant approval of Bextra for the management or prevention of acute pain, finding it to be no better than other NSAIDs. Further, Defendants did not obtain approval to promote Bextra as more effective than other NSAIDs in preventing clinically serious GI events, a potentially serious blow to Defendants. As a result, the Bextra package inserts had to include a warning that its use presented “risk of GI ulceration, bleeding, and perforation.”

Studies on Bextra and Other COX-2 Inhibitors

36. Based on studies performed on Celebrex, Vioxx, Bextra, and other COX-2 inhibitors, Defendants knew by 1998 that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

37. Studies show that COX-2 inhibitors, including Bextra, decrease blood levels of a cardioprotective fat called prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

38. For example, in an effort to demonstrate that Celebrex had greater gastrointestinal safety than traditional NSAIDs, Defendants funded a clinical trial, the results of which were published in 2000: the Celecoxib Long-Term Arthritis Safety Study ("CLASS"). Defendants expected CLASS to show that Celebrex was statistically significant in reducing serious GI complications over traditional NSAIDs.

39. The CLASS trial was a long-term, double-blind study of gastrointestinal toxicity in 8,059 patients taking Celebrex, ibuprofen, or diclofenac to treat arthritis. Patients with heart problems were allowed to participate in the CLASS trial, and were permitted to take low doses of aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

40. When the CLASS study was completed, the results were reported to the U.S. Food and Drug Administration's Arthritis Drugs Advisory Committee (the "Committee") as part of a request to exempt Celebrex from including a gastrointestinal safety warning in its package insert. After reviewing the CLASS results, however, the Committee concluded that patients taking Celebrex had not experienced fewer gastrointestinal complications than those taking traditional NSAIDs. Moreover, the CLASS study demonstrated a trend toward cardiovascular risks for those taking the selective COX-2 inhibitor Celebrex.

41. A post hoc analysis and comparison of CLASS study patients taking low-dose aspirin for cardiac protection and patients not taking low-dose aspirin revealed that the rate of combined anginal adverse events was 1.4% in the celecoxib (Celebrex) group versus 1.0% in the ibuprofen and diclofenac groups. Although not a statistically significant difference, this tendency towards increased cardiovascular toxicity was

described by the FDA Medical Officer Dr. Witter, who stated that “[f]or anginal disorders (especially the combined disorders), there seems to be a trend toward more [cardiac adverse] events in those patients receiving celecoxib, regardless of aspirin use.

42. This trend was magnified in those patients not taking low-dose aspirin. Combined anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0% in the diclofenac and ibuprofen groups, respectively. There were also more combined atrial serious cardiac adverse events with celecoxib, 0.3% compared to 0.1% and 0% in the diclofenac and ibuprofen groups, respectively. Dr. Witter commented that “[i]n the non-aspirin users, there appears to be a slight trend toward more [serious cardiac adverse] events in those patients receiving celecoxib for combined atrial and anginal disorders.” Additionally, the rate of myocardial infarction was higher in the celecoxib group, 0.2%, compared with the other two drugs, 0.1%. Dr. Witter also referred to data from the original New Drug Application (“NDA”) for celecoxib in his discussion, stating that “[t]here were suggestions of a dose-response relationship (... 100mg BID celecoxib, 0% crude mortality rate vs. 400mg BID celecoxib, 0.64% crude mortality rate) between cardiovascular mortality and [increased] celecoxib use that could not be adequately addressed by the data.”

43. The FDA was concerned enough that they ordered a cardiorenal consult by Medical Officer Dr. Throckmorton on the same CLASS study data. In his report he noted, “[t]he CLASS trial data do not support a large adverse effect of celecoxib on cardiovascular mortality or on serious adverse events related to thrombosis relative to either diclofenac or ibuprofen. The data do not exclude a less apparent pro-thrombotic effect of celecoxib, such as might be reflected in the relative rates of cardiac adverse events related to ischemia.”

44. While none of the CLASS data was statistically significant, they revealed a consistent and worrisome trend toward increased cardiovascular toxicity, particularly that related to increased thrombosis.

45. Importantly, the reviewers' recommended that "[o]ur findings suggest a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors ... definitive evidence of such an adverse effect will require a prospective randomized clinical trial.... Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents. Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular morbidity." Although employing a placebo group from a different trial weakens the validity of their analysis, the author's call for a prospective randomized clinical trial powered to truly analyze the cardiovascular risk to benefit ratio was then exactly correct. A subsequent placebo-controlled trial of celecoxib clearly demonstrated this risk.

46. The subsequent trial was the APC colon polyp recurrence prevention study, in which approximately 2000 patients took celecoxib or placebo. Interestingly, this was the longest celecoxib trial to date with mean duration of treatment being 33 months as opposed to the much shorter 12-month duration of the CLASS study. A statistically significant elevation in the risk for a major fatal or non-fatal cardiovascular event (a composite endpoint of cardiovascular death, acute myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in the placebo group. This followed a dose-response relationship: the relative risk at 400mg/day of celecoxib was 2.5 while the relative risk at 800mg/day was 3.4. Because of this unacceptable danger, the trial was prematurely halted. The FDA released an explanatory statement which said, "[w]hile we have not seen all available data on Celebrex, these findings are similar to

recent results from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently voluntarily withdrawn by Merck.”

47. Merck had previously conducted a large-scale, long-term, double-blind study of gastrointestinal toxicity in patients taking Vioxx or naproxen to treat arthritis. This study came to be called the Vioxx Gastrointestinal Outcomes Research study (“VIGOR”). As with the CLASS study, VIGOR ultimately demonstrated a trend toward cardiovascular risks for those taking the selective COX-2 inhibitor Vioxx.

48. Although Merck designed VIGOR to produce the absolute minimum number of cardiovascular events by excluding patients with known heart problems from the study and by allowing participants to take aspirin during the study, the VIGOR results nevertheless showed that patients taking Vioxx suffered more than twice the number of adverse cardiovascular events and five times the number of heart attacks as patients taking naproxen.

49. In October 2000, Merck sent its cardiovascular data from the VIGOR trial to the FDA for review. In February 2001, the FDA published a Memorandum on the Vioxx cardiovascular safety data gathered during VIGOR. In this Memorandum, the FDA concluded that there “is an increased risk of cardiovascular thrombotic events, particularly [heart attack], in the [Vioxx] group compared with the naproxen group.” The FDA considered and rejected all defenses raised by Merck to explain the statistically significant increase of cardiovascular incidents among Vioxx users. In February 2001, the FDA also concluded that Merck should have to add a cardiovascular warning to its Vioxx packaging: “it would be difficult to imagine inclusion of VIGOR results in the [Vioxx] labeling without mentioning cardiovascular safety results in the study description as well as the Warnings sections.”

50. In August 2001, independent doctors from the Cleveland Clinic performed their own meta-analysis of the Celebrex and Vioxx clinical trials on the issue of

cardiovascular safety. Their conclusion was that Celebrex and Vioxx posed an increased risk of adverse cardiovascular events. These doctors, concerned with the increased number of heart attacks experienced by patients taking selective COX-2 inhibitors, urged further trials to quantify the specific cardiovascular risks of such drugs.

51. In light of these studies and findings, Defendants were well aware of the serious cardiovascular risks posed by selective COX-2 inhibitors, including Bextra, long before Defendants began marketing Bextra as being safe and more effective than traditional NSAIDs for all patients, without regard for cardiovascular risks.

52. On December 9, 2004, the FDA issued new information on side effects associated with the use of Bextra and required the addition of certain warnings to, and the strengthening of other warnings on, the Bextra label. The enhanced warnings followed in the wake of the results of additional cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA regarding severe skin reactions.

53. Defendants' study, completed in 2004, showed an increased cardiovascular risk in patients treated with Bextra after undergoing coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood clots in the legs and lungs.

54. The FDA also required the strengthening of warnings about the risk of life-threatening skin reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis. Stevens-Johnson Syndrome is marked by blistering lesions on the body, prone to rupture and secondary infection, and has been described as burning from the inside out. Patients with toxic epidermal necrolysis, also known as TENS, develop multiple large blisters, followed by the sloughing off of most of the skin and mucous membranes.

55. By November 2004, the FDA had received nearly ninety reports of such severe skin reactions, some of which resulted in hospitalization and death. While other

NSAIDs also pose a risk for rare, serious skin reactions, the reported rate of such side effects was vastly higher in individuals taking Bextra.

56. In mid-January 2005, a peer-reviewed paper from the University of Pennsylvania found that in patients having heart bypass surgery, those who took Bextra, as opposed to a placebo, were three times more likely to have a heart attack or stroke.

57. In February 2005, WellPoint, Inc., the nation's largest provider of health care benefits, released a study it conducted in conjunction with researchers at Indiana University's medical school on the risks of cardiovascular events in patients taking COX-2 inhibitors. The study involved the records of more than 635,000 patients and demonstrated that COX-2 inhibitors do increase the risk of adverse cardiovascular events. However, while Vioxx and Celebrex increased patients' risk of heart attack and stroke by approximately 20%, Bextra increased the risk by 50%. Dr. Sam Nussbaum, WellPoint's executive vice president and chief medical officer, noted that the study was further evidence of an "increasingly compelling trend" of data showing that COX-2 inhibitors elevate patients' risk of adverse cardiovascular events.

58. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham stated that COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette smoking, hypertension, and diabetes.

59. An Australian study released in March 2005 analyzed results from all nineteen randomized controlled trials of COX-2 inhibitors published before May 2004 and found that individuals taking COX-2 inhibitors, including Bextra, had a 60% higher chance of elevated blood pressure compared with those on a placebo.

60. Despite years of studies on COX-2 inhibitors, as well as disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any action to protect the health and welfare of patients and instead continued to offer the drug for sale.

61. On April 7, 2005, the FDA requested that Defendants voluntarily withdraw Bextra from the market, stating:

...the Agency has concluded that the overall risk versus benefit profile of Bextra is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that Bextra has not been shown to offer any unique advantage over the other available NSAIDs.

FDA Alert for Healthcare Professionals, April 7, 2005. Continuing, the FDA noted:

Bextra has been demonstrated to be associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery.... FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for Bextra from the short-term CABG trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding.... To date, there have been no studies that demonstrate an advantage of Bextra over other NSAIDs that might offset the concern about the[] serious skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.

Id.

Marketing and Promotion

62. Despite knowing that COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, Defendants made a business decision to push Bextra to market on claimed improvements in gastrointestinal safety, while downplaying its cardiovascular and skin dangers.

63. Defendants initiated extensive marketing campaigns to convey the uniform message that Bextra provided effective pain relief without the gastrointestinal side effects of traditional NSAIDs. Defendants also intentionally suppressed data showing cardiovascular and skin risks associated with the use of Bextra. Defendants pursued this strategy to benefit from the assumption that, in the absence of information to the contrary, Bextra possessed the same cardio-protective properties and skin dangers as traditional NSAIDs.

64. Defendants' advertising efforts included blitzing doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Bextra was a superior drug for treatment of osteoarthritis, acute, and chronic pain. They aggressively promoted Bextra as an improvement over other NSAIDs, like naproxen and ibuprofen, claiming it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote or provide any balanced presentation as to Bextra having an unacceptably high risk of other side effects, such as heart attacks, strokes, unstable angina, cardiac clotting, hypertension, and severe skin reactions.

65. Such marketing efforts to physicians have become commonplace in recent years. Drugs, including Bextra, that might once have been used primarily by specialists are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs' full research record. Drug companies, with Pfizer in the forefront, spent \$8 billion on such "detailing" to physicians—*i.e.*, sales people dropping by to leave marketing materials and

speaking to physicians about their companies' drugs—in the twelve months through October 2004.

66. Such large-scale marketing efforts have paid huge dividends to Defendants and other drug companies. The number of blockbuster drugs, defined as drugs with more than \$1 billion in annual retail prescription sales, was only fifteen in 1999, but grew to thirty-four in 2003.

Risks Posed by Bextra

67. Despite the effectiveness of their advertising campaigns, Defendants' uniform failure to disclose Bextra's risks of cardiovascular injury and severe skin reactions did not quell concerns about selective COX-2 inhibitors in the medical community.

68. In 1997, the link between COX-2 inhibition, prostacyclin levels, and blood clotting was receiving sporadic attention in medical journals.

69. In 1998, independent doctors established a link between selective COX-2 inhibitors and increased blood clotting, and suggested that these drugs would cause an increase in clot-related cardiovascular events. These doctors suggested that these drugs should not be given to patients with known cardiovascular disease, and that patients taking these drugs would have to be monitored for cardiovascular complications.

70. In light of the enormous sales of Bextra, Celebrex, and Vioxx, and the related increase in serious cardiovascular events among patients taking such drugs, the link between selective COX-2 inhibition and cardiovascular problems received increased attention.

71. As set forth above, the cardiovascular safety of selective COX-2 inhibitors was directly challenged for the first time in August 2001, when independent doctors from the Cleveland Clinic published a meta-analysis of the Celebrex and Vioxx trials, and concluded that such drugs posed an increased risk of adverse cardiovascular events.

72. Over the next eight months, many pre-eminent doctors and medical organizations continued to discuss the cardiovascular risks of selective COX-2 inhibitors. The vast majority, regardless of whether they were on Defendants' payrolls, agreed that cardiovascular risk factors should be considered in deciding whether to prescribe selective COX-2 inhibitors, and that well-designed, comprehensive studies were needed to assess their effects on human heart function.

73. Despite the mounting evidence that Bextra caused or exacerbated clot-related cardiovascular disorders, Defendants continued to issue uniformly misleading advertisements and promotional materials touting Bextra as being safe and more effective than traditional NSAIDs for all patients, without regard for cardiovascular risks.

74. Defendants' advertising and packaging materials for Bextra are uniformly fraudulent and misleading because they fail to adequately warn consumers that Bextra poses known risks of heart attacks, strokes, unstable angina, cardiac clotting, hypertension, and severe skin reactions.

CLASS ACTION ALLEGATIONS

75. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(b)(1), (2), and (3) as a representative of the following Class: All entities in the United States and its territories who, since 2001, have purchased, reimbursed or paid for some or all of the purchase price for Bextra. Defendants' employees, officers, and agents, and their immediate families, are excluded from the Class, as are individuals who assert personal injury claims against Defendants.

76. The members of the Class are so numerous that joinder would be impractical. Bextra has been prescribed to, paid for, and ingested by millions of consumers nationwide.

77. There are questions of law and fact common to the Class that predominate over questions affecting only individual members, including, but not limited to:

- a. whether Defendants engaged in a fraudulent and/or deceptive scheme to portray Bextra as a drug having superior qualities to other NSAIDs;
- b. whether Defendants engaged in a scheme to create consumer demand for Bextra based on deceptive statements concerning Bextra's safety and efficacy;
- c. whether as a result of this scheme Bextra was overprescribed;
- d. whether the price of Bextra was inflated as a result of the scheme;
- e. whether Defendants formed an enterprise for the purposes of carrying out the scheme;
- f. whether Defendants used the U.S. mails and wires to facilitate the scheme;
- g. whether Defendants' conduct violated RICO;
- h. whether Defendants are liable to Plaintiffs and the Class for damages under state consumer protection statutes;
- i. whether Defendants made material misrepresentations or material omissions about the cardiovascular risks associated with using Bextra, the risks of serious skin reactions, and the effectiveness of Bextra; and
- j. whether members of the Class are entitled to damages based on their payments for Bextra, and, if so, the nature and amount of such damages.

78. Plaintiffs' claims and defenses are typical of the claims and defenses of other members of the Class because Defendants have uniformly misrepresented that Bextra is safer and more effective than traditional NSAIDs, and uniformly omitted and failed to disclose the material risks associated with Bextra. Defendants' actions have

deprived Plaintiffs and the members of the Class of their ability to make an informed decision about whether to pay for Bextra.

79. Plaintiffs will fairly and adequately assert and protect the interests of other members of the Class because Plaintiffs have retained counsel competent and experienced in complex class action litigation, and Plaintiffs have no interests adverse to any Class members.

80. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(A) because the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, and would establish incompatible standards of conduct for Defendants.

81. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(B) because the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to individual Class members which would, as a practical matter, be dispositive of the interests of the other members not parties to these adjudications and/or substantially impair their ability to protect these interests.

82. Class certification is proper under Federal Rule of Civil Procedure 23(b)(2) because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate for the Class.

83. Class certification is proper under Federal Rule of Civil Procedure 23(b)(3) because common issues of law and fact predominate over any questions affecting only individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

84. The need for Class-wide notice does not provide a barrier to certification, in that notice can be effectively disseminated to the Class by techniques customarily used in consumer class actions, including published notice, Internet notice, and direct mailings based on readily available computer databases.

FIRST CLAIM FOR RELIEF
(violations of 18 U.S.C. § 1962(c))

85. Plaintiffs incorporates by reference the preceding paragraphs as if they were fully set forth herein.

86. This claim, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against Defendants on behalf of the Class.

87. Plaintiffs, the members of the Class, and Defendants are each “persons” as that term is defined in 18 U.S.C. § 1961(3).

88. At all relevant times, in violation of 18 U.S.C. § 1962(c), Defendants conducted the affairs of an association-in-fact enterprise identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

Bextra Enterprise

89. For purposes of this claim, the RICO “Enterprise” is an association-in-fact consisting of each of the Defendants, including their directors, employees, and agents, and includes outside advertising agencies utilized by Defendants and the Medical Directors of Pfizer, Pharmacia, and Searle. While maintaining their separate legal identities and titles, each of these entities and persons joined together to run the Enterprise. The association-in-fact is referred to herein as the “Bextra Enterprise.” At all relevant times, the Bextra Enterprise was an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating information about Bextra, which all too often includes disseminating false

and misleading information, (b) jointly presenting data to the FDA and medical journals that is misleading and/or has been manipulated to distort the results of clinical trials, (c) selling, promoting, and distributing Bextra to Plaintiffs and Class members, (d) achieving the goal of breaking the NSAID barrier (*i.e.* having Bextra replace other NSAIDs as a preferred treatment), and (e) deriving profits from these activities beyond those that could have been attained without operation of the Enterprise. The Enterprise had as a common purpose creating and perpetuating a demand for Bextra in a class of consumers who could have used lower-priced NSAIDs and achieved the same pain relief at a lower cost. Defendants had this as a purpose because without the scheme, they would not have been able to sell Bextra at the prices at which it was sold. During most of the time relevant to this complaint, each Defendant maintained a separate legal identity while operating the Enterprise, and others associated with and part of the Enterprise maintained their separate identities. The Enterprise continues to operate through Pfizer and through the instructions it issues to its agents for the purpose of carrying out the objectives of the Bextra Enterprise. Agents and members of the Enterprise include advertising agencies used to create Bextra advertisements and doctors who co-author articles promoting the efficacy of Bextra. As to each Defendant, the association-in-fact met on a regular basis to discuss the operations of the Enterprise and the Enterprise's efforts were coordinated and agreed to by each Defendant.

90. Each of the members of the Enterprise had a systemic linkage, because there are contractual relationships, financial ties, and continuing coordination of activities between the Defendants and the Enterprise. As to each Defendant there was a common communication network by which information concerning the Bextra Enterprise was exchanged on a regular basis. Typically this communication occurred by the use of electronic mail or the telephone, with which Defendants planned the operation of the Enterprise alleged herein and ran its continuing operation.

91. With the merger of Pfizer and Pharmacia and the purchase of Searle by Pharmacia, the Enterprise is now an association-in-fact consisting of the individuals at Pfizer in charge of running the Bextra Enterprise, including the sales executives in charge of marketing efforts, executives in charge of advertising, and those in charge of developing responses to safety issues. This association-in-fact meets on a regular basis to guide the operation of the Enterprise.

92. At all relevant times, each of the Defendants was a knowing participant in the Enterprise and benefited from its operation.

Defendants' Use of the U.S. Mails and Interstate Wire Facilities

93. The Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning Bextra; the sale, promotion, and/or distribution of Bextra; the transmission and/or receipt of sales and marketing literature; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of Bextra.

94. Defendants' illegal conduct and wrongful practices were carried out by an array of employees, as well as by consultants and doctors, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products, and funds by the U.S. mails and interstate wire facilities.

95. The nature and pervasiveness of the Bextra Enterprise, which was orchestrated out of the corporate headquarters of Defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the various local district managers overseeing the sales force(s), the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers, and employees who communicated with the public.

96. Many of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Bextra Enterprise alleged herein depended upon secrecy, and as alleged above, Defendants took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Bextra Enterprise, and does so below.

97. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the Enterprise involved thousands of communications, including *inter alia*:

- a. Marketing materials about Bextra, which were sent by Defendants to health care providers located across the country;
- b. Written representations made by Defendants, which were made at least annually and in many cases several times during a single year;
- c. Documents submitted to the FDA, JAMA, and other medical journals designed to conceal the risks of Bextra and to falsely promote its safety and superiority;
- d. Written and oral communications directed to U.S. Government agencies that fraudulently misrepresented Bextra;
- e. Written and oral communications with health insurers and patients, including Plaintiffs and members of the Class, inducing payments that were made in reliance on the safety and effectiveness of Bextra; and
- f. Receipts of money sent on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Bextra Enterprise.

98. In addition to the above-referenced RICO predicate acts, it was foreseeable to Defendants that others would distribute publications containing false information about the effectiveness of Bextra through the U.S. mails and by interstate wire facilities.

Further, Defendants' corporate headquarters have, in furtherance of the Enterprise, communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions.

Conduct of the RICO Enterprise's Affairs

99. Defendants exerted control over their Bextra Enterprise and, in violation of Section 1962(c) of RICO, conducted or participated in the conduct of the affairs of that RICO enterprise, directly or indirectly, in the following ways:

- a. Each Defendant has directly controlled the written and televised promotional materials with respect to Bextra;
- b. Each Defendant has directly controlled some of the medical literature regarding the effectiveness of Bextra;
- c. Each Defendant has directly or indirectly controlled the goals of the Enterprise (*i.e.*, to have Bextra break the NSAID barrier);
- d. Each Defendant has controlled the sales and marketing plans for Bextra;
- e. Each Defendant has directly controlled the creation and distribution of marketing, sales, and other materials used to inform health care providers nationwide of the benefits of using Bextra;
- f. Each Defendant has controlled and participated in the affairs of the Bextra Enterprise by using a fraudulent scheme to manufacture, market, and sell Bextra; and
- g. Each Defendant intended to (and did) distribute publications containing false information through the U.S. mails and by interstate wire facilities.

100. The Bextra Enterprise had a hierarchical decision-making structure, under which Defendants issued instructions on how Bextra was to be promoted and as to how the affairs of the Enterprise should be conducted.

101. In violation of Section 1962(c) of RICO, each Defendant conducted the affairs of the Bextra Enterprise with which they associated by reporting fraudulent information as to the safety of Bextra that were then disseminated nationwide.

Defendants' Pattern of Racketeering Activity

102. Each Defendant conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5), by means of which Defendants intended to defraud Plaintiffs, members of the Class, and other intended victims of the Enterprise.

103. Defendants' fraudulent and unlawful Enterprise consisted, in part, of disseminating by means of the U.S. mails and interstate wire facilities fraudulent information as to the safety of Bextra. As a result, Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

104. Defendants' racketeering activities amounted to a common course of conduct with similar pattern and purpose intended to deceive Plaintiffs and members of the Class. Each separate use of the U.S. mails and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Class. Each Defendant has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Enterprise.

Defendants' Motive

105. Defendants' motive in creating and operating the Enterprise and conducting the affairs of the Enterprise described herein was to fraudulently obtain sales of Bextra and associated profits.

106. The Enterprise was designed to, and did, encourage others, including health care providers, to advocate the use of Bextra. Thus, each Defendant used the Enterprise to sell more Bextra, thereby fraudulently gaining sales and market share and profits.

Damages Caused by Defendants' Scheme

107. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Class to be injured in their business or property because Plaintiffs and members of the Class have paid many hundreds of millions of dollars in inflated reimbursements or other payments for Bextra.

108. Defendants used the U.S. mails and/or interstate wire facilities in furtherance of their conduct. Plaintiffs and members of the Class have made inflated payments for Bextra.

109. Under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiffs and members of the Class for three times the damages that Plaintiffs and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

SECOND CLAIM FOR RELIEF **(VIOLATION OF STATE CONSUMER PROTECTION STATUTES)**

110. Plaintiffs incorporates by reference the preceding paragraphs as if they were fully set forth herein.

111. At all relevant times, there was in effect the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1, *et seq.*, the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.*, and the New York consumer protection statute, N.Y. Gen. Bus. L. §§ 349-350. Each of the Defendants has its principal place of business in one of those three States. Furthermore, the Michigan Consumer Protection Act, MCLA 445.901, *et seq.*, prohibits the actions engaged in by Defendants. Those statutes uniformly forbid consumer fraud in connection with the sale or advertisement of merchandise.

112. Pursuant to those statutes, Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion, and sale of Bextra to Plaintiffs and the Class members.

113. Defendants intended that Plaintiffs and the Class members rely on their materially deceptive practices and purchase Bextra as a consequence of the deceptive practices, including Defendants' misrepresentations and omissions of material fact with respect to the true nature of Bextra:

a. Defendants' promotions of Bextra as a safe drug for the treatment of pain and as having fewer side effects than comparable drugs on the market were deceptive, unfair, and unlawful in that Bextra actually had an undisclosed risk of adverse cardiovascular events and of serious skin reactions, did not have added benefits over NSAIDs, and was promoted solely for financial reasons and not due to any material increase in medical safety or efficacy over NSAIDs;

b. Defendants' conduct was unfair, unlawful, and deceptive in that Defendants knew Bextra was unsafe and increased the risk of adverse cardiovascular events, such as heart attack and stroke, to unacceptable levels, but omitted to disclose these facts to doctors and patients until 2005;

c. Defendants' conduct was unfair, unlawful, and deceptive in that they suppressed, manipulated, and concealed information that would demonstrate Bextra was not superior to NSAIDs in the majority of patients;

d. Defendants portrayed Bextra as a relief for symptoms and diseases without any statistically significant evidence for doing so;

e. Defendants omitted material information known to it in order to induce doctors to prescribe Bextra and consumers to purchase Bextra at a price that exceeded its actual worth;

f. Defendants established Bextra as a standard course of treatment based upon the use of reprints of articles appearing in prestigious medical journals which Defendants knew were false and/or misleading; and

g. Defendants committed unlawful acts by promoting and advertising Bextra in a manner that violated the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f), and (n) and 355(a).

114. Defendants' deceptive representations and material omissions to Plaintiffs and the Class members were, and are, unfair and deceptive acts and practices.

115. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, significant sums of money from Plaintiffs and the Class members.

116. Plaintiffs and the Class members were deceived by Defendants' omissions and misrepresentations.

117. As a proximate result of the Defendants' misrepresentations, Plaintiffs and the Class members have suffered ascertainable losses in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF
(UNJUST ENRICHMENT)

118. Plaintiffs incorporates by reference the preceding paragraphs as if they were fully set forth herein.

119. To the detriment of Plaintiffs and members of the Class, Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, *inter alia*, payments for Bextra.

120. Defendants have unjustly benefited through the unlawful and/or wrongful collection of, *inter alia*, payments for Bextra and continue to so benefit to the detriment and at the expense of Plaintiffs and members of the Class.

121. Accordingly, Plaintiffs and members of the Class seek full restitution of Defendants' enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

FOURTH CLAIM FOR RELIEF
(Breach of Implied Warranty)

122. Plaintiffs incorporates by reference the preceding paragraphs as if they were fully set forth herein.

123. Defendants are merchants and are in the business of selling selective COX-2 inhibitor drugs such as Bextra.

124. In marketing and selling Bextra, Defendants impliedly warranted that Bextra provided effective pain relief without the gastrointestinal side effects of traditional NSAIDs.

125. In marketing and selling Bextra, Defendants intentionally mislead purchasers to believe, and impliedly warranted, that Bextra possessed the same cardio-protective properties and skin dangers as traditional NSAIDs.

126. In reality, Bextra failed to provide effective pain relief without the gastrointestinal side effects of traditional NSAIDs. Bextra also did not possess the same cardio-protective properties and skin dangers as traditional NSAIDs. In fact, Bextra

caused or exacerbated cardiovascular injury far more often than traditional NSAIDs, and even more often than other selective COX-2 inhibitor drugs. Accordingly, for these and other reasons, Bextra was not fit for the purposes for which it was sold and used, and it does not pass without objection in the trade.

127. Defendants did not effectively disclaim or otherwise limit their implied warranty of merchantability with respect to Bextra. Therefore, Defendants breached the implied warranty of merchantability as to Plaintiffs and each member of the Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable, and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring Plaintiffs as representative of the Class and Plaintiffs' counsel as counsel for the Class;

B. The conduct alleged herein be declared, adjudged, and decreed to be unlawful;

C. Plaintiffs and the Class be granted an award of damages in such amount to be determined at trial, with treble damages as provided by law;

D. Plaintiffs and the Class be granted an award of punitive damages in such amount to be determined at trial;

E. Defendants be enjoined from continuing the illegal activities alleged herein;

F. Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

G. Plaintiffs and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

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Dated: April 12, 2005