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13 UNITED STATES DISTRICT COURT
14
15 NORTHERN DISTRICT OF CALIFORNIA

16 IN RE: BEXTRA MARKETING SALES
17 PRACTICES AND PRODUCT LIABILITY
18 LITIGATION

19 Case No. M:05-CV-01699-CRB
20 MDL No. 1699

21 THIS PLEADING RELATES TO:

22 **THIRD AMENDED PURCHASE
23 CLAIMS MASTER BEXTRA
24 COMPLAINT**

25 *ASEA/AFSCME Local 52 Health Benefits Trust v.
26 Pfizer, Inc., et al.*, Case No.: 1:05-cv-03803-LTS
27 (S.D.N.Y.)

28 *Clara Fontanilles v. Pfizer, Inc.*, Case No.:
05-21241-CIV-Martinez/Banstra (S.D. Fla.)

Linda A. Watters, et al. v. Pfizer, Inc., et al., Case
No.: 2:05cv71434 (E.D. Mich.)

Ronnie L. Hatcher v. Pfizer, Inc., et al., Case
No. 1:05-cv-00208-SLR (D. Del.)

*Steamfitters' Indus. Welfare Fund, et al. v. Pfizer,
Inc., et al.*, Case No.: 05 cv 3814 (S.D.N.Y.)

Nancy Ayers, et al. v. Pfizer, Inc., et al., Case
No. 05-CV-03770 (N.D. Cal.)

Betty A. Alexander, et al. v. Pfizer, Inc., et al., Case
No.: 05-cv-01720-ML-ALC

National Health Ins. Co. v. Pfizer, Inc., et al., Case
No.: 05-cv-04073 (N.D. Cal.)

Nancy Milano v. Pfizer, Inc., Case No.: C-05-3710
MHP (N.D. Cal.)

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I. NATURE OF THIS ACTION

A. Procedural Introduction

1. This Master Complaint is submitted to serve the administrative functions of efficiency and economy through presenting certain common claims and common questions of fact and law for appropriate action by this court in the context of this Multidistrict proceeding. This Master Complaint does not include all claims asserted in all of the purchase claims actions that have been transferred to this Court under 28 U.S.C. § 1407. Those matters are set forth in the individual and class actions filed by purchased claims Plaintiffs and served against Defendants. This Master Complaint does not constitute a waiver or dismissal of said actions or the claims asserted therein.

2. This Class Action is brought by and on behalf of all Consumers and Third-Party Payors (Consumers and Third-Party Payors are referred to herein collectively as “Plaintiffs,” “Class Members,” and “End-Payors”) who purchased or paid for the prescription drug Bextra (“Bextra”), an anti-inflammatory drug researched, manufactured, marketed, promoted, advertised, sold, and distributed by a combination and/or collaboration of Defendants Pfizer, Inc. (“Pfizer”), Pharmacia Corporation (“Pharmacia”), and G.D. Searle & Co. (“Searle”).

3. Pursuant to Rule 23(b)(1), 23(b)(2), 23(b)(3), and/or 23(c)(4)(A) of the Federal Rules of Civil Procedure, Plaintiffs will seek certification of a national End-Payor purchase claims class, through one or more actions transferred to or filed in this Court in the MDL 1699 litigation, consisting of:

All End-Payors located in the United States, including Consumers and Third Party Payors,¹ who purchased and/or paid for Bextra.²

4. Alternatively, in the event that this Court determines that a national End-Payor purchase claims class would not satisfy the requirements for class certification pursuant to Fed. R. Civ. P. 23, Plaintiffs would move for the certification of individual state class actions, grouped

¹ Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

² The class is further defined in Section VI, *infra*.

1 according to commonalities of state law consisting of, as to each state for which certification is
2 sought:

3 All End-Payers located in [State], including consumers and Third
4 Party Payers, who purchased and/or paid for Bextra.³

5 5. In the event that Plaintiffs are directed to pursue the statewide class course of action
6 set forth in the forgoing paragraph, Plaintiffs intend to request the Panel for Multi-District
7 Litigation (“MDL Panel” or “Panel”) to remand, to its transferor forum, each state class action as to
8 which Plaintiffs seek certification, solely for purposes of addressing the class certification question.
9 Remand of the class certification question will allow appellate review of the statewide class
10 certification question by the appropriate Circuit Court(s), thus ensuring that no party will have been
11 prejudiced by the Panel’s random selection of a transferee forum whose procedural jurisprudence
12 would determine the class certification issue differently from that of the transferor forum that is
13 charged with its ultimate trial. For purposes of uniformity and judicial efficiency, Plaintiffs would
14 further move the MDL Panel to appoint this Court to sit, by *ad hoc* designation, over the class
15 certification issue in each transferor court as to which such remand is sought.

16 **B. Summary of Allegations**

17 6. Non-steroidal anti-inflammatory drugs (“NSAIDs”) have been widely used to treat
18 arthritis, acute and chronic pain for nearly 40 years. The pain relief offered by such NSAIDs
19 comes at the expense of important adverse effects, most notably upper gastrointestinal toxicity.
20 Use of NSAIDs leads to admission to hospital for ulcer complications (bleeding and perforation) in
21 around 1% of users annually and results in thousands of deaths every year.

22 7. In 1989, scientists made a breakthrough in understanding how NSAIDs worked.
23 Cyclo-oxygenase, the enzyme inhibited by NSAIDs, exists in at least two forms in the body.
24 Traditional NSAIDs inhibit both the cyclo-oxygenase 2 (“COX-2”) enzyme, which is inducible
25 and expressed at sites of inflammation, and the COX-1 enzyme, which is constitutive and
26 expressed in the gastrointestinal (“GI”) system. Inhibition of the COX-2 enzyme decreases
27 inflammation and alleviates pain. Inhibition of the COX-1 enzyme, however, decreases the

28 ³ This Class is further defined in Section VI and in the specific claims for relief.

1 protection in the GI tract. Defendants leapt at this new understanding, hoping to create a new
2 breed of NSAID that alleviated pain, but did not have the GI toxicity associated with traditional
3 NSAIDs.

4 8. Bextra was one of the new COX-2 inhibitors, Vioxx and Celebrex are others.
5 Defendants believed that Bextra had the potential to be a new blockbuster drug with yearly sales in
6 the billions of dollars.

7 9. As part of the unlawful scheme set forth below, Defendants promoted the use of
8 Bextra in information disseminated to doctors, Pharmacy Benefit Managers (“PBMs”), third-party
9 payors and consumers. Defendants promoted Bextra as a “breakthrough” drug providing important
10 clinical advantages over older and far less expensive NSAIDs. Defendants were never able to
11 establish, however, that Bextra was any more efficacious or safer than traditional NSAIDs. To the
12 contrary, studies showed risks for gastrointestinal and cardiovascular (“CV”) adverse event rates
13 similar to or greater than traditional NSAIDs. The FDA approved label warned of GI and CV risks
14 similar to other NSAIDs. Even so, as part of the unlawful scheme set forth below, Defendants
15 embarked on a massive marketing campaign directed to doctors, third party payors and consumers
16 to market Bextra as a “Powerful” drug clinically superior to and safer than older and far less
17 expensive NSAIDs.

18 10. Defendants falsely represented that Bextra provided symptomatic relief similar to
19 ibuprofen and naproxen but was clinically superior because it was significantly less likely to cause
20 the gastrointestinal adverse side effects associated with these and other NSAIDs. For instance,
21 NSAIDs can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-
22 term use. Defendants falsely promoted Bextra as a safe and effective alternative that would have
23 less deleterious and painful impact on the gut, but that would be just as effective, if not more so, for
24 pain relief.

25 11. The extent to which a drug is paid for by third-party payors is determined by that
26 drug’s status on the third-party payor’s “formulary,” which is a list of drugs that plan participants
27 are authorized to purchase for payment under the benefit plan.

28

1 12. Placement of a prescription drug on the formularies of third-party payors, medical
2 care organizations, and or prescription benefit managers (who are employed by the third-party
3 payors to design or administer the benefit plans) is critical to the success of the drug. Defendants
4 knew that preferred placement on these formularies would guarantee commercial success for
5 Bextra.

6 13. In an elaborate and sophisticated manner, Defendants aggressively marketed Bextra
7 directly to medical professionals (including physicians, dentists, and leading medical scholars) in
8 order to leverage pressure on third-party payors, medical care organizations, and large institutional
9 buyers (*e.g.*, hospitals) to include Bextra on their formularies. Bextra's marketing campaign
10 specifically targeted third-party payors, physicians and dentists, and was designed to convince
11 them of both the therapeutic and economic value of Bextra. Faced with the increased demand for
12 the drug by health care professionals that resulted from Bextra's successful advertising and
13 marketing blitz, third-party payors were compelled to add Bextra to their formularies.

14 14. Defendants' marketing and promotion of Bextra was part of a scheme to create the
15 impression of, and demand for, Bextra as a wide-ranging pain reliever, particularly for the
16 treatment of arthritis pain and/or pain in general (a use for which it was not FDA approved). The
17 scheme was accomplished by unlawful means including, but not limited to, the (i) false promotion,
18 including promotion contrary to the FDA approved label, of the overall efficacy and safety of
19 Bextra as superior to less expensive alternatives, (ii) false promotion, including promotion contrary
20 to the FDA approved label of the CV and GI safety of Bextra, (iii) manipulation of data to give the
21 appearance of superiority over other NSAIDs in pain relief efficacy, CV and GI safety when such
22 superiority did not exist and was contrary to the FDA approved label, (iv) false promotions,
23 including promotions contrary to the FDA approved label, directed to doctors, third party payors
24 and consumers, touting the superior efficacy and GI and CV safety of Bextra, which promotions
25 exceeded the scope of FDA approval, (v) use of reprinted articles from prestigious medical journals
26 that falsely claimed Bextra was proven to be safer than other NSAIDs contrary to the FDA
27 approved label and (vi) co-promotion of Bextra with Celebrex in an attempt to convince doctors
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1 incorrectly that the alleged benefits of one drug applied to both even though such claims were
2 contrary to the FDA approved label of each drug.

3 15. As a result of Defendants' scheme, they were able to create a market for Bextra and
4 to sell Bextra at a premium price over NSAIDs and to have it become a standard treatment option
5 in many circumstances as opposed to use of less expensive NSAIDs. Bextra sales reached
6 \$1.29 billion in 2004.

7 16. The success of Defendants' scheme was recently documented in a study released on
8 January 24, 2005, in the ARCHIVES OF INTERNAL MEDICINE, Volume 165, entitled *National Trends*
9 *in Cyclooxygenase-2 Inhibitor Use Since Market Release*. The authors of that study concluded that
10 the "aggressive marketing techniques to patients and physicians" caused a growth not only in use
11 of COX-2 inhibitors but also in overall market demand, resulting in the use of such drugs for
12 patients who did not need them.

13 17. In fact, Bextra has been promoted as a superior pain reliever when for most patients
14 it has no proven superiority over other NSAIDs. To date there are *no* clinical studies that
15 demonstrate an advantage of Bextra over other NSAIDs that would offset concerns about serious
16 skin risks (*e.g.*, toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme),
17 such as studies showing a GI safety benefit compared to other products. In addition, Bextra has
18 been documented to be associated with increased risk of serious adverse cardiovascular events to
19 such an extent, that on April 7, 2005, the Federal Drug Administration ("FDA") requested Pfizer to
20 withdraw Bextra from the United States market and Pfizer has done so. At the FDA briefing called
21 to explain its request that Pfizer withdraw Bextra from the market, the FDA's director of the Office
22 of New Drugs said that Bextra "had no unique benefit and it had the unique risk: the skin
23 reaction."⁴

24 18. Bextra sold during the Class Period for \$2.53 to \$6.45 per day depending upon the
25 dose, while NSAIDs sold for as little as \$0.21 to \$0.31 per day. Billions of dollars have thus been
26 wasted in which Plaintiffs and Class Members have paid a premium price for a drug (and the
27 doctor visits necessary to obtain prescriptions for Bextra) that is not a premium or superior product

28 ⁴ Rita Rubin, "Another drug for pain off market," *USA Today*, 4/7/2005.

1 over equally available, less expensive NSAIDs and other pain medications. If Defendants had not
2 engaged in the wrongful marketing, advertising and promotion of Bextra, Plaintiffs and Class
3 Members would have paid for other, equally effective and less expensive medications or would
4 have purchased no medication at all. Had the truth been told about its safety and efficacy, Bextra
5 would have sold at a price similar to that of other NSAIDs and would not have become a standard
6 in the treatment of arthritis, dysmenorrhea and other non-FDA approved forms of pain relief,
7 and/or Bextra would not have been marketed at all and would not have been approved on
8 formularies. The plain fact is that at no time did Bextra, as compared to other, equally effective
9 and less expensive therapeutic regimens, have a proven advantage for patients either at no risk or at
10 high-risk for GI complications. Thus, for virtually every purchaser – and contrary to Defendants’
11 widespread marketing program – Bextra was neither more effective nor safer than older, less
12 expensive NSAIDs and thus was not a superior product.

13 19. In this action Plaintiffs seek damages arising from the purchases of Bextra resulting
14 from Defendants’ illegal scheme and/or conduct.

15 **II. JURISDICTION**

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

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

25 22. A substantial part of the events or omissions giving rise to the claims in this action
26 occurred in this judicial District, and Defendants may be found within this judicial District. Venue
27 is proper in this jurisdiction under 28 U.S.C. § 1391. Defendants implemented their fraudulent
28 marketing scheme in this District, as well as nationwide, through providers and sales

1 representatives who reside or transact business in this District, and thereby affected Class Members
2 who similarly reside or transact business in this District.

3 **III. PARTIES**

4 **A. Plaintiffs**

5 23. Plaintiff Betty A. Alexander, who filed Civil Action No. 05-1720 (E.D. La.), is a
6 person of the full age of majority domiciled in Orleans Parish, Louisiana, and is a Louisiana
7 consumer who paid for the prescription drugs Bextra and Celebrex.

8 24. Plaintiff Allied Services Division Welfare Fund (“ASD”), who filed Civil Action
9 No. 05-1720 (E.D. La.), is a health and welfare benefit fund with its principal place of business at
10 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of
11 providing health and pension benefits, among others, to covered lives. ASD is a multi-employer
12 employee welfare benefit plan within the meaning of the Employee Retirement Income Security
13 Act, 29 U.S.C. § 1001(2), and § 1002(37). ASD paid for prescriptions of Bextra and Celebrex
14 dispensed to covered lives in several states. ASD has paid and provided, and will in the future pay
15 and provide, health care benefits to its members and insureds as a direct result of the wrongful
16 conduct of the Defendants as fully alleged herein.

17 25. Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust (“ASEA”), who filed
18 Civil Action No. 1:05-cv-03803-LTS (S.D.N.Y.), is a self-funded health benefit trust that was
19 created through collective bargaining between the State of Alaska and ASEA/AFSMCE Local 52
20 to provide reimbursement for eligible health, vision, dental and prescription drug claims incurred
21 by employees of the State of Alaska who are members of the General Governmental Unit
22 represented by ASEA/AFSCME Local 52. ASEA’s Anchorage headquarters are located at 1577 C
23 Street, Suite 201, Anchorage, Alaska 99501. ASEA paid some or the entire purchase price for
24 Bextra during the relevant period and was injured by the illegal conduct alleged herein.

25 26. Plaintiff Clara Fontanilles (“Fontanilles”), who filed Civil Action
26 No. 05-21241-CIV-Martinez/Banstra (S.D. Fla.), is a resident of Miami-Dade County, Florida, and
27 is otherwise *sui juris*. During the proposed Class Period, Fontanilles was prescribed, purchased
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1 and consumed Bextra within the state of Florida, and is a member of the proposed Class as defined
2 below.

3 27. Plaintiff Frankenmuth Financial Group, Inc. (“Frankenmuth”), who filed Civil
4 Action No. 2:05cv71434 (E.D. Mich.), is a Michigan corporation headquartered in Saginaw
5 County, Michigan. At all times relevant to this Complaint, Frankenmuth was a third-party payor
6 whose function was to assume the risk of payment of medical and prescription costs on behalf of
7 the participants in its plan. During times relevant to this lawsuit, Frankenmuth paid for
8 prescriptions for Bextra and was injured by the illegal conduct alleged herein.

9 28. Plaintiff Ronnie L. Hatcher (“Hatcher”), who filed Civil Action No. 1:05-cv-00208-
10 SLR (D. Del.), resides in Elizabethtown, Kentucky. During the Class Period, Mr. Hatcher was
11 prescribed and paid for part of the purchase price of the Bextra and was injured by the illegal
12 conduct alleged herein.

13 29. Plaintiff Nancy Milano (“Milano”), who filed Civil Action No. C-05-3710 MHP
14 (N.D. Cal.), is a resident of San Mateo County, California. During the Class Period, Ms. Milano
15 was prescribed and paid for part of the purchase price of Bextra and was injured by the illegal
16 conduct alleged herein.

17 30. Plaintiff Metal Trades Branch Welfare Fund (“Metal Trades”), who filed Civil
18 Action No. 05 cv 3814 (S.D.N.Y.), is a union health and welfare fund that provides health and
19 prescription drug benefits to its members, and specifically, it has paid or reimbursed members for
20 prescription drug benefits for Bextra and was injured by the illegal conduct alleged herein. Metal
21 Trades is headquartered in the city of New York, in the State of New York.

22 31. Plaintiff National Healthcare Insurance Company (“NHCI”), who filed Civil Action
23 C05-04073 (N.D. Cal.), is a life and health insurance company with its principal place of business
24 at 1901 North State Highway 360, Grand Prairie, Texas 75050, and is involved in the business of
25 providing health benefits, among others, to covered lives. NHCI paid for prescriptions of Bextra
26 and Celebrex dispensed to covered lives in several states. NHCI has paid and provided, and will in
27 the future pay and provide, health care benefits to its members and insureds as a direct result of the
28 wrongful conduct of Defendants as fully alleged herein.

1 32. Plaintiff Vernon Shepherd (“Shepherd”), who filed Civil Action No. 05 CH 9482, is
2 an adult resident of Mundelein, Illinois in Lake County. Mr. Shepherd first began taking Bextra in
3 early 2005 when Bextra was prescribed for him by his doctor and he purchased the drug.
4 Mr. Shepherd was continually prescribed, purchased and used Bextra from early 2005 until April
5 2005 when the product had been removed from the market. At that time, he heeded Pfizer’s
6 instructions to consult his doctor for alternative treatment. He made an appointment and visited his
7 doctor. He was thereafter charged with the cost of this doctor visit.

8 33. Plaintiff Steamfitters’ Industry Welfare Fund (“Steamfitters”), who filed Civil
9 Action No. 05 cv 3814 (S.D.N.Y.), is a union health and welfare fund that provides health and
10 prescription drug benefits to its members, and specifically, it has paid or reimbursed members for
11 prescription drug benefits for Bextra for its members and was injured by the illegal conduct alleged
12 herein. Steamfitters is headquartered in the city of New York, in the State of New York.

13 34. Plaintiff Linda A. Watters, Commissioner, Offices of Financial and Insurance
14 Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her
15 capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known
16 as OmniCare Health Plan, Inc., who filed Civil Action 2:05cv71434 9 (E.D. Mich.), is a Michigan
17 official whose function is to collect and liquidate all assets and liabilities of the former private
18 third-party payors’ Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness
19 Plan and OmniCare were private third-party payors whose function was to assume the risk of
20 payment of medical and prescription costs on behalf of the participants in its plan. During times
21 relevant to this lawsuit, Wellness Plan and OmniCare paid for prescriptions of Bextra and was
22 injured by the illegal conduct alleged herein.

23 35. Plaintiff Nancy Ayers (“Ayers”), who filed Civil Action No. 05-CV-03770, was at
24 all relevant times, an adult resident citizen of the State of California, and resident of Bakersfield,
25 Kern County.

26 36. Plaintiff Nancy Ayers was prescribed, and began taking, Bextra on or about
27 October 12, 2004. She paid for two prescriptions of Bextra, which each cost her \$21.52 in out-of-
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1 pocket expenses for a total expenditure of \$43.04. She had switched to Bextra after Vioxx was
2 recalled.

3 37. As a direct and proximate result of using Bextra, Plaintiff Nancy Ayers suffered
4 severe cardiovascular and cerebrovascular injuries. Specifically, on December 6 and 7, 2004,
5 Plaintiff Nancy Ayers suffered a stroke, which has caused and will continue to cause Plaintiffs to
6 suffer damages, and places Plaintiff Nancy Ayers at risk of further serious injury or death.

7 38. Unaware of the risks presented by Bextra, or that Bextra was the cause of her
8 injuries, Plaintiff's doctors continued to give her Bextra until December 9 or 10, 2004.

9 39. Plaintiffs and Plaintiff Nancy Ayers' healthcare providers were, at the time that she
10 was prescribed Bextra, unaware, and could not have reasonably known or have learned through
11 reasonable diligence, that injuries could result from Plaintiff's ingestion of Bextra and Defendants'
12 negligent and otherwise culpable acts, omissions, and misrepresentations.

13 40. Plaintiff Nancy Ayers used Bextra in a proper and reasonably foreseeable manner
14 and used it in a condition that was substantially the same as the condition in which it was
15 manufactured and sold.

16 41. Plaintiffs would not have purchased and Plaintiff Nancy Ayers would not have used
17 Bextra had Defendants properly disclosed the risks associated with the drug, and through diligent
18 effort were not able to discovery the risk from Bextra prior to Nancy's use of the drug.

19 42. Inclusion of claims in the master complaint does not waive any of the claims for
20 personal injury or otherwise filed by the proposed representative in any individual action already
21 on file.

22 **B. Defendants**

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

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

1 body, traditional NSAIDs do not cause blood clots, and aspirin even reduces the risk of clots and
2 helps protect heart function in some people, an effect commonly referred to as “cardioprotection.”

3 53. For decades, in the absence of other treatment options, consumers seeking pain
4 relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs
5 counteract the GI effect with other medication, or take nothing and live with the pain.

6 54. Defendants set out to remedy this problem by developing “selective” inhibitors that
7 would block only COX-2 production, and thus the *theory* – although not the clinically proven fact
8 – was that this might allow the proper maintenance of gastric tissue while still reducing pain
9 sensations.

10 55. In making this decision, Defendants either intentionally ignored or recklessly
11 disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels
12 without a counterbalancing reduction in thromboxane production, thereby increasing the risk of
13 blood clots and various clot-related cardiovascular events, including heart attack, stroke, unstable
14 angina and peripheral blood clots.

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

20 57. Defendants sought approval of a second generation COX-2 inhibitor and filed for
21 FDA approval of Bextra (valdecoxib) on January 16, 2001 for the (i) prevention and treatment of
22 acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of
23 osteoarthritis and adult rheumatoid arthritis.

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

1 59. Pre-approval marketing plans were to stress that Bextra was superior to other
2 NSAIDs in terms of both efficacy and safety, offering a significant reduction in GI complications.
3 Pre-approval marketing plans also anticipated that the FDA would approve Bextra for the treatment
4 of acute pain in adults.

5 60. In September 2000, Defendants submitted a new drug application for an injectible
6 COX-2, generically named “parecoxib” (a “pro-drug” of Bextra that gets metabolized immediately
7 into Bextra after its administration). In July 2001, the FDA declined to approve parecoxib. In the
8 disapproval letter, the FDA states,

9 The safety of parecoxib in the multiple dose setting has not been
10 adequately established. Findings in Study 035 raise the possibility
11 that parecoxib is associated with serious, life-threatening adverse
12 events including myocardial infarction, thrombo-embolic events
13 (such as cerebrovascular accidents, deep venous thrombosis and
14 luminary embolism), pericarditis, upper gastrointestinal injury, and
15 hypotension. Hypoxia, renal dysfunction and hypertension were also
16 experienced more frequently with parecoxib use than the comparator
17 analgesic. All four deaths in the study occurred in the parecoxib
18 treated group.

19 Defendants ignored this clear cardiovascular signal with a drug almost identical to Bextra and
20 continued their deceptive launch plans.

21 61. The FDA granted approval of Bextra on November 16, 2001 for two particular uses:
22 treatment of primary dysmenorrhea and relief for the signs and symptoms of osteoarthritis and
23 rheumatoid arthritis.

24 62. However, the agency did not grant approval of Bextra for the management or
25 prevention of acute pain. In rebuking the effort to obtain such a broad indication for Bextra, the
26 FDA determined that Bextra had not been proven as more effective than other NSAIDs, and that
27 given the ongoing concerns regarding COX-2s generally at that time, broader indications in that
28 class should not be granted. Further, Defendants did not obtain approval to promote Bextra as less
likely than other NSAIDs to cause 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.”

1 63. The FDA also warned that Bextra had not demonstrated safety and efficacy for
2 opioid sparing, noting,

3 ...adverse events associated with opioids such as hypotension were
4 seen more frequently in the valdecoxib treated patients. There was
5 no clear evidence of less confusion, somnolence, respiratory
6 depression, nausea and vomiting or constipation to suggest a clinical
7 advantage associated with the lower does of opioid used. The clinical
8 benefit of post-operative co-administration of fixed dosing of
9 valdecoxib and ad lib opioid dosing has not been demonstrated.

10 As described in detail below, Defendants ignored these warnings and limitations on the indications
11 for Bextra and falsely touted it as a powerful pain reliever with opioid sparing benefits.

12 64. The original label for Bextra also contained the following precautions relating to the
13 cardiovascular risks associated with Bextra:

14 **Renal Effects**

15 Long-term administration of NSAIDs has resulted in renal papillary
16 necrosis and other renal injury. Renal toxicity has also been seen in
17 patients in whom renal prostaglandins have a compensatory role in
18 the maintenance of renal perfusion. In these patients, administration
19 of a nonsteroidal anti-inflammatory drug may cause a dose-
20 dependent reduction in prostaglandin formation and, secondarily, in
21 renal blood flow, which may precipitate overt renal decompensation.
22 Patients at greatest risk of this reaction are those with impaired renal
23 function, heart failure, liver dysfunction, those taking diuretics and
24 Angiotensin Converting Enzyme (ACE) inhibitors, and the elderly.

25 ...

26 **Fluid Retention and Edema**

27 Fluid retention and edema have been observed in some patients
28 taking BEXTRA (see ADVERSE REACTIONS). Therefore,
29 BEXTRA should be used with caution in patients with fluid
30 retention, hypertension, or heart failure.

31 The label warned of particular interactions with other medicines, including,

32 *Aspirin*: Concomitant administration of aspirin with valdecoxib may
33 result in an increased risk of GI ulceration and complications
34 compared to valdecoxib alone. Because of its lack of anti-platelet
35 effect valdecoxib is not a substitute for aspirin for cardiovascular
36 prophylaxis.

37 The ADVERSE REACTIONS section of the original label warned that adverse CV events
38 including, aggravated hypertension, aneurysm, angina pectoris, arrhythmia, cardiomyopathy,

1 congestive heart failure, coronary artery disorder, heart murmur, hypotension, bradycardia,
2 palpitation, and tachycardia had been observed in patients treated with Bextra.

3 65. Even though the Defendants were required to market Bextra only as described in the
4 FDA approved label, they marketed Bextra's safety and efficacy as far superior than the
5 information that appeared in its labeling. For example, in a February 2002 letter from the FDA to
6 Pharmacia, the FDA reviewer found multiple misleading claims in the launch advertisements
7 submitted. The FDA warned, "[y]our proposed detail aid is misleading because it contains claims
8 that overstate the effectiveness of Bextra" and stated that claims made in the same detail aid were
9 "misleading because these efficacy claims have not been demonstrated by substantial evidence."

10 66. In the same letter, the FDA reviewer specifically criticized Pharmacia's "misleading
11 presentations" including, (1) presentation of data that had not been sufficiently replicated, (2)
12 selective presentation of the most positive results and failure to include results that were not
13 favorable, (3) presentation of data from a prospective subgroup analysis, when the original study
14 did not contemplate analysis of the data in such subgroups, falsely producing positive results, (4)
15 pooling of data from trials that were not designed with the endpoints the defendants presented, (5)
16 use of theoretical models that had not been demonstrated by substantial evidence, (6) unbalanced
17 presentation of benefits versus risks, specifically, portraying benefits in bold, large type at the top
18 of the ad and risks in small, light type at the bottom of the ad. Although Defendants were provided
19 this direction prior to the launch of Bextra, they ignored it and proceeded to use all of the above
20 misleading marketing techniques throughout Bextra's reign in the market.

21 67. Almost three years later, in January 2005, the FDA continued to criticize
22 Defendants misleading marketing methods. In response to submitted promotional pieces for
23 Bextra and Celebrex, the FDA commented generally,

24 [t]hese five promotional pieces variously: omit material facts,
25 including the indication and risk information; fail to make adequate
26 provision for the dissemination of the FDA-approved product
27 labeling; and make misleading safety, unsubstantiated superiority,
28 and unsubstantiated effectiveness claims. They are, therefore, in
violation of the Federal Food, Drug, and Cosmetic Act (Act) and
FDA implementing regulations.

1 The letter pointed out that a particular advertisement, “arthritis tips TV ad” was not even submitted
2 to the FDA as required by federal regulations. The letter went on to warn,

3 [t]he omission or minimization of risk information in these
4 promotional materials is a public health concern because Celebrex
5 and Bextra are contraindicated for several patient populations, both
6 products contain warnings of serious gastrointestinal (GI) effects and
7 anaphylactoid reactions and Bextra contains an additional warning
8 regarding serious, possibly life-threatening skin reactions.

9 The letter called attention to the numerous potential risks stated in both drugs respective labels, but
10 lacking in the Defendants advertisements, including,

11 [s]pecific warnings related to: gastrointestinal (GI) effects, including
12 risks of GI ulceration, bleeding and perforation; hypersensitivity
13 reactions including anaphylactoid reactions and angioedema; use in
14 patients with advanced renal disease, due to lack of controlled
15 clinical studies regarding use of the products in this population; and
16 use in patients with preexisting asthma.

17 The letter concluded that the violations it discusses are of a “serious nature” and Defendants should
18 “act to avoid disseminating similarly misleading promotion[s]...in the future.” The Defendants are
19 further warned that the violations discussed in the letter are not an “exhaustive list” and that “[i]t is
20 [Defendants’] responsibility to ensure that your promotional materials for Celebrex and Bextra
21 comply with each applicable requirement of the Act and FDA implementing regulations.”

22 68. Defendants coolly responded that they disagreed with the FDA’s interpretation of
23 the advertisements. Instead of immediately halting the advertisements or the misleading methods
24 highlighted by the FDA, Defendants explicitly told the FDA that they would “consider DDMAC’s
25 comments” when developing advertisements in the future.

26 **B. Studies on Bextra and Other COX-2 Inhibitors**

27 69. Based on studies performed on Celebrex, Vioxx, Bextra, and other COX-2
28 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.

70. 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

1 expected CLASS to show that Celebrex produced significantly fewer serious GI complications than
2 traditional NSAIDs.

3 71. The CLASS trial was a long-term, double-blind study of gastrointestinal toxicity in
4 8,059 patients taking Celebrex, ibuprofen, or diclofenac to treat arthritis. Patients with heart
5 problems were allowed to participate in the CLASS trial, and were permitted to take low doses of
6 aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

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

14 73. A post hoc analysis and comparison of CLASS study patients taking low-dose
15 aspirin for cardiac protection and patients not taking low-dose aspirin revealed that the rate of
16 combined anginal adverse events was 1.4% in the celecoxib (Celebrex) group versus 1.0% in the
17 ibuprofen and diclofenac groups. Although not a statistically significant difference, this tendency
18 towards increased cardiovascular toxicity was described by the FDA Medical Officer Dr. Witter,
19 who stated that "[f]or anginal disorders (especially the combined disorders), there seems to be a
20 trend toward more [cardiac adverse] events in those patients receiving celecoxib, regardless of
21 aspirin use."

22 74. This trend was magnified in those patients not taking low-dose aspirin. Combined
23 anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0%
24 in the diclofenac and ibuprofen groups, respectively. There were also more combined atrial serious
25 cardiac adverse events with celecoxib, 0.3% compared to 0.1% and 0% in the diclofenac and
26 ibuprofen groups, respectively. Dr. Witter commented that "[i]n the non-aspirin users, there
27 appears to be a slight trend toward more [serious cardiac adverse] events in those patients receiving
28 celecoxib for combined atrial and anginal disorders." Additionally, the rate of myocardial

1 infarction was higher in the celecoxib group, 0.2%, compared with the other two drugs, 0.1%.
2 Dr. Witter also referred to data from the original New Drug Application (“NDA”) for celecoxib in
3 his discussion, stating that “[t]here were suggestions of a dose-response relationship (... 100 mg
4 BID celecoxib, 0% crude mortality rate vs. 400 mg BID celecoxib, 0.64% crude mortality rate)
5 between cardiovascular mortality and [increased] celecoxib use that could not be adequately
6 addressed by the data.”

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

13 76. While none of the CLASS data was statistically significant, they revealed a
14 consistent and worrisome trend toward increased cardiovascular toxicity, particularly with regard
15 to increased thrombosis.

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

26 78. The subsequent trial was the APC colon polyp recurrence prevention study, in
27 which approximately 2000 patients took celecoxib or a placebo. Interestingly, this was the longest
28 celecoxib trial to date with mean duration of treatment being 33 months as opposed to the much

1 shorter 12-month duration of the CLASS study. A statistically significant elevation in the risk of
2 major fatal or non-fatal cardiovascular events (a composite endpoint of cardiovascular death, acute
3 myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in
4 the placebo group. This followed a dose-response relationship: the relative risk at 400 mg/day of
5 celecoxib was 2.5 while the relative risk at 800 mg/day was 3.4. Because of this unacceptable
6 danger, the trial was prematurely halted. The FDA released an explanatory statement which said,
7 “[w]hile we have not seen all available data on Celebrex, these findings are similar to recent results
8 from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently
9 voluntarily withdrawn by Merck.”

10 79. Merck had previously conducted a large-scale, long-term, double-blind study of
11 gastrointestinal toxicity in patients taking Vioxx or naproxen to treat arthritis. This study came to
12 be called the Vioxx Gastrointestinal Outcomes Research study (“VIGOR”).

13 80. Merck designed VIGOR to produce the absolute minimum number of
14 cardiovascular events by excluding patients with (a) a history of heart attack or coronary artery
15 bypass surgery within the past year; (b) a history of stroke or transient ischemic attack within the
16 past two years; or (c) or those who “required or who had been receiving treatment with aspirin,”
17 effectively excluding patients with a history of coronary artery or cerebrovascular disease. Despite
18 being designed so that participants would have far less cardiovascular disease than the normal
19 population taking NSAIDs and thereby minimizing the apparent cardiovascular risk of Vioxx in
20 comparison to naproxen, the VIGOR results still showed that patients taking Vioxx suffered more
21 than twice the number of serious thrombotic cardiovascular events and five times the number of
22 heart attacks as patients taking naproxen.

23 81. In October 2000, Merck sent its cardiovascular data from the VIGOR trial to the
24 FDA for review. In February 2001, the FDA published a Memorandum on the Vioxx
25 cardiovascular safety data gathered during VIGOR. In this Memorandum, the FDA concluded that
26 there “is an increased risk of cardiovascular thrombotic events, particularly [heart attack], in the
27 [Vioxx] group compared with the naproxen group.” The FDA considered and rejected all defenses
28 raised by Merck to explain the statistically significant increase of cardiovascular incidents among

1 Vioxx users. In February 2001, the FDA also concluded that Merck should have to add a
2 cardiovascular warning to its Vioxx packaging: “it would be difficult to imagine inclusion of
3 VIGOR results in the [Vioxx] labeling without mentioning cardiovascular safety results in the
4 study description as well as the Warnings sections.”

5 82. In August 2001, independent doctors from the Cleveland Clinic performed their
6 own meta-analysis of the Celebrex and Vioxx clinical trials on the issue of cardiovascular safety.
7 Their findings “suggest a potential increase in cardiovascular event rates for the presently available
8 COX-2 inhibitors.” Based on their findings and the widespread use of COX-2 inhibitors, these
9 doctors concluded “that it is mandatory to conduct a trial specifically assessing cardiovascular risk
10 and benefit of these agents.”

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

15 84. Studies show that COX-2 inhibitors, including Bextra, decrease production of a
16 cardioprotective substance called prostacyclin. When prostacyclin synthesis is suppressed the
17 arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

18 85. Label changes implemented in November 2004 reflected the growing scientific data
19 that Bextra and parecoxib posed serious cardiovascular risks. A contraindication was added for the
20 treatment of post-operative pain immediately following coronary artery bypass graft surgery based
21 on the results of three placebo-controlled studies (two coronary artery bypass graft (CABG)
22 surgery studies and one general surgery study) that were conducted to evaluate the safety of Bextra
23 and parecoxib. As reflected in the new labeling, results of the first CABG study (“CABG I”)
24 showed,

25 a significantly ($p < 0.05$) greater incidence of
26 cardiovascular/thromboembolic events (myocardial infarction,
27 ischemia, cerebrovascular accident, deep vein thrombosis and
28 pulmonary embolism)...in the parecoxib/vadecoxib treatment group
compared to the placebo/placebo treatment group for the IV dosing
period (2.2% and 0.0% respectively) and over the entire study period
(4.8% and 1.3% respectively).

1 CABG I results also revealed an increased rate of surgical wound complications in patients treated
2 with valdecoxib and parecoxib.

3 86. The results of CABG II, as reflected in the new label, emphasized these
4 cardiovascular risk concerns. CABG II revealed,

5 [a] significantly...greater incidence of events in the
6 cardiovascular/thromboembolic category...in the
7 parecoxib/valdecoxib treatment group (2.0%) compared to the
8 placebo/placebo treatment group (0.5%). Placebo/valdecoxib
treatment was also associated with a higher incidence of CV
thromboembolic events versus placebo treatment, but this difference
did not reach statistical significance.

9 Although the third general surgery study did not reveal significant differences in the overall safety
10 profile of the comparators, the FDA found the data as a whole compelling enough to include the
11 new contraindication for CABG patients in the labeling.

12 87. Another new addition to the label, entitled “Cardiovascular Safety Analysis from
13 Osteoarthritis and Rheumatoid Arthritis Studies,” explains that although “no apparent differences
14 were detected in the exposure-adjusted serious cardiovascular thromboembolic event rates between
15 patients receiving BEXTRA, placebo and NSAIDs,” Bextra has not been studied in controlled
16 clinical trials longer than one year and the clinical studies that have been conducted were not
17 powered to detect differences cardiovascular events in a chronic setting.

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

24 89. By November 2004, the FDA had received nearly ninety reports of such severe skin
25 reactions, some of which resulted in hospitalization and death. While other NSAIDs also pose a
26 risk for rare, serious skin reactions, the reported rate of such side effects was vastly higher in
27 individuals taking Bextra.

28

1 90. In mid-January 2005, an editorial in *Circulation* combined the results of two studies
2 of Bextra and parecoxib in post-cardiac bypass surgery patients (separate from the studies
3 described above). The results showed that those taking Bextra and parecoxib developed three
4 times more heart attacks and strokes (statistically significant) than those given a placebo.

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

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

19 93. A paper published in the December 4, 2004 LANCET found, after analyzing 18
20 randomized controlled trials and 11 observational studies, that by the year 2000 these studies
21 showed an increased risk of myocardial infarction from use of Vioxx and that it should have been
22 withdrawn years earlier. Pfizer was aware of each of these studies and should not have advertised
23 Bextra as generally safe.

24 94. An Australian study released in March 2005 analyzed results from all nineteen
25 randomized controlled trials of COX-2 inhibitors published before May 2004 and found that those
26 studies indicated that individuals taking COX-2 inhibitors, including Bextra, had a 60% higher
27 chance of elevated blood pressure compared with those on a placebo.
28

1 95. Despite years of studies on COX-2 inhibitors, as well as disturbing new studies
2 specifically analyzing the risks of Bextra, Defendants failed to take any action to protect the health
3 and welfare of patients and instead continued to promote the CV safety of Bextra.

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

6 ...the Agency has concluded that the overall risk versus benefit
7 profile of Bextra is unfavorable. This conclusion is based on the
8 potential increased risk for serious cardiovascular (CV) adverse
9 events, which appears to be a class effect of non-steroidal anti-
10 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.

11 FDA Alert for Healthcare Professionals, April 7, 2005.

12 97. Continuing, the FDA noted:

13 Bextra has been demonstrated to be associated with an increased risk
14 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
15 extrapolate the adverse CV risk information for Bextra from the
short-term CABG trials to chronic use given the fact that other COX-
16 2 selective NSAIDs have been shown in long-term controlled clinical
trials to be associated with an increased risk of serious adverse CV
17 events (e.g., death, MI, stroke), and the well described risk of serious,
and often life-threatening gastrointestinal bleeding.... To date, there
18 have been no studies that demonstrate an advantage of Bextra over
other NSAIDs that might offset the concern about the[] serious skin
19 risks, such as studies that show a GI safety benefit, better efficacy
compared to other products, or efficacy in a setting of patients who
20 are refractory to treatment with other products.

21 *Id.*

22 98. Pfizer agreed to suspend sales of Bextra, and Bextra has been withdrawn from the
23 market as of April 7, 2005.

24 **C. Marketing and Promotion**

25 99. Despite knowing (i) that Bextra posed serious cardiovascular risks for anyone who
26 took it, along with the risk of a death-causing skin disease, (ii) that Bextra provided no clinically
27 proven improvement over pain relief for OA and RA, (iii) that Bextra was not indicated for the
28 treatment of acute pain and (iv) that Bextra provided no clinically proven improvement for GI

1 safety, Defendants made a business decision to push Bextra to market on claimed improvements in
2 GI and CV safety, while downplaying its skin dangers.

3 100. Defendants initiated extensive marketing campaigns to convey the uniform message
4 that Bextra provided effective pain relief without the gastrointestinal and cardiovascular side
5 effects of other NSAIDs. Such claims were not permitted by the FDA. Defendants also falsely
6 promoted Bextra as safe by downplaying or omitting the serious skin risks posed by use of the
7 drug. Defendants pursued this strategy to benefit from the assumption that, in the absence of
8 information to the contrary, Bextra possessed the same skin dangers as traditional NSAIDs.

9 101. Defendants' advertising efforts included blitzing doctors' offices with literature and
10 verbal presentations designed to convince both doctors and consumers that Bextra was a superior
11 drug for treatment of osteo- and rheumatoid arthritis and primary dysmenorrhea. They
12 aggressively promoted Bextra as an improvement over older, less expensive NSAIDs, like
13 naproxen and ibuprofen, claiming it had a lower risk of gastrointestinal side effects such as
14 gastrointestinal ulcers and bleeding. Defendants did not promote or provide any balanced
15 presentation as to Bextra having an unacceptably high risk of other side effects, such as heart
16 attacks, strokes, unstable angina, cardiac clotting, hypertension, and severe skin reactions.

17 102. Such marketing efforts to physicians have become commonplace in recent years.
18 Drug companies pay national and local "thought leaders" or "key opinion leaders," including local
19 specialists, to speak at continuing medical education events that promote the use of expensive new
20 drugs such as Bextra. In addition, drug companies – with Pfizer in the forefront – spent billions on
21 "detailing" to physicians – *i.e.*, having their sales representatives visit doctors in their offices,
22 frequently bringing gifts and lunch, to "educate" doctors about their companies' drugs.

23 103. The deceptive marketing techniques that Pfizer employed through "thought leaders"
24 are apparent in an internal summary document of a November 2001 advisory committee meeting
25 regarding the marketing of Bextra. Even though Defendants received feedback at the meeting from
26 its advisors that "CV concerns with Bextra seem real, considering: · 92% of OA patients in study
27 #047 developed hypertension · Hypertensive patients undergoing CABG have higher incidence of
28 MI," they also received the following marketing feedback:

1 Do not draw unnecessary attention to CABG data by communicating
2 about it too much.

3 ...

4 [It is] [h]ard to position Bextra for pain and Celebrex for arthritis,
5 when labeling positions Bextra for arthritis not pain – **marketing
6 plan is out of sync with the label.**

7 ...

8 Physician education will be crucial to explain why Bextra should be
9 used instead of other NSAIDs when the product has no pain
10 indication · **Pain data must be disseminated via medical education
11 initiatives.**

12 ...

13 Publish BEXTRA acute pain abstracts soon and often. It sends a
14 powerful message.

15 (emphasis added). Defendants clearly heeded this advice and did exactly as recommended by (1)
16 downplaying any cardiovascular safety signals by not raising or avoiding negative data, even
17 though such data was in sync with the cardiovascular risks noted in the Bextra label, (2) marketing
18 Bextra for acute pain, an indication for which it was not approved, and (3) avoiding the limits
19 placed on Bextra’s marketing by the FDA labeling by providing one sided pain data to doctors
20 under the guise of “medical education.”

21 104. The Defendants marketed Bextra for use in the treatment of pain, contrary to its
22 FDA approved labeling, directly to doctors. In a summary document of “Final Evaluations” from
23 the 2002 National Consultant’s Meeting for Orthopedic Surgeons organized by Defendants,
24 participant responses to the question “which specific information presented did you find most
25 compelling,” included,

- 26 · Valde[coxib] used as pain med.
- 27 · Pain data – synergy of multimodal therapy
- 28 · Safety & efficacy of Celebrex & Bextra
- ...
 - Gastrointestinal safety profile of COX-2 inhibitors
- ...

- 1 · Although Bextra doesn't have a pain indication, it is effective in
- 2 pain management
- 3 · Use of Bextra as a pre-op adjunct and post op for management of
- 4 pain...

5 The physician responses establish that Defendants were ignoring the FDA indications for Bextra
6 and moving forward with their marketing strategy, falsely marketing Bextra as generally safe and
7 effective especially for GI and promoting it for pain even though the FDA refused to approve it for
8 the treatment of pain.

9 105. At meetings with analysts, Pfizer revealed its marketing strategy and the message it
10 was conveying to medical providers for the use of Bextra, as reported in a December 21, 2001
11 report published in ESPIcom Business Intelligence Ltd:

12 Pfizer also received regulatory approval for Bextra, a second-
13 generation Cox-2 inhibitor for the treatment of osteoarthritis (OA),
14 rheumatoid arthritis (RA) and menstrual pain. Co-promoted with
15 Pharmacia, Bextra is a new, once-daily option for people with OA
16 and RA. It offers improved gastrointestinal toleration with no
17 increase in renal or cardiovascular risk versus traditional NSAIDs.

18 106. In this and other press releases and promotional devices Defendants falsely
19 promoted the GI and CV superiority of Bextra as compared to other NSAIDs.

20 107. Based on information supplied by Pfizer, the following appeared in the August 9,
21 2003, CHEMIST & DRUGGIST:

22 Bextra is a new... Cox-2 inhibitor from Pfizer indicated for treatment
23 of symptoms of osteoarthritis and rheumatoid arthritis as well as
24 dysmenorrhoea. In clinical trials it showed similar efficacy to
25 maximum doses of naproxen, ibuprofen and diclofenac, but has a
26 lower incidence of gastroduodenal ulcers than the traditional
27 NSAIDs. Bextra contains valdecoxib, a Cox-2 enzyme inhibitor.

28 108. Based on information supplied by Pfizer the following appeared in COMMUNITY
PHARMACY on July 21, 2003:

 Bextra (valdecoxib), from Pharmacia, is a new cyclooxygenase-2
(Cox-2) selective inhibitor, indicated for the symptomatic relief of
osteoarthritis (OA), rheumatoid arthritis (RA) and primary
dysmenorrhoea. In the UK, 20 million people have an arthritic
condition and up to pounds 920 million, excluding indirect costs, is
spent annually on their care. **Bextra** offers a powerful alternative to
maximum doses of the traditional non-steroidal anti-inflammatory
drugs (NSAIDs), diclofenac, naproxen and ibuprofen in OA and RA,
and a powerful alternative to naproxen sodium for those patients

1 suffering pain associated with primary dysmenorrhoea, says the
2 company. *Additionally, being selective it largely avoids*
gastrointestinal side effects. (Emphasis added.)

3 109. The following was published at the request of Pfizer in THE PRACTITIONER on
4 July 7, 2003:

5 **Bextra** is a fast-acting oral COX-2 selective inhibitor for the
6 treatment of osteoarthritis, rheumatoid arthritis and primary
7 dysmenorrhoea, and was developed to offer an alternative to
8 maximum dose traditional **NSAIDs**. The recommended dose in
arthritis is 10mg once- daily, although some patients may benefit
from a 20mg dose daily. Patients suffering from menstrual cramps
are recommended to take 40mg doses.

9 110. On or about May 19, 2003, Pfizer issued the following statement:

10 Pfizer Inc Receives Approval to Market New Oral COX-2 Inhibitor
11 Bextra (Valdecoxib) in Europe

12 Pfizer Now Offers the Widest COX-2 Inhibitor Portfolio

13 NEW YORK, May 19 – Pfizer Inc said today that it has
14 received approval to market Bextra(R) (valdecoxib) film coated
15 tablets, the newest COX-2 selective inhibitor in its portfolio, in
Europe for treatment of patients with pain and inflammation
associated with osteoarthritis (OA), rheumatoid arthritis (RA) and
primary dysmenorrheal (painful menstrual cramping).

16 Valdecoxib received marketing authorization from the
17 European Commission with labeling that is valid in all 15 European
18 Union (EU) member states, and the approval will be extended to
Norway and Iceland. This approval allows Pfizer to offer the widest
portfolio of COX-2 selective inhibitors in Europe.

19 “We are pleased with the EU Commission decision to
20 approve Bextra and look forward to offering patients and physicians
21 a new option for treating osteoarthritis, rheumatoid arthritis and
22 primary dysmenorrheal,” said Dr. Jack Watters, Pfizer’s Vice
23 President, Medical and Regulatory, Europe and Canada. “COX-2
24 selective inhibitors are an innovative class of medicines specifically
developed to relieve pain and inflammation as effectively as widely
used conventional non-steroidal anti-inflammatory drugs, *while*
offering an improved upper gastrointestinal safety profile,” he
added. (Emphasis added.)

25 111. Each of the foregoing releases was designed to create demand for Bextra by those
26 making decisions concerning the use of Bextra by patients. Each of the foregoing were just
27 examples of dozens of such marketing ploys disseminated by Defendants.
28

1 112. Another of Defendants’ marketing ploys was to detail Bextra along side of
 2 Celebrex, revealing only the positive data for each drug so that doctors would think that the
 3 positive data actually applied to both drugs. The Defendants referred to this marketing strategy as
 4 the “Halo Effect.” The Halo Effect is contrary to the FDA approved labeling for both drugs in that
 5 it promoted each drug with data that had no scientific connection whatsoever to that drug.
 6 Defendants’ employment of the Halo Effect shows a clear lack of fair balance in the Defendants’
 7 detailing methods – ignoring the risks of one drug and touting its benefits. As revealed in the sales
 8 training presentation below, the Halo Effect was taught as a technique for marketing both drugs.
 9 Such selective presentation of safety data was contrary to the FDA approved labeling.

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Joint Master VisAid

A Dramatic Difference

The Difference	The Rationale
<ul style="list-style-type: none"> ■ Only 5 Spreads (vs. 20!!)... With Efficacy Focus 	<p>➤ <i>FOCUS on What's Important</i></p>
<ul style="list-style-type: none"> ■ Safety Data <ul style="list-style-type: none"> - GI → Only in Celebrex Section - CV → Only in Bextra Section 	<p>➤ <i>Halo Effect! Physicians Assume Data Apply to Both Products</i></p>
<ul style="list-style-type: none"> ■ New Patients <ul style="list-style-type: none"> - Celebrex Patients: Older, Vibrant, Productive - Bextra Patients: Younger, Active 	<p>➤ <i>Helps Differentiate Brands</i></p>

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27 113. Another of Defendants’ marketing and promotional devices that was deceptive and
 28 contrary to its FDA approved labeling was the funding of research designed to falsely produce

1 positive outcomes with Bextra usage. These findings were then published in medical journals and
2 distributed via press releases and other public relations techniques to medical and non-medical
3 media, targeted at doctors, the public and others in the drug purchasing decision chain. During the
4 Class Period, these paid researchers touted the safety of Bextra. For example, the following doctor
5 was quoted in a Pharmacia press release, dated November 27, 2002, as follows:

6 “Our analysis suggests that valdecoxib shows no greater incidence of
7 cardiovascular events than either naproxen or placebo,” said lead
8 author Andrew Whelton, M.D., adjunct professor of Medicine, Johns
9 Hopkins University, Baltimore, Maryland. “While more data are
10 necessary to confirm this conclusion, our findings suggest that
11 valdecoxib demonstrates a cardiovascular safety profile similar to
12 that of placebo or naproxen.”

10 According to Whelton, “Whether patients were or were not taking
11 aspirin did not significantly impact the incidence of serious adverse
12 events.”

12 114. Such a claim is not permitted by the FDA label or within the scope of FDA
13 approval.

14 115. Another example of Defendants’ deceptive marketing is the republication, in a press
15 release issued on August 1, 2002, of the results of a study in the JOURNAL OF OBSTETRICS AND
16 GYNECOLOGY purporting *to show that Bextra was more effective than Naproxen for treatment of*
17 *pain during menstruation*. The study compared Bextra 40 mg twice daily (BID) as needed, Bextra
18 20 mg BID as needed, naproxen sodium 550 mg BID as needed, to placebo for up to 3 days for the
19 treatment of pain associated with menstruation (dysmenorrhea). The maximum dose of Bextra
20 approved by the FDA for the treatment of primary dysmenorrhea was up to 20 mg BID per day.
21 On every measure of pain relief, naproxen sodium 550 mg provided better pain relief than Bextra
22 20 mg BID (some of the differences achieved statistical significance). Furthermore, patients taking
23 Bextra 20 mg BID experienced more than twice as many of the most common side effects as did
24 the patients taking naproxen sodium 550 mg BID. In other words, Bextra provided inferior pain
25 relief, caused more side effects, and cost far more than naproxen sodium – it’s hard to understand
26 how this data could be used to make the case that Bextra was the superior choice – but that is just
27 what Defendants did. SCIREX Clinical Research Center, a company owned in part by OMNICON,
28 one of the largest advertising agencies, was hired by Pfizer to conduct this study. Pfizer reprinted

1 parts of the study, omitting the known risks of cardiovascular and skin disorders. Again, any
2 claims of pain superiority over other drugs was not permitted by the FDA label.

3 116. Defendants also used SCIREX, to promote Bextra via an article and an
4 accompanying continuing education quiz published in the JOURNAL OF THE AMERICAN DENTAL
5 ASSOCIATION. The study, featured by Pharmacia in a press release dated May 8, 2002, purported to
6 show Bextra's superiority for use in pain relief. No disclosure was made of the researchers'
7 financial ties to Pharmacia or to the known adverse effects associated with Bextra. One of the three
8 scientific reviewers of the paper – an associate editor of the journal – told the NY Times that, had
9 he known that Bextra had not been approved by the FDA for relief of dental pain, he would have
10 recommended the paper be rejected. As it was, the paper was published in the journal, along with a
11 continuing education quiz to reinforce the message that Bextra is helpful for post-dental surgery
12 pain, an indication for which Bextra was not approved.

13 117. These and similar studies helped increase the acceptance of Bextra by medical and
14 dental providers.

15 118. The Defendants also targeted consumers directly with false marketing claims
16 regarding Bextra. Some of the methods they used to reach consumers included leaving patient
17 directed brochures at doctors' offices and providing marketing materials to doctors that could be
18 distributed to their patients. Defendants also maintained websites and a toll free telephone number
19 that conveyed misleading information regarding the safety and efficacy of Bextra. As noted in an
20 internal memorandum, "there are several successful programs in the market now with proven value
21 in generating consumer demand for Bextra (e.g. TIME/PEOPLE Coverwrap MD Office program,
22 PERFORM magazine, In Office brochure) and this POA we will shortly roll out the very
23 successful unbranded "On the Road to Pain Relief" long format (30min) direct response TV ad."

24 119. As referenced above, the use of "unbranded" advertising is another all too common
25 and sophisticated method of advertising that Defendants used to market Bextra to consumers. It is
26 also a method of advertising that Defendants hoped would shield them from responsibility for false
27 claims conveyed. As one of Pfizer's sales managers describes in October 2004, immediately after
28 the withdrawal of Vioxx, "[w]e are currently running an unbranded long-format ad as well as a 60-

1 second ad about arthritis symptoms and appropriate treatment options. Consumers who respond to
2 these advertisements receive branded information on CELEBREX and/or Bextra.” Thus, the
3 “unbranded” advertisements were clearly used to market Celebrex and Bextra directly to
4 consumers.

5 120. After the withdrawal of Vioxx, and just one day before the Celebrex APC trial was
6 halted because of CV safety concerns, Defendants produced a document entitled “US Field Force
7 Selling Objections and Answers.” The document warns that it is “Company confidential,” “for
8 internal use only,” “DO NOT DETAIL” and “This document is provided to you for your
9 background information only,” but then goes on to describe how to respond to “objections health
10 professionals may raise regarding Bextra.” The first question and answer highlight how the Bextra
11 sales force was trained to promote the CV and GI safety of Bextra, even in the face of scientific
12 evidence to the contrary:⁵

13 Q1: How can I prescribe Bextra when patients with arthritis often
14 have increased CV risk?

15 A: Bextra still can be administered safely to patients with arthritis.
16 In a large pooled analysis of 10 arthritis trials in which almost half
17 the patients had at least 1 coronary risk factor, there were no apparent
18 differences detected in the serious CV thrombotic event rates
19 between patients receiving Bextra, placebo, and nonspecific
20 NSAIDs. In this analysis, 13% of patients were taking daily low-
21 dose aspirin, with no increase in CV risk with Bextra. While Bextra
22 is contraindicated for the treatment of postoperative pain following
23 coronary artery bypass graft, or CABG, surgery, it remains an
24 effective and safe treatment for vast number of patients with arthritis
25 who need pain relief along with superior GI safety.

26 121. Thus, as reflected above, the Defendants instructed their sales force to market
27 Bextra in a manner that the FDA had not approved and in direct contradiction to the approved FDA
28 labeling.

122. In another “objection response” in the same document, Defendants again tout the GI
superiority of Bextra, again in direct contradiction to the FDA approved labeling:

Q1: How can I prescribe Bextra when it is so difficult to get
reimbursement for COX-2 specific inhibitors?

⁵ The entire document from which this is excerpted is attached hereto as Exhibit 1.

1 The formulary status for Bextra has not changed dramatically. And
2 several managed care plans may be using the latest developments as
3 a reason to question the clinical value and appropriateness of the
4 COX-2 specific inhibitor class. However, managed care plans do
5 realize that only physicians know the appropriate therapy for their
6 patients. Because the risk of GI bleeding remains a serious issue
7 with nonspecific NSAIDs, treatment guidelines still stress COX-2
8 specific inhibitors as first-line treatment for patients at GI risk.
9 Consequently, managed care plans will continue to reimburse for
10 drugs such as COX-2 specific inhibitors as long as physicians
11 confidently affirm that these medications are medically necessary
12 and appropriate for their patients.

13 123. Defendants’ false promotions of the cardiovascular safety and superiority of Bextra
14 are evident in the following advertisement. In the advertisement, doctors are falsely reassured that
15 they can safely prescribe Bextra because of its “established CV profile,” even though no such
16 established CV profile existed and no such profile appears in the FDA approved labeling.
17 Furthermore, the bold statement “Prescribe CELEBREX and BEXTRA With Confidence” implies
18 that absolutely none of the risk information contained in the FDA approved labeling even exists.
19 Such advertising is deceptive and contrary to the FDA approved label for Bextra.⁶

**Prescribe CELEBREX and BEXTRA
With Confidence**

**CV safety with the efficacy your patients
may need**

- CELEBREX and BEXTRA have an established CV profile²
- CELEBREX and BEXTRA both provide joint pain relief with established CV safety^{3,4}

20 124. The Defendants strategically placed comments on the CV safety of Bextra with
21 claims of superior efficacy. In the following advertisement, Defendants imply that there is no CV
22 risk with Bextra because in unspecified “clinical trials,” the incidence of CV events is similar to a
23 placebo. Such a claim lacks fair balance, since it implies that there are no clinical trials in which
24 CV events are higher as compared to placebo – which there were – and is in direct contradiction to
25
26
27

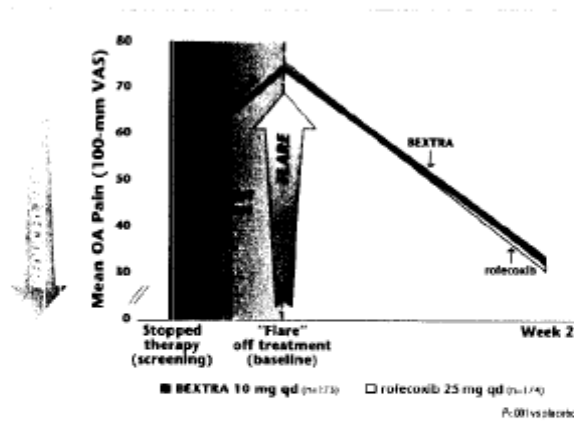
28 ⁶ The excerpt above appears at bates number Cele NDA 20-99800022356 of Defendants’ document attached hereto as Exhibit 2.

1 the FDA approved labeling. The footnote after the false CV claim leads a reader to the dead end
 2 "Data on file, Pfizer Inc., New York, NY," and hence, does not cure the deceptive presentation.⁷



BEXTRA POWER FOR SIGNIFICANT RELIEF OF OA FLARE PAIN*

BEXTRA 10 mg power vs rofecoxib 25 mg compared with baseline



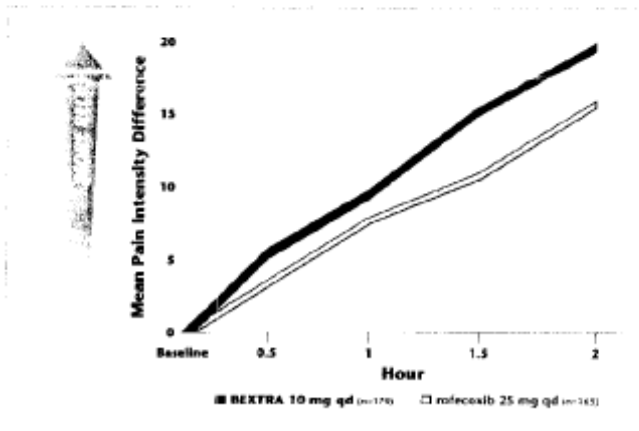
Mean OA Pain (VAS) at week 2

Randomized, multicenter, double-blind, 2-week comparison study (N=500) of the efficacy and safety of BEXTRA 10 mg qd, rofecoxib 25 mg qd, and placebo in patients with OA of the knee in a flare state. Assessments were based on a Visual Analog Scale (VAS) from 0 (no pain) to 100 (most severe pain). Patient's Assessment of OA Pain-VAS at Week 2 (N=439 in evaluable cohort) was a primary end point.

83% of patients were taking previous medications at screening, including 1% rofecoxib, 13% prescription nonsteroidal anti-inflammatory drugs (NSAIDs), 7% Ultram/Ultracet[®] or narcotic combinations, and 25% others (eg, over-the-counter NSAIDs, including aspirin).

*BEXTRA was statistically significant vs placebo (P<0.01). (Mean change from baseline with placebo was 28.2.)

Source: Data on file.



Pain relief through hour 2 on day 1

See study design above. Pain Intensity Difference (PID) (N=425 in evaluable cohort) at 0, 30, 60, 90, 120, and 180 minutes after first dose at clinic as well as at hours 4, 5, and 6 at home on day 1 was a secondary end point. PID baseline values: 69.6 mm for BEXTRA and 96.3 mm for rofecoxib.

Source: Data on file.

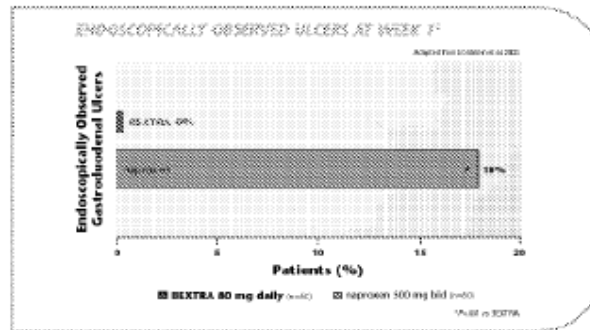
In clinical trials, incidence of CV adverse events with BEXTRA 10 to 20 mg was similar to placebo¹

25
26
27
28 ⁷ The referenced excerpt appears at bates number Bex NDA 21-341 00013129 of Defendants' document attached hereto as Exhibit 3.

1 125. In this December 2004 ad, Bextra was falsely promoted, contrary to its FDA
 2 approved labeling, as having “SUPERIOR 3-MONTH GI SAFETY DATA” and deceptive data
 3 was presented as “POOLED ANALYSIS” in support of that claim. In a January 2001 letter,
 4 however, the FDA scolded Defendants about the continuous onslaught of misleading
 5 advertisements and advertising methods, stating, “[w]e are not aware of any evidence showing that
 6 Celebrex or Bextra has superior effectiveness to non-selective NSAIDs.”⁸



**IN A RANDOMIZED 1-WEEK STUDY,
 NO PATIENTS TAKING BEXTRA AT SUPRATHERAPEUTIC DOSES DEVELOPED ULCERS**



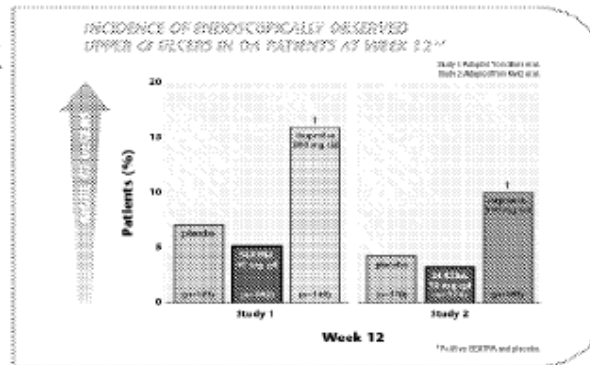
Randomized, double-blind, 1-week study (N=188) comparing the safety of BEXTRA 40 mg bid, naproxen 500 mg bid, and placebo in healthy elderly subjects with endoscopically observed normal upper GI mucosa. Upper GI safety was determined by comparing gastric and duodenal ulceration rates and endoscopy scores between treatment groups. An ulcer was defined as any lesion of any size with unequivocal depth.

Source: Goldstein et al, 2003.

The correlation between findings of endoscopic studies and the incidence of clinically significant serious upper GI events has not been established.

■ 18% of patients taking naproxen developed ulcers³

SUPERIOR 3-MONTH GI SAFETY DATA



Study 1: Randomized, multicenter, double-blind, 12-week study (N=1067) comparing GI safety and tolerability of BEXTRA 10 and 20 mg qd with ibuprofen 800 mg tid, diclofenac sodium 75 mg bid, and placebo in patients with OA. Upper GI endoscopies were performed prior to and 12 weeks after the first dose of study medication or at early termination. An ulcer was defined as a lesion of at least 3 mm in diameter with unequivocal depth. At Week 12, the incidence of endoscopically observed upper GI ulcers in patients taking diclofenac sodium 75 mg bid was 17% (P<0.05 vs BEXTRA 10 mg qd and placebo).

Study 2: Randomized, multicenter, double-blind, 12-week comparison study (N=1019) of the efficacy and safety of BEXTRA 5, 10, and 20 mg qd, naproxen 500 mg bid, and placebo in patients with OA of the knee. Upper GI endoscopy was performed at baseline and Week 12.

Source: Study 1, Sikes et al; Study 2, Kivitz et al.

IN A POOLED ANALYSIS³

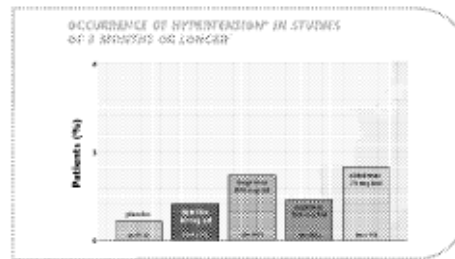
■ BEXTRA 5 to 80 mg (8 times the recommended dose for arthritis) had a statistically significant (P=.018), 3-fold low annualized incidence of upper GI ulcer complications compared with the nonspecific NSAIDs naproxen, ibuprofen, and diclofenac (0.68% vs 1.96%)⁵

⁸ The image above appears at bates number Litwac-A 10000617953 in Defendants’ document attached hereto as Exhibit 4.

1 126. The same detailing brochure contains this false pronouncement of the
 2 “CARDIORENAL SAFETY PROFILE” of Bextra. The graphic used include deceptive pooled
 3 analyses of data and includes partial and small print risk information that fails to present a fair
 4 balance of the risks associated with Bextra as detailed in its FDA approved labeling.⁹

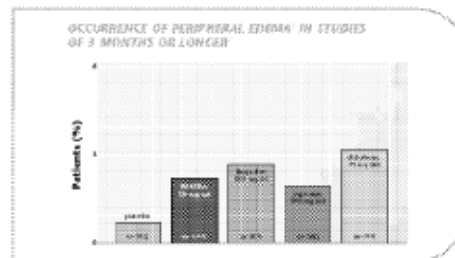


INCIDENCE OF HYPERTENSION VS COMPARATOR NSAIDS



Pooled analysis of 7 controlled studies (N=5048) conducted in patients with OA or RA. More than 2800 patients have received BEXTRA 10 mg per day or more for at least 6 months, and 988 of these have received BEXTRA for at least 1 year.
 *Investigator reported.
 Source: BEXTRA prescribing information.

INCIDENCE OF PERIPHERAL EDEMA VS COMPARATOR NSAIDS



See study design above.
 *Investigator reported.
 Source: BEXTRA prescribing information.

The incidence of renal events observed in this analysis was significantly higher with BEXTRA and comparator nonsteroidal anti-inflammatory drugs (NSAIDs) than with placebo.

SUPRATHERAPEUTIC-DOSE SAFETY INFORMATION

- In a separate study, at supratherapeutic dosages, the incidence of renal events,¹ including hypertension and edema, was significantly greater in the BEXTRA 80 mg daily group (12%) (4 to 8 times the recommended therapeutic dosage) than in the naproxen group (5%).¹
- The clinical relevance of renal events observed with supratherapeutic dosages (4 to 8 times the recommended therapeutic dosage) of BEXTRA is not known.

¹The renal end point was defined as any of the following: new/increase in edema, new/increase in congestive heart failure, increase in blood pressure (BP): >20 mm Hg systolic, >10 mm Hg diastolic; new/increase in BP treatment, new/increase in diuretic therapy, creatinine increase over 30% (or >1.2 mg/dL if baseline <0.9 mg/dL), BUN increase over 200% or >50 mg/dL, 24-hour urinary protein increase to >500 mg (if baseline 0 to 150 mg or >750 mg if baseline 151 to 300 mg or >1000 mg if baseline 301 to 500 mg), serum potassium increase to >6 mEq/L, or serum sodium decrease to <130 mEq/L.

BEXTRA is contraindicated for the treatment of postoperative pain immediately following coronary artery bypass graft (CABG) surgery and should not be used in this setting.

Fluid retention and edema have been observed in some patients taking BEXTRA. Therefore, BEXTRA should be used with caution in patients with fluid retention, hypertension, or heart failure.

NSAIDs have been associated with worsening renal function; therefore, use in advanced renal disease is not recommended.

Not to be left with physician.
 Please see accompanying full prescribing information.



⁹ The image above appears at bates number Litwac-A 10000617955 of Defendants’ document attached hereto as Exhibit 5.

1 127. Each of the foregoing advertisements was designed to create demand for Bextra by
2 those making decisions concerning the use of Bextra by patients. Each of the foregoing were just
3 examples of dozens of such marketing ploys disseminated by Defendants either orally to doctors or
4 in written material.

5 **D. Risks Posed by Bextra**

6 128. Despite the effectiveness of their advertising campaigns, Defendants' false
7 promotion of Bextra by touting it as GI and CV safe and downplaying its risk of severe skin
8 reactions did not quell concerns about selective COX-2 inhibitors in the medical community.

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

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

16 131. The cardiovascular safety of selective COX-2 inhibitors was directly challenged in
17 August 2001, when independent doctors from the Cleveland Clinic published a meta-analysis of
18 the CLASS trial that concluded these drugs posed an increased risk of adverse cardiovascular
19 events compared to naproxen, a traditional NSAID.

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

24 133. Defendants' advertising and packaging materials for Bextra are uniformly
25 fraudulent and misleading because they falsely promote Bextra as safe, even though Bextra was
26 known to pose risks of gastrointestinal adverse events, heart attacks, strokes, unstable angina,
27 cardiac clotting, hypertension, and severe skin reactions.

28

1 134. At the Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and
2 Risk Management Advisory Committee, the Committee concluded that “no clear data shows GI
3 benefit for Celebrex and Bextra.” The Committee noted that the GI benefits are “less than first
4 reported,” referring to reports by Defendants and others regarding trials they had coordinated
5 purporting to show GI benefits.

6 **E. Defendants’ Continued Unlawful Marketing Campaign Caused Overcharges to End-
7 Payors for Bextra**

8 135. As a result of Defendants’ claims, Plaintiffs and members of the Class purchased
9 and/or paid for Bextra even though a monthly supply was much more expensive than other
10 NSAIDs.

11 136. To justify the disparity of Bextra’s pricing as compared to other NSAIDs and to
12 ensure that physicians would prescribe and that End-Payors would purchase the drug, Defendants
13 misrepresented the safety and efficacy of Bextra and suppressed the risks, dangers, and
14 disadvantages of the drug. Consequently, Bextra captured a large market share of anti-
15 inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of Bextra exceeded
16 \$1.2 billion, despite the significantly higher cost of Bextra as compared to other pain relievers in
17 the same family of drugs.

18 137. Defendants’ deceptive and misleading marketing campaign concealed, omitted, and
19 suppressed information that resulted in overcharges to consumers and third-party payors, such as
20 Plaintiffs and the Class, for, in whole or in part, the costs of Bextra. Millions of End-Payors,
21 including consumers and third-party payors, have already paid for, and/or purchased and consumed
22 Bextra at prices based on the proposed wholesale price, which was about one hundred times the
23 cost of a generic aspirin. These End-Payors did not get the benefit of the bargain that Defendants
24 held out to them, and as a result End-Payors paid more than they would have or should have
25 because Bextra was promoted and advertised as a premium drug with reduced side effects for the
26 purpose of deceiving consumers and End-Payors about Bextra’s adverse gastrointestinal,
27 cardiovascular, cerebrovascular and cardiorenal effects. Had the truth been told and Bextra not
28

1 been promoted contrary to its approved labeling it would not have been placed on formularies and
2 not been paid for by End Payors.

3 **V. FRAUDULENT CONCEALMENT**

4 138. Throughout the Class Period, Defendants affirmatively and fraudulently concealed
5 its unlawful conduct from Plaintiffs and the Class.

6 139. Plaintiffs and the Class did not discover, and could not discover through the exercise
7 of reasonable diligence, that Defendants were falsely over promoting the safety and efficacy of
8 Bextra until April 7, 2005, when Pfizer withdrew Bextra from the market. Defendants conducted
9 its unlawful activities in secret, concealed the nature of their unlawful conduct, and attempted to
10 confine information concerning the adverse effects of Bextra. Defendants attempted to withhold
11 such information from Plaintiffs and members of the Class, the medical community, regulators and
12 the public. Defendants fraudulently concealed its activities through various means and methods
13 designed to avoid detection.

14 140. Plaintiffs and the Class could not have discovered Defendants' unlawful conduct at
15 an earlier date through the exercise of reasonable diligence because Defendants actively and
16 purposefully concealed their unlawful activities.

17 141. Defendants engaged in a successful, illegal fraud on consumers, third-party payors
18 and the general public, by which they deliberately and affirmatively misrepresented the risks,
19 dangers, defects, and disadvantages of Bextra, in at least the following respects:

20 a. By falsely promoting the safety and efficacy of Bextra to Plaintiffs, the
21 Class, the medical community, and the public in a manner that exceeded the scope of FDA
22 approval;

23 b. By omitting adverse event risks from its promotions of Bextra to the Class,
24 the medical community, and the public in a manner that made its promotion not fairly balanced and
25 inconsistent with the express label or the intent of the label;

26 c. By agreements among senior Pfizer and Pharmacia officials in meetings and
27 in communications not to discuss publicly, or otherwise reveal, the totality of the adverse effects
28

1 caused by Bextra, Defendants’ concealment of those adverse effects, and the nature and substance
2 of other acts and communications in furtherance of Defendants’ illegal scheme; and

3 d. By giving false and pretextual reasons for the existence of apparent adverse
4 effects in studies of COX-2 drugs, including, for example, by claiming that naproxen’s
5 cardioprotective effect was responsible for a noted increase in cardiovascular events in the VIGOR
6 study in Vioxx versus naproxen patients, when, in fact, Vioxx is another COX-2 inhibitor which
7 was the cause of the reported increased incidence of cardiovascular effects.

8 142. As a result of Defendants’ fraudulent concealment, Plaintiffs and the Class
9 purchased and/or paid for Bextra and could not reasonably have discovered Defendants’
10 misconduct regarding Bextra prior to April 7, 2005. Plaintiffs and the Class therefore assert the
11 tolling of any applicable statute of limitations affecting the rights of action of Plaintiffs and the
12 Class.

13 **VI. CLASS ACTION ALLEGATIONS**

14 143. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs seek
15 certification of a national Class defined as follows:

16 All End-Payors located in the United States, including Consumers
17 and Third-Party Payors,¹⁰ who purchased and/or paid for Bextra.

18 Excluded from the proposed Class are (i) Defendants, any entity in
19 which Defendants have a controlling interest or which have a
20 controlling interest in Defendant, and Defendants’ legal
21 representatives, predecessors, successors and assigns; (ii) the judicial
22 officers to whom this case is assigned; (iii) any member of the
23 immediate families of excluded persons; (iv) governmental agencies
24 and (v) those who resold Bextra.¹¹

25 144. Plaintiffs also define state law subclasses as defined in the various claims for relief
26 in the counts set forth below.

27 ¹⁰ Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes
28 prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription
drugs prescribed and dispensed to those persons pursuant to a health plan.

¹¹ Plaintiffs have named class representatives for the Class, but have not named class representatives for every
jurisdiction. Should the Court so require or direct, Plaintiffs are prepared to name proposed class representative
Plaintiffs for every jurisdiction, or for each statewide class, and for each subclass the Court may designate.

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

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

6 a. Whether Defendants engaged in a fraudulent and/or deceptive scheme to
7 portray Bextra as a drug having superior qualities to other NSAIDs;

8 b. Whether Defendants engaged in a scheme to create demand for Bextra based
9 on deceptive statements concerning Bextra's safety and efficacy;

10 c. Whether as a result of this scheme Bextra was over prescribed;

11 d. Whether unnecessary physician visits were deliberately generated by falsely
12 creating the impression that Bextra – available only by prescription – offered greater benefit than
13 equally effective and far less expensive NSAIDs, several of which could be purchased without a
14 prescription;

15 e. Whether Defendants are liable to Plaintiffs and the Class for damages under
16 state consumer protection statutes;

17 f. Whether Defendants made material misrepresentations or material omissions
18 about the cardiovascular and gastrointestinal risks associated with using Bextra and regarding the
19 effectiveness of Bextra; and

20 g. Whether members of the Class are entitled to damages based on their
21 payments for Bextra, and, if so, the nature and amount of such damages.

22 147. Plaintiffs' claims and defenses are typical of the claims and defenses belonging to
23 absent members of the Class, because Defendants have uniformly misrepresented that Bextra is
24 safer and more effective than traditional NSAIDs and uniformly omitted skin adverse event risks
25 associated with Bextra. Defendants' actions have deprived Plaintiffs and the members of the Class
26 of their ability to make informed decisions about whether to pay for Bextra and if so at what price.

27
28

1 148. Plaintiffs will fairly and adequately assert and protect the interests of absent
2 members of the Class, because Plaintiffs have retained counsel competent and experienced in
3 complex class action litigation and have no interest adverse to any absent Class Members.

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

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

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

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

20 153. The need for Class-wide notice does not provide a barrier to certification, in that
21 notice can be effectively disseminated to Class by techniques customarily used in consumer class
22 actions, including published notice, Internet notice and direct mailings based on readily available
23 computer databases (such as the one Defendants used to send their “Dear Patient” correspondence).

24 **FIRST CLAIM FOR RELIEF**
25 **(Violation of the State Consumer Protection Laws)**

26 154. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set
27 forth herein.
28

1 155. Defendants intended that Plaintiffs and Class Members rely on their materially
2 deceptive practices and purchase Bextra as a consequence of the deceptive practices, including
3 Defendants' misrepresentations and omissions of material fact in their marketing of Bextra
4 contrary to its FDA label:

5 a. Defendants' promotions of Bextra as a safe drug, and as being safer than
6 comparable drugs on the market, were deceptive, unfair, and unlawful in that Bextra
7 actually carried a risk of adverse serious skin reactions, did not have added benefits over
8 older, less expensive NSAIDs, and was promoted solely for financial reasons and not due to
9 any material increase in medical safety or efficacy over NSAIDs;

10 b. Defendants' conduct was unfair, unlawful, and deceptive in that Defendants
11 knew Bextra was unsafe and increased the risk of adverse cardiovascular events, such as
12 heart attack and stroke, to unacceptable levels, but falsely promoted the cardiovascular
13 safety to doctors, third party payors and patients until 2005;

14 c. Defendants' conduct was unfair, unlawful and deceptive in that Defendants'
15 falsely advertised that scientific studies showed a clinical benefit over other NSAIDs that
16 would offset any risk of serious skin reactions (*e.g.*, toxic epidermal necrolysis, Stevens-
17 Johnson Syndrome, erythema multiforme), such as studies that purported to show superior
18 GI safety, general safety and/or superior efficacy, such studies were misleading both in
19 their design and their use as promotional materials for Bextra.

20 d. Defendants' conduct was unfair, unlawful, and deceptive in that they falsely
21 represented that Bextra was proven safe in clinical trials even though trials had been
22 conducted comparing Bextra to placebos and non-selective NSAIDs that contradicted that
23 claim including the two short term trials of patients provided Bextra after coronary artery
24 bypass graft ("CABG") surgery that had a two-fold increases in the risk of serious adverse
25 cardiovascular events compared to placebos.

26 e. Blitzing doctors' offices with literature falsely claiming that Bextra was
27 superior to NSAIDs with respect to GI side effects and with material that did not fairly
28 balance the CV risks of Bextra;

1 f. Instructing sales agents to hide CV risks and/or the lack of approval for pain
2 relief and in fact claiming “pain” superiority when pitching Bextra, contrary to its approved
3 labeling;

4 g. Issuing advertisements that lacked a fair balance concerning the safety and
5 efficacy of Bextra;

6 h. Defendants’ conduct was unfair, unlawful, and deceptive in that they falsely
7 claimed that Bextra was superior to other NSAIDs in the vast majority of patients;

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

10 j. Defendants falsely portrayed Bextra with knowledge of such falsity in order
11 to induce doctors to prescribe Bextra and consumers to purchase Bextra at a price that
12 exceeded its actual worth;

13 k. Defendants established Bextra as a standard course of treatment based upon
14 the purchase and distribution of reprints of articles appearing in prestigious medical
15 journals which Defendants knew were false and/or misleading; and

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

19 156. Defendants’ deceptive representations and material omissions to Plaintiffs and the
20 Class Members were, and are, unfair and deceptive acts and practices.

21 157. Defendants’ actions, as complained of herein, constitute unfair competition or
22 unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state
23 consumer protection statutes that allow third-party payors to bring claims. Plaintiffs assert this
24 claim on behalf of third-party payors who are Class Members located in the states that permit TPP
25 claims under the consumer protection laws as set forth below.

26 (a) Defendants have engaged in unfair competition or unfair or deceptive acts or
27 practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

28

1 (b) Defendants have engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

3 (c) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of Ark. Code §§ 4-88-101, *et seq.*, including § 4-88-113(f), and § 4-8-102(5);

5 (d) Defendants have engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and the Consumer Legal
7 Remedies Act (“CLRA”) § 1750, *et seq.* and §§ 1770(e) and (g) of the Civ. Code;

8 (e) Defendants have engaged in unfair competition or unfair or deceptive acts or
9 practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*, including § 6-1-113(1)(c) and
10 § 6-1-102(b);

11 (f) Defendants have engaged in unfair competition or unfair or deceptive acts or
12 practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*, including § 42-110(a)(3);

13 (g) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of 6 Del. Code § 2511, *et seq.*, including 6 Del. Code § 2512;

15 (h) Defendants have engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of D.C. Code § 28-3901, *et seq.*, including § 28-390(1);

17 (i) Defendants have engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of Fla. Stat. § 501.201, *et seq.*;

19 (j) Defendants have engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of Haw. Rev. Stat. § 480, *et seq.*, including § 481A-2;

21 (k) Defendants have engaged in unfair competition or unfair or deceptive acts or
22 practices in violation of Idaho Code § 48-601, *et seq.*, including § 48-602;

23 (l) Defendants have engaged in unfair competition or unfair or deceptive acts or
24 practices in violation of 815 ILCS § 505/1, *et seq.*;

25 (m) Defendants have engaged in unfair competition or unfair or deceptive acts or
26 practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

27 (n) Defendants have engaged in unfair competition or unfair or deceptive acts or
28 practices in violation of Md. Com. Law Code § 13-101, *et seq.*, including § 13-101(h);

1 (o) Defendants have engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

3 (p) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of Mich. Stat. § 445.901, *et seq.*, including § 445-902(c);

5 (q) Defendants have engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of Minn. Stat. § 325F.67, *et seq.*, including § 407.010(5);

7 (r) Defendants have engaged in unfair competition or unfair or deceptive acts or
8 practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

9 (s) Defendants have engaged in unfair competition or unfair or deceptive acts or
10 practices in violation of Mont. Code § 30-14-101, *et seq.*, including § 30-14-102(5);

11 (t) Defendants have engaged in unfair competition or unfair or deceptive acts or
12 practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, including § 59-160(1);

13 (u) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

15 (v) Defendants have engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*, including § 358-A:1(1);

17 (w) Defendants have engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*, § 56:8-1(d);

19 (x) Defendants have engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

21 (y) Defendants have engaged in unfair competition or unfair or deceptive acts or
22 practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

23 (z) Defendants have engaged in unfair competition or unfair or deceptive acts or
24 practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

25 (aa) Defendants have engaged in unfair competition or unfair or deceptive acts or
26 practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*, including § 51-15-01(4);

27 (bb) Defendants have engaged in unfair competition or unfair or deceptive acts or
28 practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

1 (cc) Defendants have engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of Or. Rev. Stat. § 646.605, *et seq.*, including § 646.605(4);

3 (dd) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of 73 Pa. Stat. § 201-1, *et seq.*, including § 201-2(2);

5 (ee) Defendants have engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*, including § 6-13.1(3);

7 (ff) Defendants have engaged in unfair competition or unfair or deceptive acts or
8 practices in violation of S.C. Code Laws § 39-5-10, *et seq.*, including § 39-5-10(9);

9 (gg) Defendants have engaged in unfair competition or unfair or deceptive acts or
10 practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, including § 37-24-1(8);

11 (hh) Defendants have engaged in unfair competition or unfair or deceptive acts or
12 practices in violation of Tenn. Code § 47-18-101, *et seq.*, including § 47-18-103(9);

13 (ii) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

15 (jj) Defendants have engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

17 (kk) Defendants have engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of Va. Code § 59.1-196, *et seq.*, including § 59.1-198;

19 (ll) Defendants have engaged in unfair competition or unfair, deceptive acts or
20 fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, including
21 § 19.86.010(1);

22 (mm) Defendants have engaged in unfair competition or unfair or deceptive acts or
23 practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

24 (nn) Defendants have engaged in unfair competition or unfair or deceptive acts or
25 practices in violation of Wis. Stat. § 100.20, *et seq.*; and

26 (oo) Defendants have engaged in unfair competition or unfair or deceptive acts or
27 practices in violation of Wyo. Stat. § 40-12-100, *et seq.*, including § 40-12-102(a)(i).
28

1 158. Defendants' actions, as complained of herein, constitute unfair competition or
2 unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state
3 consumer protection statutes that allow consumers to pursue claims. Plaintiffs thus assert this
4 claim on behalf of Class Members in the states identified below and pursuant to the statutes
5 identified below:

6 (a) Defendants have engaged in unfair competition or unfair or deceptive acts or
7 practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

8 (b) Defendants have engaged in unfair competition or unfair or deceptive acts or
9 practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

10 (c) Defendants have engaged in unfair competition or unfair or deceptive acts or
11 practices in violation of Ark. Code § 4-88-101, *et seq.*;

12 (d) Defendants have engaged in unfair competition or unfair or deceptive acts or
13 practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and the Consumer Legal
14 Remedies Act, Civ. Code § 1750 *et seq.*; and §§ 1770(e) and (g);

15 (e) Defendants have engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

17 (f) Defendants have engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

19 (g) Defendants have engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of 6 Del. Code § 2511, *et seq.*;

21 (h) Defendants have engaged in unfair competition or unfair or deceptive acts or
22 practices in violation of D.C. Code § 28-3901, *et seq.*;

23 (i) Defendants have engaged in unfair competition or unfair or deceptive acts or
24 practices in violation of Fla. Stat. § 501.201, *et seq.*;

25 (j) Defendants have engaged in unfair competition or unfair or deceptive acts or
26 practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

27 (k) Defendants have engaged in unfair competition or unfair or deceptive acts or
28 practices in violation of Idaho Code § 48-601, *et seq.*;

1 (l) Defendants have engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of 815 ILCS § 505/1, *et seq.*;

3 (m) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

5 (n) Defendants have engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of Kan. Stat. § 50-623, *et seq.*;

7 (o) Defendants have engaged in unfair competition or unfair or deceptive acts or
8 practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

9 (p) Defendants have engaged in unfair competition or unfair or deceptive acts or
10 practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

11 (q) Defendants have engaged in unfair competition or unfair or deceptive acts or
12 practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

13 (r) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

15 (s) Defendants have engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of Mich. Stat. § 445.901, *et seq.*;

17 (t) Defendants have engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of Minn. Stat. § 325F.67, *et seq.*;

19 (u) Defendants have engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

21 (v) Defendants have engaged in unfair competition or unfair or deceptive acts or
22 practices in violation of Mont. Code § 30-14-101, *et seq.*;

23 (w) Defendants have engaged in unfair competition or unfair or deceptive acts or
24 practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

25 (x) Defendants have engaged in unfair competition or unfair or deceptive acts or
26 practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

27 (y) Defendants have engaged in unfair competition or unfair or deceptive acts or
28 practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

1 (z) Defendants have engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

3 (aa) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

5 (bb) Defendants have engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

7 (cc) Defendants have engaged in unfair competition or unfair or deceptive acts or
8 practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

9 (dd) Defendants have engaged in unfair competition or unfair or deceptive acts or
10 practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

11 (ee) Defendants have engaged in unfair competition or unfair or deceptive acts or
12 practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

13 (ff) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

15 (gg) Defendants have engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

17 (hh) Defendants have engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

19 (ii) Defendants have engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

21 (jj) Defendants have engaged in unfair competition or unfair or deceptive acts or
22 practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

23 (kk) Defendants have engaged in unfair competition or unfair or deceptive acts or
24 practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

25 (ll) Defendants have engaged in unfair competition or unfair or deceptive acts or
26 practices in violation of Tenn. Code § 47-18-101, *et seq.*;

27 (mm) Defendants have engaged in unfair competition or unfair or deceptive acts or
28 practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

1 (nn) Defendants have engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

3 (oo) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

5 (pp) Defendants have engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of Va. Code § 59.1-196, *et seq.*;

7 (qq) Defendants have engaged in unfair competition or unfair, deceptive acts or
8 fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

9 (rr) Defendants have engaged in unfair competition or unfair or deceptive acts or
10 practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

11 (ss) Defendants have engaged in unfair competition or unfair or deceptive acts or
12 practices in violation of Wis. Stat. § 100.20, *et seq.*; and

13 (tt) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

15 159. Plaintiffs provided notice of this litigation as follows: On March 1, 2006, notice
16 was sent to each Attorney General in each of the states requiring notice and where demand on a
17 defendant is required, such demand was made on March 1, 2006.

18 160. Pursuant to Section 1782 of the CLRA, in conjunction with the filing of this action,
19 Plaintiffs have notified Defendants in writing of the particular violations of Section 1770 of the
20 CLRA (the "Notice") and has demanded that Defendants refund the purchase price of Bextra.
21 Plaintiffs sent the Notice by certified mail, return-receipt requested to Defendants' registered agent
22 of service/principal place of business in California.

23 161. If Defendants deny the existence of the defect in Bextra and notify Plaintiffs'
24 Counsel that they will not comply with the demand that Plaintiffs included in Notice, Plaintiffs will
25 amend to request actual damages under Section 1750 on behalf of themselves and all other persons
26 and entities who have purchased and/or paid for Bextra.

27 162. If Plaintiffs and members of the Class had not been deceived concerning the safety
28 and effectiveness of Bextra, they would have taken steps so as to not purchase Bextra at the prices

1 set by Defendants, or would not have purchased Bextra, or would not have paid for physician visits
2 to obtain prescriptions for Bextra, which offered no meaningful advantage and posed greater risk of
3 harm than equally effective and far less expensive NSAIDs, available without a prescription.

4 Among the possible steps taken would be to exclude Bextra from approved formulary schedules,
5 set a lower scheduled value in the formulary, set a high co-pay obligation, and otherwise dissuade
6 doctors from prescribing Bextra, or to not purchase Bextra.

7 163. Defendants' unlawful actions caused the purchase of, or payment for Bextra by
8 Plaintiffs and payment for physician visits to discuss or obtain prescriptions for Bextra and as a
9 result Plaintiffs paid more than they otherwise would have for NSAIDs: had a reasonable plaintiff
10 known the truth that Defendants misrepresented and concealed that Plaintiffs would have used
11 and/or paid for another, cheaper NSAIDs or would have purchased nothing and lived with the pain,
12 Defendants would have lost a sale, and Plaintiffs would have avoided a loss.

13 164. Plaintiffs and members of the Class were injured by the cumulative and indivisible
14 nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at
15 physicians and consumers was to artificially create demand for Bextra in lieu of other NSAIDs
16 and/or caused Bextra to command overpayments from Plaintiffs and Class Members. Each aspect
17 of Defendants' conduct combined to artificially create sales of Bextra.

18 165. As a direct and proximate result of Defendants' unfair methods of competition and
19 unfair or deceptive acts or practices, Plaintiffs and the Class have suffered actual economic damage
20 by paying for Bextra and unnecessary physician visits related thereto in lieu of other less
21 expensive, equally effective and safer drugs and/or to pay at an artificially inflated price.

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

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

**SECOND CLAIM FOR RELIEF
(Unjust Enrichment)**

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3 168. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set
4 forth herein.

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

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

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

VII. PRAYER FOR RELIEF

14 WHEREFORE, Plaintiffs pray that:

15 A. The Court determine that this action may be maintained as a class action pursuant to
16 Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for
17 declaratory, equitable, and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil
18 Procedure with respect to the claims for damages, and declaring Plaintiffs as representatives of the
19 Class and Plaintiffs' counsel as counsel for the Class; and designating such 23(c)(4)(A) class issues
20 and/or 23 (c)(4)(B) subclasses as it may deem appropriate.

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

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

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

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