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8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA

10
11 IN RE: BEXTRA MARKETING SALES
PRACTICES AND PRODUCT LIABILITY
12 LITIGATION

Case No. M:05-CV-01699-CRB

MDL No. 1699

13 THIS PLEADING RELATES TO:

**PURCHASE CLAIMS MASTER
BEXTRA COMPLAINT**

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

16 *Clara Fontanilles v. Pfizer, Inc.*, Case No.:
17 05-21241-CIV-Martinez/Banstra (S.D. Fla.)

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

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

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

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

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

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

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1 I. NATURE OF THIS ACTION

2 a. Procedural Introduction

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

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

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

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

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

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

² The class is further defined in Section V, *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. Although they relieve symptoms in certain
19 patients, such relief comes at the expense of important adverse effects, most notably upper
20 gastrointestinal toxicity. Use of NSAIDs leads to admission to hospital for ulcer complications
21 (bleeding and perforation) in around 1% of users annually and results in thousands of deaths every
22 year.

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

27
28 ³ This Class is further defined in Section V and in the specific claims for relief.

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

4 9. As part of the unlawful scheme set forth below, Defendants promoted the use of
5 Bextra in information disseminated to doctors, Pharmacy Benefit Managers (“PBMs”), third-party
6 payors and consumers. Defendants promoted Bextra as a “breakthrough” drug providing important
7 clinical advantages over older and far less expensive NSAIDs.

8 10. Defendants represented that Bextra provided symptomatic relief similar to ibuprofen
9 and naproxen but was clinically superior because it was significantly less likely to cause the
10 gastrointestinal adverse side effects associated with these and other non-steroidal anti-
11 inflammatory drugs (“NSAIDs”). For instance, NSAIDs can, in certain patients, cause
12 gastrointestinal perforations, ulcers and bleeding with long-term use. Pfizer promoted Bextra as a
13 safe and effective alternative that would have less deleterious and painful impact on the gut, but
14 that would be just as effective, if not more so, for pain relief.

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

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

23 13. In an elaborate and sophisticated manner, Pfizer aggressively marketed Bextra
24 directly to medical professionals (including physicians, dentists, and leading medical scholars) in
25 order to leverage pressure on third-party payors, medical care organizations, and large institutional
26 buyers (*e.g.*, hospitals) to include Bextra on their formularies. Bextra’s marketing campaign
27 specifically targeted third-party payors, physicians and dentists, and was designed to convince
28 them of both the therapeutic and economic value of Bextra. Faced with the increased demand for

1 the drug by health care professionals that resulted from Bextra's successful advertising and
2 marketing blitz, third-party payors were compelled to add Bextra to their formularies.

3 14. Defendants' marketing and promotion of Bextra was part of a scheme to create the
4 impression of, and demand for, Bextra as a wide-ranging pain reliever, particularly for the
5 treatment of arthritis pain and/or pain in general (a use for which it was not FDA approved). The
6 scheme was accomplished by unlawful means including, but not limited to, the (i) suppression of
7 data showing cardiovascular risks associated with the use of Bextra, (ii) suppression of data
8 showing risks of serious and potentially life-threatening skin reactions, (iii) manipulation of data to
9 give the appearance of superiority over other NSAIDs in pain relief efficacy and GI safety when
10 such superiority did not exist, (iv) false promotional materials directed to doctors and consumers,
11 and (v) use of reprinted articles from prestigious medical journals that falsely claimed Bextra was
12 proven to be safer than other NSAIDs.

13 15. As a result of Defendants' scheme, they were able to create a market for Bextra and
14 to sell Bextra at a premium price over NSAIDs and to have it become a standard treatment option
15 in many circumstances as opposed to use of less expensive NSAIDs. Bextra sales reached
16 \$1.29 billion in 2004.

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

23 17. In fact, Bextra has been promoted as a superior pain reliever when for most patients
24 it has no proven superiority over other NSAIDs. To date there are *no* clinical studies that
25 demonstrate an advantage of Bextra over other NSAIDs that would offset concerns about serious
26 skin risks (*e.g.*, toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme),
27 such as studies showing a GI safety benefit compared to other products. In addition, Bextra has
28 been documented to be associated with increased risk of serious adverse cardiovascular events to

1 such an extent, that on April 7, 2005, the Federal Drug Administration (“FDA”) requested Pfizer to
2 withdraw Bextra from the United States market and Pfizer has done so. At the FDA briefing called
3 to explain its request that Pfizer withdraw Bextra from the market, the FDA’s director of the Office
4 of New Drugs said that Bextra “had no unique benefit and it had the unique risk: the skin
5 reaction.”⁴

6 18. Bextra sold during the Class Period for \$2.53 to \$6.45 per day depending upon the
7 dose, while NSAIDs sold for as little as \$0.21 to \$0.31 per day. Billions of dollars have thus been
8 wasted in which Plaintiffs and Class Members have paid a premium price for a drug (and the
9 doctor visits necessary to obtain prescriptions for Bextra) that is not a premium or superior product
10 over equally available, less expensive NSAIDs and other pain medications. If Defendants had not
11 engaged in the wrongful marketing, advertising and promotion of Bextra, Plaintiffs and Class
12 Members would have paid for other, equally effective and less expensive medications. Had the
13 truth been told about its safety and efficacy, Bextra would have sold at a price similar to that of
14 other NSAIDs and would not have become a standard in the treatment of arthritis, dysmenorrhea
15 and other non-FDA approved forms of pain relief, and/or Bextra would not have been marketed at
16 all. The plain fact is that at no time did Bextra, as compared to other, equally effective and less
17 expensive therapeutic regimens, have a proven advantage for patients either at no risk or at high-
18 risk for GI complications. Thus, for virtually every purchaser – and contrary to Defendants’
19 widespread marketing program – Bextra was neither more effective nor safer than older, less
20 expensive NSAIDs and thus not a superior product.

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

23 II. JURISDICTION

24 20. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because this
25 action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action
26

27
28 ⁴ Rita Rubin, “Another drug for pain off market,” *USA Today*, 4/7/2005

1 alleges violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C.
2 §§ 1961-1968.

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

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

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

18 III. PARTIES

19 A. Plaintiffs

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

23 25. Plaintiff Allied Services Division Welfare Fund (“ASD”), who filed Civil Action
24 No. 05-1720 (E.D. La.), a division of Transportation Communication International Union –
25 AFL-CIO, CLC (“TCU”), is a health and welfare benefit fund with its principal place of business at
26 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of
27 providing health and pension benefits, among others, to covered lives. ASD is a multi-employer
28 employee welfare benefit plan within the meaning of the Employee Retirement Income Security

1 Act, 29 U.S.C. § 1001(2), and § 1002(37). ASD paid for prescriptions of Bextra and Celebrex
2 dispensed to covered lives in several states. ASD has paid and provided, and will in the future pay
3 and provide, health care benefits to its members and insureds as a direct result of the wrongful
4 conduct of the Defendant as fully alleged herein.

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

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

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

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

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

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

13 32. Plaintiff, Vernon Shepherd (“Shepherd”), who filed Civil Action No. 05 CH 9482,
14 is an adult resident of Mundelein, Illinois in Lake County. Mr. Shepherd first began taking Bextra
15 in early 2005 when Bextra was prescribed for him by his doctor and he purchased the drug.
16 Mr. Shepherd was continually prescribed, purchased and used Bextra from early 2005 until April
17 2005 when the product had been removed from the market. At that time, he heeded Pfizer’s
18 instructions to consult his doctor for alternative treatment. He made an appointment and visited his
19 doctor. He was thereafter charged with the cost of this doctor visit.

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

25 34. Plaintiff Linda A. Watters, Commissioner, Offices of Financial and Insurance
26 Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her
27 capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known
28 as OmniCare Health Plan, Inc., who filed Civil Action 2:05cv71434 9 (E.D. Mich.), is a Michigan

1 official whose function is to collect and liquidate all assets and liabilities of the former private
2 third-party payors' Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness
3 Plan and OmniCare were private third-party payors whose function was to assume the risk of
4 payment of medical and prescription costs on behalf of the participants in its plan. During times
5 relevant to this lawsuit, Wellness Plan and OmniCare paid for prescriptions of Bextra and was
6 injured by the illegal conduct alleged herein.

7 35. Plaintiff Nancy Ayers, who filed Civil Action No. 05-CV-03770, was at all relevant
8 times, an adult resident citizen of the State of California, and resident of Bakersfield, Kern County.

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

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

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

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

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

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

1 decreases the production of thromboxane in platelets, diminishing thromboxane's effect of
2 vasoconstriction and platelet aggregation, and thereby increasing the risk of abnormal bleeding.

3 51. It is generally accepted in the medical community that selectively blocking the
4 COX-2 enzyme without also blocking the COX-1 enzyme encourages the formation of blood clots
5 and increases the risk of various clot-related cardiovascular events, including heart attack, stroke,
6 unstable angina, and peripheral blood clots.

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

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

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

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

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

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

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

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

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

17 61. However, the agency did not grant approval of Bextra for the management or
18 prevention of acute pain. In rebuking the effort to obtain such a broad indication for Bextra, the
19 FDA determined that Bextra had not been proven as more effective than other NSAIDs, and that
20 given the ongoing concerns regarding COX-2s generally at that time, broader indications in that
21 class should not be granted. Further, Defendants did not obtain approval to promote Bextra as less
22 likely than other NSAIDs to cause clinically serious GI events, a potentially serious blow to
23 Defendants. As a result, the Bextra package inserts had to include a warning that its use presented
24 “risk of GI ulceration, bleeding, and perforation.”

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

26 62. Based on studies performed on Celebrex, Vioxx, Bextra, and other COX-2
27 inhibitors, Defendants knew by 1998 that selective COX-2 inhibitors posed serious cardiovascular
28

1 risks for anyone who took them, and presented a specific additional threat to anyone with existing
2 heart disease or cardiovascular risk factors.

3 63. For example, in an effort to demonstrate that Celebrex had greater gastrointestinal
4 safety than traditional NSAIDs, Defendants funded a clinical trial, the results of which were
5 published in 2000: the Celecoxib Long-Term Arthritis Safety Study (“CLASS”). Defendants
6 expected CLASS to show that Celebrex produced significantly fewer serious GI complications than
7 traditional NSAIDs.

8 64. The CLASS trial was a long-term, double-blind study of gastrointestinal toxicity in
9 8,059 patients taking Celebrex, ibuprofen, or diclofenac to treat arthritis. Patients with heart
10 problems were allowed to participate in the CLASS trial, and were permitted to take low doses of
11 aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

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

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

27 67. This trend was magnified in those patients not taking low-dose aspirin. Combined
28 anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0%

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

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

18 69. While none of the CLASS data was statistically significant, they revealed a
19 consistent and worrisome trend toward increased cardiovascular toxicity, particularly with regard
20 to increased thrombosis.

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

1 the cardiovascular risk to benefit ratio was then exactly correct. A subsequent placebo-controlled
2 trial of celecoxib clearly demonstrated this risk.

3 71. The subsequent trial was the APC colon polyp recurrence prevention study, in
4 which approximately 2000 patients took celecoxib or placebo. Interestingly, this was the longest
5 celecoxib trial to date with mean duration of treatment being 33 months as opposed to the much
6 shorter 12-month duration of the CLASS study. A statistically significant elevation in the risk of
7 major fatal or non-fatal cardiovascular event (a composite endpoint of cardiovascular death, acute
8 myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in
9 the placebo group. This followed a dose-response relationship: the relative risk at 400 mg/day of
10 celecoxib was 2.5 while the relative risk at 800 mg/day was 3.4. Because of this unacceptable
11 danger, the trial was prematurely halted. The FDA released an explanatory statement which said,
12 “[w]hile we have not seen all available data on Celebrex, these findings are similar to recent results
13 from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently
14 voluntarily withdrawn by Merck.”

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

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

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

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

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

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

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

1 79. Defendants’ study, completed in 2004 and published in the *New England Journal of*
2 *Medicine* in March of 2005, showed a 90 percent (statistically significant) increase in the incidence
3 of complications in patients treated with Bextra for just 7 days following coronary artery bypass
4 graft surgery compared to those treated with placebo. Another arm of the study showed that post-
5 cardiac surgery patients treated with intravenous parecoxib (a “pro-drug” of Bextra that gets
6 metabolized immediately into Bextra after administration) for 3 days followed by Bextra for 7
7 developed 3.7 times as many cardiovascular complications – cardiac arrest, heart attack, stroke, or
8 pulmonary embolism) than those treated with placebo.

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

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

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

23 83. In February 2005, WellPoint, Inc., the nation’s largest provider of health care
24 benefits, released a study it conducted in conjunction with researchers at Indiana University’s
25 medical school on the risks of cardiovascular events in patients taking COX-2 inhibitors. The
26 study involved the records of more than 635,000 patients and demonstrated that COX-2 inhibitors
27 do increase the risk of adverse cardiovascular events. However, while Vioxx increased patients’
28 risk of heart attack and stroke by approximately 20%, Bextra increased the risk by 50%. Dr. Sam

1 Nussbaum, WellPoint's executive vice president and chief medical officer, noted that the study was
2 further evidence of an "increasingly compelling trend" of data showing that COX-2 inhibitors
3 elevate patients' risk of adverse cardiovascular events.

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

9 85. A paper published in the December 4, 2004 LANCET found, after analyzing 18
10 randomized controlled trials and 11 observational studies, that by the year 2000 these studies
11 showed an increased risk of myocardial infarction from use of Vioxx and that it should have been
12 withdrawn years earlier. Pfizer was aware of each of these studies and should have disclosed their
13 significance and/or not sought approval for Bextra.

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

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

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

23 ...the Agency has concluded that the overall risk versus benefit
24 profile of Bextra is unfavorable. This conclusion is based on the
25 potential increased risk for serious cardiovascular (CV) adverse
26 events, which appears to be a class effect of non-steroidal anti-
27 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.

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

1 89. Continuing, the FDA noted:

2 Bextra has been demonstrated to be associated with an increased risk
3 of serious adverse CV events in two short-term trials in patients
4 immediately post-operative from coronary artery bypass graft
5 (CABG) surgery.... FDA has concluded that it is reasonable to
6 extrapolate the adverse CV risk information for Bextra from the
7 short-term CABG trials to chronic use given the fact that other COX-
8 2 selective NSAIDs have been shown in long-term controlled clinical
9 trials to be associated with an increased risk of serious adverse CV
10 events (e.g., death, MI, stroke), and the well described risk of serious,
11 and often life-threatening gastrointestinal bleeding.... To date, there
12 have been no studies that demonstrate an advantage of Bextra over
13 other NSAIDs that might offset the concern about the[] serious skin
14 risks, such as studies that show a GI safety benefit, better efficacy
15 compared to other products, or efficacy in a setting of patients who
16 are refractory to treatment with other products.

17 *Id.*

18 90. Pfizer agreed to suspend sales of Bextra, and Bextra has been withdrawn from the
19 market as of April 7, 2005.

20 **C. Marketing and Promotion**

21 91. Despite knowing (i) that COX-2 inhibitors posed serious cardiovascular risks for
22 anyone who took them, along with risk of death-causing skin disease, (ii) that Bextra provided no
23 clinically proven improvement over pain relief for OA and RA, and (iii) that Bextra provided no
24 clinically proven improvement for GI safety, Defendants made a business decision to push Bextra
25 to market on claimed improvements in gastrointestinal safety, while downplaying its
26 cardiovascular and skin dangers.

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

33 93. Defendants' advertising efforts included blitzing doctors' offices with literature and
34 verbal presentations designed to convince both doctors and consumers that Bextra was a superior
35 drug for treatment of osteo- and rheumatoid arthritis and dysmenorrheal. They aggressively

1 promoted Bextra as an improvement over older, less expensive NSAIDs, like naproxen and
2 ibuprofen, claiming it had a lower risk of gastrointestinal side effects such as gastrointestinal ulcers
3 and bleeding. Defendants did not promote or provide any balanced presentation as to Bextra
4 having an unacceptably high risk of other side effects, such as heart attacks, strokes, unstable
5 angina, cardiac clotting, hypertension, and severe skin reactions.

6 94. Such marketing efforts to physicians have become commonplace in recent years.
7 Drug companies pay national and local “thought leaders,” including local specialists, to speak at
8 continuing medical education events that promote the use of expensive new drugs such as Bextra.
9 In addition, drug companies – with Pfizer in the forefront – spent billions on “detailing” to
10 physicians – *i.e.*, having their sales representatives visit doctors in their offices, frequently bringing
11 gifts and lunch, to “educate” doctors about their companies’ drugs – in the twelve months through
12 October 2004.

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

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

22 96. In this and other press releases and promotional items Defendants did not disclose
23 the cardiovascular risks presented by Bextra and/or its lack of superiority as compared to other
24 NSAIDs.

25 97. Based on information supplied by Pfizer, the following appeared in the August 9,
26 2003, Chemist & Druggist:

27 Bextra is a new POM [WHAT IS “POM”] Cox-2 inhibitor from
28 Pfizer indicated for treatment of symptoms of osteoarthritis and
rheumatoid arthritis as well as dysmenorrhoea. In clinical trials it
showed similar efficacy to maximum doses of naproxen, ibuprofen
and diclofenac, but has a lower incidence of gastroduodenal ulcers
than the traditional NSAIDs. Bextra contains valdecoxib, a Cox-2
enzyme inhibitor.

1 98. Based on information supplied by Pfizer the following appeared in Community
2 Pharmacy on July 21, 2003:

3 Bextra (valdecoxib), from Pharmacia, is a new cyclooxygenase-2
4 (Cox-2) selective inhibitor, indicated for the symptomatic relief of
5 osteoarthritis (OA), rheumatoid arthritis (RA) and primary
6 dysmenorrhoea. In the UK, 20 million people have an arthritic
7 condition and up to pounds 920 million, excluding indirect costs, is
8 spent annually on their care. **Bextra** offers a powerful alternative to
9 maximum doses of the traditional non-steroidal anti-inflammatory
10 drugs (**NSAIDs**), diclofenac, naproxen and ibuprofen in OA and RA,
11 and a powerful alternative to naproxen sodium for those patients
12 suffering pain associated with primary dysmenorrhoea, says the
13 company. *Additionally, being selective it largely avoids*
14 *gastrointestinal side effects.* (Emphasis added.)

15 99. The following was published at the request of Pfizer in THE PRACTITIONER on
16 July 7, 2003:

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

24 100. On or about May 19, 2003, Pfizer issued the following statement:

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

27 Pfizer Now Offers the Widest COX-2 Inhibitor Portfolio

28 NEW YORK, May 19 – Pfizer Inc said today that it has
received approval to market Bextra(R) (valdecoxib) film coated
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).

Valdecoxib received marketing authorization from the
European Commission with labeling that is valid in all 15 European
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.

“We are pleased with the EU Commission decision to
approve Bextra and look forward to offering patients and physicians
a new option for treating osteoarthritis, rheumatoid arthritis and
primary dysmenorrheal,” said Dr. Jack Watters, Pfizer’s Vice
President, Medical and Regulatory, Europe and Canada. “COX-2
selective inhibitors are an innovative class of medicines specifically

1 developed to relieve pain and inflammation as effectively as widely
2 used conventional non-steroidal anti-inflammatory drugs, *while*
3 *offering an improved upper gastrointestinal safety profile,*" he
4 added. (Emphasis added.)

5 101. Each of the foregoing releases was designed to create demand for Bextra by those
6 making decisions concerning the use of Bextra by patients. Each of the foregoing were just
7 examples of dozens of such marketing ploys disseminated by Defendants.

8 102. Another of Defendants' marketing and promotional devices was the funding of
9 research designed to report positive outcomes with use of Bextra. These findings were then
10 published in medical journals and distributed via press releases and other public relations
11 techniques to medical and non-medical media, targeted at doctors, the public and others in the drug
12 purchasing decision chain. During the class period, these paid researchers touted the safety of
13 Bextra. For example, the following doctor was quoted in a Pharmacia press release, dated
14 November 27, 2002, as follows:

15 "Our analysis suggests that valdecoxib shows no greater incidence of
16 cardiovascular events than either naproxen or placebo," said lead
17 author Andrew Whelton, M.D., adjunct professor of Medicine, Johns
18 Hopkins University, Baltimore, Maryland. "While more data are
19 necessary to confirm this conclusion, our findings suggest that
20 valdecoxib demonstrates a cardiovascular safety profile similar to
21 that of placebo or naproxen."

22 According to Whelton, "Whether patients were or were not taking
23 aspirin did not significantly impact the incidence of serious adverse
24 events."

25 103. Another example of Defendants' marketing is the republication, in a press release
26 issued, on August 1, 2002, of the results of a study in the JOURNAL OF OBSTETRICS AND
27 GYNECOLOGY purporting to show that Bextra was more effective than Naproxen for treatment of
28 pain during menstruation. The study compared Bextra 40 mg twice daily (BID) as needed, Bextra
20 mg BID as needed, naproxen sodium 550 mg BID as needed, to placebo for up to 3 days for the
treatment of pain associated with menstruation (dysmenorrhea). The maximum dose of Bextra
approved by the FDA for the treatment of dysmenorrhea was up to 20 mg BID per day. On every
measure of pain relief, naproxen sodium 550 mg provided better pain relief than Bextra 20 mg BID
(some of the differences achieved statistical significance). Furthermore, patients taking Bextra 20

1 mg BID experienced more than twice as many of the most common side effects as did the patients
2 taking naproxen sodium 550 mg BID. In other words, Bextra provided inferior pain relief, caused
3 more side effects, and cost far more than naproxen sodium –it’s hard to understand how this data
4 could be used to make the case that Bextra was the superior choice. SCIREX Clinical Research
5 Center, a company owned in part by OMNICON, one of the largest advertising agencies, was hired
6 by Pfizer to conduct this study. Pfizer reprinted parts of the study, omitting the known risks of
7 cardiovascular and skin disorders.

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

18 105. These and similar studies helped increase the acceptance of Bextra by medical and
19 dental providers.

20 **D. Risks Posed by Bextra**

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

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

26 108. In 1998, independent doctors established a link between selective COX-2 inhibitors
27 and increased blood clotting, and suggested that these drugs would cause an increase in clot-related
28 cardiovascular events. These doctors suggested that these drugs should not be given to patients

1 with known cardiovascular disease, and that patients taking these drugs would have to be
2 monitored for cardiovascular complications.

3 109. The cardiovascular safety of selective COX-2 inhibitors was directly challenged for
4 the first time in August 2001, when independent doctors from the Cleveland Clinic published a
5 meta-analysis of the CLASS trial that concluded these drugs posed an increased risk of adverse
6 cardiovascular events compared to naproxen, a traditional NSAID.

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

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

15 112. At the Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and
16 Risk Management Advisory Committee, the Committee concluded that "no clear data shows GI
17 benefit for Celebrex and Bextra." The Committee noted that the GI benefits are "less than first
18 reported," referring to reports by Defendants and others regarding trials they had coordinated
19 purporting to show GI benefits.

20 **E. Defendants' Continued Unlawful Marketing Campaign Caused Active Concealment**
21 **of Bextra's Deficiencies and Overcharges to End-Payers for Bextra**

22 113. As a result of Defendants' claims, Plaintiffs and members of the Class purchased
23 and/or paid for Bextra even though a monthly supply was much more expensive than other
24 NSAIDs.

25 114. To justify the disparity of Bextra's pricing as compared to other NSAIDs and to
26 ensure that physicians would prescribe and that End-Payers would purchase and pay for the drug,
27 Defendants misrepresented the safety and efficacy of Bextra and omitted, concealed and
28 suppressed the risks, dangers, and disadvantages of the drug. Consequently, Bextra captured a

1 large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone,
2 sales of Bextra exceeded \$1.2 billion, despite the significantly higher cost of Bextra as compared to
3 other pain relievers in the same family of drugs.

4 115. Defendants' deceptive and misleading marketing campaign concealed, omitted, and
5 suppressed information that resulted in overcharges to consumers and third-party payors, such as
6 Plaintiffs and the Class, for, in whole or in part, the costs of Bextra. Millions of End-Payors,
7 including consumers and third-party payors, have already paid for, and/or purchased and consumed
8 Bextra at prices based on the proposed wholesale price, which was about one hundred times the
9 cost of a generic aspirin. These End-Payors did not get the benefit of the bargain that Defendants
10 held out to them, and as a result End-Payors paid more than they would have or should have
11 because Bextra was promoted and advertised as a premium drug with reduced side effects for the
12 purpose of deceiving consumers and End-Payors about Bextra's adverse cardiovascular and
13 cerebrovascular effects.

14 **V. FRAUDULENT CONCEALMENT**

15 116. Throughout the Class Period, Defendants affirmatively and fraudulently concealed
16 its unlawful conduct from Plaintiffs and the Class.

17 117. Plaintiffs and the Class did not discover, and could not discover through the exercise
18 of reasonable diligence, that Defendants had unlawfully concealed, omitted, and suppressed the
19 serious adverse effects of Bextra until April 7, 2005, when Pfizer withdrew Bextra from the
20 market. Defendants conducted its unlawful activities in secret, concealed the nature of their
21 unlawful conduct, and attempted to confine information concerning the adverse effects of Bextra.
22 Defendants attempted to withhold such information from Plaintiffs and members of the Class, the
23 medical community, regulators and the public. Defendants fraudulently concealed its activities
24 through various means and methods designed to avoid detection.

25 118. Plaintiffs and the Class could not have discovered Defendants' unlawful conduct at
26 an earlier date through the exercise of reasonable diligence because Defendants actively and
27 purposefully concealed their unlawful activities.

1 All End-Payers located in the United States, including Consumers
2 and Third-Party Payers,⁵ who purchased and/or paid for Bextra.

3 Excluded from the proposed Class are (i) Defendants, any entity in
4 which Defendants have a controlling interest or which have a
5 controlling interest in Defendant, and Defendants' legal
6 representatives, predecessors, successors and assigns; (ii) the judicial
7 officers to whom this case is assigned; (iii) any member of the
8 immediate families of excluded persons; (iv) governmental agencies
9 and (v) those who resold Bextra.⁶

10 122. Plaintiffs also define state law subclasses as defined in the various claims for relief
11 in the counts set forth below.

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

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

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

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

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

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

26 e. Whether Defendants formed an enterprise for the purposes of carrying out
27 the scheme;

28 ⁵ Third-Party Payers 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.

⁶ 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 f. Whether Defendants used the U.S. mails and wires to facilitate the scheme;
- 2 g. Whether Defendants' conduct violated RICO;
- 3 h. Whether Defendants are liable to Plaintiffs and the Class for damages under
- 4 state consumer protection statutes;
- 5 i. Whether Defendants made material misrepresentations or material omissions
- 6 about the cardiovascular risks associated with using Bextra and regarding the effectiveness of
- 7 Bextra; and
- 8 j. Whether members of the Class are entitled to damages based on their
- 9 payments for Bextra, and, if so, the nature and amount of such damages.

10 125. Plaintiffs' claims and defenses are typical of the claims and defenses belonging to

11 absent members of the Class, because Defendants have uniformly misrepresented that Bextra is

12 safer and more effective than traditional NSAIDs and uniformly failed to disclose the material

13 cardiovascular risks associated with Bextra. Defendants' actions have deprived Plaintiffs and the

14 members of the Class of their ability to make informed decisions about whether to pay for Bextra

15 and if so at what price.

16 126. Plaintiffs will fairly and adequately assert and protect the interests of absent

17 members of the Class, because Plaintiffs have retained counsel competent and experienced in

18 complex class action litigation and have no interest adverse to any absent Class Members.

19 127. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(A),

20 because the prosecution of separate actions by individual Class Members would create a risk of

21 inconsistent or varying adjudications with respect to individual members of the Class and establish

22 incompatible standards of conduct for Defendants.

23 128. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(B),

24 because the prosecution of separate actions by individual Class Members would create a risk of

25 adjudications with respects to individual Class Members which would, as a practical matter, be

26 dispositive of the interest of the other members not parties to these adjudications and/or

27 substantially impair their ability to protect these interests.

28

1 legal identities and titles, each of these entities and persons joined together to run the Enterprise.
2 The association-in-fact is referred to herein as the “Bextra Enterprise.” At all relevant times, until
3 the withdrawal of Bextra from the market the Bextra Enterprise was an ongoing and continuing
4 business organization consisting of both corporations and individuals that are and have been
5 associated for the common or shared purposes of (a) publishing or otherwise disseminating
6 information about Bextra, which all too often included disseminating false and misleading
7 information, (b) jointly presenting data to the FDA and medical journals that is misleading and/or
8 has been manipulated to distort the results of clinical trials, (c) selling, promoting, and distributing
9 Bextra to Plaintiffs and Class Members, (d) achieving the goal of breaking the NSAID barrier (*i.e.*,
10 having Bextra replace NSAIDs as a preferred treatment), and (e) deriving profits from these
11 activities beyond those that could have been attained without operation of the Enterprise. The
12 Enterprise had as a common purpose creating and perpetuating a demand for Bextra in a class of
13 consumers who could have used lower-priced NSAIDs and achieved the same pain relief at a lower
14 cost. Defendants had this as a purpose because without the scheme, they would not have been able
15 to sell Bextra and/or achieve the economic benefits each obtained as a result of the operation of the
16 Bextra Enterprise. During most of the time relevant to this complaint, each Defendant maintained
17 a separate legal identity while operating the Enterprise, and others associated with and part of the
18 Enterprise maintained their separate identities. The Enterprise continues to operate through Pfizer
19 and through the instructions it issues to its agents for the purpose of carrying out the objectives of
20 the Bextra Enterprise. Agents and members of the Enterprise include advertising agencies used to
21 create Bextra advertisements and doctors who co-author articles promoting the efficacy of Bextra.
22 As to each Defendant, the association-in-fact met on a regular basis to discuss the operations of the
23 Enterprise and the Enterprise’s efforts were coordinated and agreed to by each Defendant.

24 137. Each of the members of the Enterprise had a systemic linkage, because there are
25 contractual relationships, financial ties, and continuing coordination of activities between the
26 Defendants and the Enterprise. As to each Defendant, there was a common communication
27 network by which information concerning the Bextra Enterprise was exchanged on a regular basis.
28

1 Typically this communication occurred by the use of electronic mail or the telephone, with which
2 Defendants planned the operation of the Enterprise alleged herein and ran its continuing operation.

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

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

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

11 140. The Enterprise engaged in and affected interstate commerce because it engaged in
12 the following activities across state boundaries: the transmission and publication of false and
13 misleading information concerning Bextra; the sale, promotion, and/or distribution of Bextra; the
14 transmission and/or receipt of sales and marketing literature (including Defendant-sponsored
15 research articles published in medical journals linked to contracts to purchase reprints to be used in
16 marketing); and/or the transmission and/or receipt of invoices, statements, and payments related to
17 the use or administration of Bextra.

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

22 142. The nature and pervasiveness of the Bextra Enterprise, which was orchestrated out
23 of the corporate headquarters of Defendants, necessarily required those headquarters to
24 communicate directly and frequently by the U.S. mails and by interstate wire facilities with the
25 various local district managers overseeing the sales force(s), the numerous pharmaceutical sales
26 representatives who, in turn, directly communicated with providers, and employees who
27 communicated with the public.
28

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

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

- 10 a. Marketing materials about Bextra, which were sent by Defendants to health
11 care providers, PBMs and third-party payors located across the country;
- 12 b. Written representations made by Defendants, which were made at least
13 annually and in many cases several times during a single year;
- 14 c. Documents submitted to the FDA, *Journal of Obstetrics and Gynecology*,
15 the *Journal of the American Dental Association*, the *Journal of Family Practice*, and other
16 medical journals designed to conceal the risks of Bextra and to falsely promote its safety
17 and superiority;
- 18 d. Written and oral communications directed to U.S. Government agencies that
19 fraudulently misrepresented Bextra;
- 20 e. Written and oral communications with health insurers and patients, including
21 Plaintiffs and members of the Class, inducing payments that were made in reliance on the
22 safety and effectiveness of Bextra; and
- 23 f. Receipts of money sent on tens of thousands of occasions through the U.S.
24 mails and interstate wire facilities – the wrongful proceeds of the Bextra Enterprise.

25 145. In addition to the above-referenced RICO predicate acts, it was foreseeable to
26 Defendants that others would distribute publications containing false information about the
27 effectiveness of Bextra through the U.S. mails and by interstate wire facilities. Further,
28 Defendants' corporate headquarters have, in furtherance of the Enterprise, communicated through

1 use of the U.S. mails and by interstate wire facilities with their various local headquarters or
2 divisions.

3 **Conduct of the RICO Enterprise's Affairs**

4 146. Defendants exerted control over their Bextra Enterprise and, in violation of Section
5 1962(c) of RICO, conducted or participated in the conduct of the affairs of that RICO enterprise,
6 directly or indirectly, in the following ways:

7 a. Each Defendant has directly controlled the written and televised promotional
8 materials with respect to Bextra;

9 b. Each Defendant has directly controlled some of the medical literature
10 regarding the effectiveness of Bextra;

11 c. Each Defendant has directly or indirectly controlled the goals of the
12 Enterprise (*i.e.*, to have Bextra break the NSAID barrier);

13 d. Each Defendant has controlled the sales and marketing plans for Bextra;

14 e. Each Defendant has directly controlled the creation and distribution of
15 marketing, sales, and other materials used to inform health care providers nationwide of the
16 benefits of using Bextra;

17 f. Each Defendant has controlled and participated in the affairs of the Bextra
18 Enterprise by using a fraudulent scheme to manufacture, market, and sell Bextra; and

19 g. Each Defendant intended to (and did) distribute publications containing false
20 information through the U.S. mails and by interstate wire facilities.

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

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

1 **Defendants’ Pattern of Racketeering Activity**

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

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

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

22 **Defendants’ Motive**

23 152. Defendants’ motive in creating and operating the Enterprise and conducting the
24 affairs of the Enterprise described herein was to fraudulently obtain sales of Bextra and associated
25 profits.

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

1 **Damages Caused by Defendants' Scheme**

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

6 155. Through the use of the RICO enterprise, Defendants engaged in a pattern of
7 racketeering activity including at least multiple episodes of mail fraud and wire fraud. Consumers
8 and third party payors were injured in their property by reason of these violations, by, among other
9 things, having to pay hundreds of millions of dollars for Bextra by reason of the unlawful
10 conduct.... Defendants and their co-conspirators engaged in numerous overt predicate fraudulent
11 racketeering acts in furtherance of the conspiracy, and by reason of this conduct consumers and
12 third party payors were injured in their property.

13 156. Defendants' use of the mails and wires to perpetrate its fraud involved thousands of
14 communications, including but not limited to: communications with health insurers and patients,
15 including Plaintiffs, inducing payments for Bextra to be made based on misrepresentations
16 concerning the safety, efficacy, and usefulness of Bextra.

17 157. Defendants' fraudulent scheme consisted of, *inter alia*: deliberately misrepresenting
18 the uses for which Bextra was safe and effective so that Plaintiffs and members of the Class paid
19 for this drug to treat symptoms for which it was not scientifically proven to be safe and effective
20 and actively concealing and causing others to conceal, information about the true safety and
21 efficacy of Bextra.

22 158. Plaintiffs and members of the Class have been injured in their business and property
23 by reason of these violations in that Plaintiffs and the members of the Class have made hundreds of
24 millions of dollars in payment for Bextra that they would not have made had Defendants not
25 engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by
26 Defendants, Plaintiffs and the Class have suffered ascertainable loss of damages.

27 159. Plaintiffs' harm is caused by an indivisible course of conduct. It is impossible to
28 segregate the cumulative and compounding effect of Defendants' multi-faceted wrongful conduct

1 in creating the artificial demand for Bextra as well as its price inflation. The intent of Defendants'
2 conduct was to have the multi-faceted nature of its conduct increase demand for Bextra and inflate
3 its price.

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

8 **SECOND CLAIM FOR RELIEF**
9 **(Violation of the State Consumer Protection Laws)**

10 161. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set
11 forth herein.

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

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

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

26 c. Defendants' conduct was unfair, unlawful and deceptive in that Defendants'
27 failed to disclose that no clinical studies demonstrated an advantage of Bextra over other
28 NSAIDs that would offset serious skin reactions (*e.g.*, toxic epidermal necrolysis, Stevens-

1 Johnson Syndrome, erythema multiforme), such as studies that show a better GI safety
2 benefit, better efficacy compared to products, absent such studies there was no medical or
3 economic reason to market Bextra to doctors, dentists, PBMs or TPPs and absent disclosure
4 of this fact, any marketing of this product was false, misleading, unfair and deceptive.

5 d. Defendants' conduct was unfair, unlawful, and deceptive in that they failed
6 to adequately disclose that no long term clinical trials have been conducted comparing
7 valdecoxib to either placebo or non-selective NSAIDs, and that two short term trials of
8 patients provided valdecoxib after coronary artery bypass graft ("CABG") surgery should
9 have a two-fold increased risk of serious adverse cardiovascular events compared to a
10 placebo.

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

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

16 g. Defendants omitted material information known to them in order to induce
17 doctors to prescribe Bextra and consumers to purchase Bextra at a price that exceeded its
18 actual worth;

19 h. Defendants established Bextra as a standard course of treatment based upon
20 the purchase and distribution of reprints of articles appearing in prestigious medical
21 journals which Defendants knew were false and/or misleading; and

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

25 163. Defendants' deceptive representations and material omissions to Plaintiffs and the
26 Class Members were, and are, unfair and deceptive acts and practices.

27 164. Defendants' actions, as complained of herein, constitute unfair competition or
28 unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state

1 consumer protection statutes that allow third-party payors to bring claims. Plaintiffs assert this
2 claim on behalf of third-party payors who are Class Members located in the states that permit TPP
3 claims under the consumer protection laws as set forth below.

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

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

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

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

13 (e) Defendants have engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*, including § 6-1-113(1)© and
15 § 6-1-102(b);

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

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

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

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

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

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

28

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 Md. Com. Law Code § 13-101, *et seq.*, including § 13-101(h);

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (aa) Defendants have engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*, including § 1345.01(B);

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

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

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

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

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

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

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

19 (ii) Defendants have engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*, including § 17.45(4);

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

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

25 (ll) Defendants have engaged in unfair competition or unfair, deceptive acts or
26 fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, including
27 § 19.86.010(1);
28

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

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

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

7 165. Defendants' actions, as complained of herein, constitute unfair competition or
8 unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state
9 consumer protection statutes that allow consumers to pursue claims. Plaintiffs thus assert this
10 claim on behalf of Class Members in the states identified below and pursuant to the statutes
11 identified below:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 167. Pursuant to Section 1782 of the CLRA, in conjunction with the filing of this action,
25 Plaintiffs have notified Defendants in writing of the particular violations of Section 1770 of the
26 CLRA (the “Notice”) and has demanded that Defendants refund the purchase price of Bextra.
27 Plaintiffs sent the Notice by certified mail, return-receipt requested to Defendants’ registered agent
28 of service/principal place of business in California.

1 168. If Defendants deny the existence of the defect in Bextra and notify Plaintiffs’
2 Counsel that they will not comply with the demand that Plaintiffs included in Notice, Plaintiffs will
3 amend to request actual damages under Section 1750 on behalf of themselves and all other persons
4 and entities who have purchased and/or paid for Bextra.

5 169. If plaintiffs and members of the Class had not been deceived concerning the safety
6 and effectiveness of Bextra, they would have taken steps so as to not purchase Bextra at the prices
7 set by Defendants, or would not have purchased Bextra, or and would not have paid for physician
8 visits to obtain prescriptions for Bextra, which offered no meaningful advantage and posed greater
9 risk of harm than equally effective and far less expensive NSAIDs, available without a
10 prescription. Among the possible steps taken would be to exclude Bextra from approved formulary
11 schedules, set a lower scheduled value in the formulary, set a high co-pay obligation, and otherwise
12 dissuade doctors from prescribing Bextra, or to not purchase Bextra.

13 170. Defendants’ unlawful actions caused the purchase of, or payment for Bextra by
14 Plaintiffs and payment for physician visits to discuss or obtain prescriptions for Bextra and as a
15 result Plaintiffs paid more than they otherwise would have for NSAIDs: had a reasonable plaintiff
16 known the truth that Defendants misrepresented and concealed that Plaintiffs would have used
17 and/or paid for another, cheaper NSAIDs. Defendants would have lost a sale, and Plaintiffs would
18 have avoided a loss.

19 171. Plaintiffs and members of the Class were injured by the cumulative and indivisible
20 nature of Defendants’ conduct. The cumulative effect of Defendants’ conduct directed at
21 physicians and consumers was to artificially create demand for Bextra in lieu of other NSAIDs
22 and/or caused Bextra to command overpayments from Plaintiffs and Class Members. Each aspect
23 of Defendants’ conduct combined to artificially create sales of Bextra.

24 172. As a direct and proximate result of Defendants’ unfair methods of competition and
25 unfair or deceptive acts or practices, Plaintiffs and the Class have suffered actual economic damage
26 by paying for Bextra and unnecessary physician visits related thereto in lieu of other less
27 expensive, equally effective and safer drugs and/or to pay at an artificially inflated price.
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1 183. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
2 for such use in violation of Alaska St. § 45.02.314, *et seq.*

3 184. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
4 for such use in violation of Ariz. Rev. Stat. Ann. § 47-2314, *et seq.*

5 185. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
6 for such use in violation of Ark. Code Ann. § 4-2-314, *et seq.*

7 186. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
8 for such use in violation of Cal. Comm. Code § 2314, *et seq.*

9 187. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
10 for such use in violation of Co. Rev. St. § 4-2-314, *et seq.*

11 188. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
12 for such use in violation of Conn. Gen. Stat. Ann. § 42a-2-314, *et seq.*

13 189. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
14 for such use in violation of 6 Del. C. § 2-314, *et seq.*

15 190. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
16 for such use in violation of D.C. Code Ann. § 28:2-314, *et seq.*

17 191. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
18 for such use in violation of Fla. Stat. Ann. § 672.314, *et seq.*

19 192. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
20 for such use in violation of Ga. Code Ann. § 11-2-314, *et seq.*

21 193. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
22 for such use in violation of Haw. Rev. Stat. § 490:2-314, *et seq.*

23 194. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
24 for such use in violation of Id. Code § 28-314, *et seq.*

25 195. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
26 for such use in violation of Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*

27 196. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
28 for such use in violation of Indiana Code Ann. § 26-1-2-314, *et seq.*

1 217. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
2 for such use in violation of Iowa Code Ann. § 554.2314, *et seq.*

3 218. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
4 for such use in violation of Kansas Stat. Ann. § 84-2-314, *et seq.*

5 219. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
6 for such use in violation of Ky. Rev. Stat. § 355.2-314, *et seq.*

7 220. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
8 for such use in violation of, and is liable in redhibition under, La. Civ. Code Ann. art. 2520, *et seq.*

9 221. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
10 for such use in violation of 11 Maine Rev. Stat. Ann. § 2-314, *et seq.*

11 222. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
12 for such use in violation of Md. Code Ann., Com. Law § 2-314, *et seq.*

13 223. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
14 for such use in violation of Mass. Gen. Laws Ann. Ch. 106, § 2-314, *et seq.*

15 224. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
16 for such use in violation of Mich. Comp. Laws Ann. § 440.2314, *et seq.*

17 225. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
18 for such use in violation of Minn. Stat. Ann. § 336.2-314, *et seq.*

19 226. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
20 for such use in violation of Miss. Code Ann. § 75-2-314, *et seq.*

21 227. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
22 for such use in violation of Missouri Rev. Stat. § 400.2-314, *et seq.*

23 228. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
24 for such use in violation of Mont. Code Ann. § 30-2-314, *et seq.*

25 229. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
26 for such use in violation of Neb. Rev. Stat. U.C.C. § 2-314, *et seq.*

27 230. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
28 for such use in violation of Nev. Rev. Stat. U.C.C. § 104.2314, *et seq.*

1 211. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
2 for such use in violation of N.H. Rev. Stat. Ann. § 382-A:2-314, *et seq.*

3 212. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
4 for such use in violation of N.J. Stat. Ann. § 12A:2-314, *et seq.*

5 213. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
6 for such use in violation of N.M. Stat. Ann. § 55-2-314, *et seq.*

7 214. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
8 for such use in violation of N.Y. U.C.C. Law § 2-314, *et seq.*

9 215. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
10 for such use in violation of N.C. Gen. Stat. Ann. § 25-2-314, *et seq.*

11 216. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
12 for such use in violation of N.D. Stat. § 41-02-31, *et seq.*

13 217. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
14 for such use in violation of Ohio Rev. Code Ann. § 1302.27, *et seq.*

15 218. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
16 for such use in violation of 12A Okla. Stat. § 2-314, *et seq.*

17 219. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
18 for such use in violation of Or. Rev. Stat. § 72.3140, *et seq.*

19 220. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
20 for such use in violation of 13 Pa. Stat. Ann. § 2314, *et seq.*

21 221. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
22 for such use in violation of R.I. Gen. Laws § 6A-2-314, *et seq.*

23 222. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
24 for such use in violation of S.C. § 36-2-314, *et seq.*

25 223. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
26 for such use in violation of S.D. ST. § 57A-2-314, *et seq.*

27 224. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
28 for such use in violation of Tenn. Code Ann. § 47-2-314, *et seq.*

1 225. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
2 for such use in violation of Tex. Bus. & Com. Code Ann. § 2.314, *et seq.*

3 226. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
4 for such use in violation of Ut. Code Ann. § 70A-2-314, *et seq.*

5 227. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
6 for such use in violation of Va. Code Ann. § 8.2-314, *et seq.*

7 228. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
8 for such use in violation of Vt. Stat. Ann. § 9A-2-314, *et seq.*

9 229. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
10 for such use in violation of Wa. Rev. Code § 62A.2-314, *et seq.*

11 230. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
12 for such use in violation of W. Va. Code § 46-2-314, *et seq.*

13 231. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
14 for such use in violation of Wis. Stat. Ann. § 402.314, *et seq.*

15 232. Pfizer breached its implied warranty that Bextra was of merchantable quality and fit
16 for such use in violation of Wyo. Stat. § 34.1-2-314, *et seq.*

17 233. As a proximate cause of Pfizer's breach of warranty, Plaintiffs and the Class
18 suffered ascertainable losses, injuries and damages as specified herein in an amount to be
19 determined at trial.

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

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

25 236. In reality, Bextra failed to provide effective pain relief without the gastrointestinal
26 side effects of traditional NSAIDs. In fact, Bextra caused or exacerbated cardiovascular and
27 potentially fatal skin injury far more often than traditional NSAIDs, and even more often than other
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1 selective COX-2 inhibitor drugs. Accordingly, for these and other reasons, Bextra was not fit for
2 the purposes for which it was sold and used, and it does not pass without objection in the trade.

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

6 **VII. PRAYER FOR RELIEF**

7 WHEREFORE, Plaintiffs pray that:

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

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

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

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

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

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

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

25 **VIII. DEMAND FOR JURY TRIAL**

26 Plaintiffs demand a jury trial on all issues so triable.
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