

STATE OF OREGON
Marion County Circuit Courts
OCT 22 2008
FILED

1
2
3
4
5
6
7
8
9
10
11
12

IN THE CIRCUIT COURT OF THE STATE OF OREGON
FOR THE COUNTY OF MARION

STATE OF OREGON ex rel HARDY
MYERS, Attorney General for the STATE OF
OREGON,

Plaintiff,

v.

PFIZER, INC.

Defendant.

Case No. 08c23533

COMPLAINT ALLEGING VIOLATIONS OF
THE UNLAWFUL TRADE PRACTICES ACT
(ORS 646.605 TO 646.656)

CLAIM NOT SUBJECT TO MANDATORY
ARBITRATION

This Complaint alleges claims for relief based upon violation of Oregon's Unlawful
Trade Practices Act (UTPA), ORS 646.605 to 646.656. Plaintiff, State of Oregon for its
Complaint alleges that at all times material herein:

ALLEGATIONS COMMON TO ALL COUNTS

1.

HARDY MYERS is the Attorney General for the State of Oregon and is suing in his
official capacity pursuant to ORS 646.632.

2.

Defendant Pfizer, a Delaware corporation with its principle place of business in New
York, is one of the world's largest pharmaceutical companies. At all relevant times, Pfizer did
business in Oregon selling and promoting prescription drugs, including Bextra® and Celebrex®.

3.

Pharmacia Corp was a Delaware corporation with its principal place of business in New
Jersey. In 2002, Pfizer purchased Pharmacia and merged the two companies Bextra and Celebrex

1 sales forces. Prior to this sale, the two companies co-marketed Bextra and Celebrex and closely
2 coordinated all promotional efforts. Pfizer is now responsible for all of Pharmacia's conduct
3 relating to the promotion of Celebrex and Bextra. Defendant Pfizer and Pharmacia shall
4 hereinafter be referred to collectively as DEFENDANT.

5 4.

6 The Circuit Court for the State of Oregon has personal jurisdiction over DEFENDANT
7 pursuant to ORCP 4A. DEFENDANT has engaged in substantial activities within the State by
8 operating a business that provides services that are primarily for personal, family, and household
9 use. All transactions took place in the course of DEFENDANT'S business.

10 5.

11 DEFENDANT was given the Notice required by ORS 646.632(2).

12 6.

13 The DEFENDANT'S conduct described in this Complaint was willful within the
14 meaning of ORS 646.605(10).

15 SUMMARY OF THE ACTION

16 7.

17 DEFENDANT engaged in repeated unfair and deceptive acts, methods and practices with
18 the purpose of achieving greater sales of Bextra than they otherwise would have been able to
19 achieve had they complied with the law. DEFENDANT achieved these sales in large part by
20 misleading physicians and health professionals, consumers and others about the safety and
21 efficacy of Bextra, and about the indications for which Bextra was approved as a new drug.
22

23 8.

24 DEFENDANT'S unlawful marketing of Bextra began in 2001 after the U.S. Food and
25 Drug Administration ("FDA") declined to approve Bextra for all of the uses and indications that
26 DEFENDANT was counting on to make Bextra a financial "blockbuster." Rather than simply

1 marketing Bextra for the more limited FDA-approved indications, DEFENDANT engaged in an
2 aggressive, deceptive, and unlawful "off label" marketing campaign to increase sales of Bextra, a
3 COX-2 inhibitor, to treat acute pain, perioperative pain and to reduce use of narcotics ("opioid
4 sparing"). These indications or uses for Bextra are referred to as "off-label" uses because they
5 have not been approved by the FDA. Bextra's FDA-approved "on-label" use is limited to 10
6 milligram doses for the treatment of pain associated with rheumatoid arthritis and osteo-arthritis
7 and 20 milligram doses for pain associated with primary dysmenorrhea (menstrual pain).
8

9 9.

10 As a part of its "off-label" campaign, DEFENDANT misrepresented that Bextra was a
11 safe alternative to schedule 2 narcotics and traditional nonsteroidal anti-inflammatories
12 ("NSAIDs") typically used in the treatment of acute and perioperative pain, marketed Bextra as
13 reducing serious gastrointestinal side effects without possessing competent and reliable evidence
14 to support this claim, and failed to disclose that Bextra increased the risk of serious adverse
15 events including death.
16

17 10.

18 DEFENDANT also commissioned and disseminated hundreds of thousands of copies of
19 positive studies relating to off-label uses of Bextra without also providing negative studies;
20 distributed hundreds of thousands of 20 milligram doses of Bextra to medical professionals such
21 as orthopedic surgeons who do not generally prescribe for menstrual pain with the intent that the
22 sample would be used off label; co-opted influential doctors to encourage off-labeling
23 prescribing; provided meals and gifts to doctors who prescribed Bextra off-label; promoted
24 Continuing Medical Education ("CME") classes that encouraged off-label uses; rewarded high
25 off-label prescribers with paid "mentorships" and consultancies; disseminated print
26

1 advertisements with text and imagery that communicated Bextra's supposed efficacy against
2 acute pain; and encouraged sales representatives to promote off-label uses in their sales calls.
3 Instead of marketing Bextra safely and responsibly for the benefit of patients, DEFENDANT
4 promoted Bextra unsafely and irresponsibly, driven by their narrow desire to maximize profits.

5
6 STATEMENT OF FACTS

7 **Cox-2 Painkillers Were Developed in a Lucrative Market.**

8 11.

9 NSAIDs such as naproxen (Aleve) and ibuprofen (Advil) have been widely prescribed for
10 many years to treat the symptoms of arthritis as well as chronic and acute pain from other causes.
11 NSAIDs are highly effective against pain and inflammation; however, they can cause
12 gastrointestinal ("GI") side effects, including serious adverse events such as obstructions, bleeds,
13 and perforations. These drugs are also sold over-the-counter ("OTC") at dosages lower than
14 prescription strength. For the most part, NSAIDs are available generically and are thus
15 significantly cheaper than branded COX-2 drugs.

16
17 12.

18 NSAIDs work against pain and inflammation by inhibiting enzymes known as
19 cyclo-oxygenase or COX. There are two forms of COX enzymes: COX-1 and COX-2. COX-1
20 is involved in the maintenance and repair of the GI system.

21 13.

22 Selective COX-2 inhibitors ("COX-2 drugs") are drugs that block COX-2 without
23 affecting COX-1. This class of drugs was developed in the 1990s in hope of reducing pain and
24 inflammation without blocking COX-1's beneficial effect on the GI system; however, the
25 scientific studies of COX-2 drugs have been inconclusive regarding gastrointestinal safety.
26

14.

1
2 The scientific rationale and justification for COX-2 drugs was safety, not efficacy. No
3 scientifically valid clinical trial has ever found COX-2 drugs to be more effective for treatment
4 of pain and inflammation than traditional NSAIDs.

5
6 15.

7 There are significant concerns that COX-2 drugs as a class may increase the risk of
8 cardiovascular ("CV") adverse events such as stroke and heart attacks.

9
10 16.

11 In total, three COX-2 drugs have been approved for sale in the United States: Celebrex
12 (celecoxib), Vioxx (rofecoxib), and Bextra (valdecoxib). DEFENDANT began marketing
13 Celebrex in early 1999 and Merck followed several months later with Vioxx. In early 2002,
14 DEFENDANT began marketing Bextra. Ultimately, Vioxx was withdrawn from the market in
15 2004; Bextra was withdrawn in 2005, and that same year, Celebrex was given a "black box"
16 warning on its label.

17
18 17.

19 DEFENDANT competed vigorously with Merck for the rapidly expanding COX-2
20 market. DEFENDANT analogized this competition to warfare; sales representatives were paid
21 bonuses to get doctors to switch patients from Vioxx to Celebrex or Bextra.

22
23 18.

24 Celebrex was disadvantaged in its competition with Vioxx because unlike Vioxx,
25 Celebrex was not initially approved for the treatment of acute pain. Although eventually
26 Celebrex was approved for this indication, the late approval impaired Celebrex's ability to

1 compete in the acute pain market and many doctors considered Celebrex less effective against
2 acute pain.

3 **Defendant Developed Bextra to Be a "Blockbuster" Painkiller but Studies Revealed**
4 **Safety Concerns.**

5 19.

6 DEFENDANT planned to "create the next [COX-2] blockbuster" by marketing Bextra as
7 a "powerful agent" for both acute and chronic pain with strength equal to that of a schedule 2
8 narcotic. Bextra's initial product profile identified acute pain, opioid sparing, and preemptive
9 analgesia associated with the treatment of surgical pain as Bextra's distinguishing qualities. By
10 focusing on these qualities, DEFENDANT sought to supplement Celebrex's perceived
11 weaknesses against acute pain with Bextra's strength and prevent Bextra from cannibalizing
12 Celebrex sales. Bextra would primarily target young active patients with acute pain while
13 Celebrex would primarily target older patients with chronic pain (e.g. – pain associated with
14 arthritis). Bextra would compete directly against Vioxx in the acute pain market while Celebrex
15 would compete primarily against traditional NSAIDs including OTC drugs, for chronic pain.
16

17 20.

18 On November 27, 2001, the FDA approved the 10mg dose Bextra for the treatment of
19 pain associated with rheumatoid arthritis and osteo-arthritis and the 20 milligram dose for pain
20 associated with primary dysmenorrhea, but expressly rejected Bextra's use at any dose for acute
21 and perioperative pain and opioid sparing indications. The FDA rejected Bextra for those uses
22 primarily because the Coronary Artery Bypass Graft Study 035 ("CABG I") demonstrated an
23 excess of serious adverse events including death in association with Bextra and Bextra's pro-
24 drug, paracoxib.
25

26 ///

21.

CABG I was a randomized, double-blind comparison of two groups of patients who underwent coronary artery bypass graft surgery. One group in the study received Bextra and paracoxib, along with narcotics, to treat perioperative pain. The other group only received narcotics (also known as the "standard of care"). DEFENDANT'S goal for CABG I was to demonstrate that Bextra was safe and effective to treat surgical pain and reduce the incidence of narcotic related adverse events such as nausea, constipation, and somnambulence. The results of the CABG I study, however, showed that although patients given Bextra used fewer narcotics, there was no reduction in narcotic related side effects. Further, patients given Bextra suffered twice as many Serious Adverse Events ("SAEs") compared to patients who did not receive Bextra.

22.

To minimize the safety concerns raised by CABG I, DEFENDANT compared Bextra's SAE rate with observational reports outside the study and claimed that Bextra's SAE rate was within normal limits. This substitution of an after the fact control group data is scientifically dishonest and contrary to generally accepted scientific methods. DEFENDANT attempted to further minimize the negative results of CABG I by claiming there was a "failure of randomization" that caused weaker patients to be placed in the Bextra test group.

23.

In an attempt to frame the negative CABG I results as a fluke, on or about January 28, 2003, DEFENDANT began a second clinical trial relating to Bextra and CABG surgery. The "CABG II" study compared three similarly sized groups: patients who received narcotics;

1 patients who received narcotics plus Bextra; and patients who received narcotics, Bextra, and
2 paracoxib.

3 24.

4 DEFENDANT enrolled patients into their CABG II study without disclosing to them that
5 their counterparts in CABG I experienced a doubling of SAEs. Rather, the increased SAE rate
6 was minimized and potential subjects were told that side effects in CABG I were within the
7 expected number of side effects typically seen in CABG surgeries.
8

9 25.

10 CABG II confirmed the risk of high dose Bextra for post-operative pain relief: patients
11 who received Bextra experienced significantly more heart attacks and other cardiovascular
12 problems compared to patients who did not receive Bextra.’

13 26.

14 CABG II combined with CABG I raised significant concerns about the safety of Bextra
15 for all patients, even at low doses. Nonetheless, DEFENDANT continued to promote high dose
16 Bextra for acute pain and peri-operative uses.
17

18 27.

19 In November 2004, the FDA required DEFENDANT to disclose the negative SAE data
20 results of both CABG studies in a revised package insert for Bextra.

21 28.

22 Despite clear evidence of CV risks associated with high dosing of Bextra, DEFENDANT
23 proceeded with their original marketing plan to market Bextra for the now FDA-disapproved
24 indications of acute, perioperative pain and opioid sparing indications.
25
26

Defendant Created and Distributed Biased Science and Unfair and Imbalanced Information.

29.

As part of their illegal marketing efforts, DEFENDANT unlawfully distributed and discussed many studies that described off-label indications. Notwithstanding official and legal admonitions against using off-label studies for marketing efforts, DEFENDANT disseminated hundreds of thousands of clinical studies that supported using Bextra for acute and perioperative pain and opioid sparing use for the purpose of promoting Bextra off-label. DEFENDANT did not comply with requirements to balance favorable information by the equal distribution of relevant unfavorable studies, and DEFENDANT did not disclose the negative results from the CABG studies or the FDA's rejection of Bextra for acute, perioperative pain and opioid sparing indications.

30.

DEFENDANT disseminated hundreds of thousands of copies of an article entitled "Valdecoxib, a COX-2 -- Specific Inhibitor, Is an Efficacious Opioid-Sparing Analgesic in Patients Undergoing Hip Arthroplasty," by Frederic Camu, M.D., which was published in the American Journal of Therapeutics in 2002. DEFENDANT distributed the Camu study to orthopedic surgeons, anesthesiologists, and other surgical specialists knowing these specialists would be prescribing Bextra off-label for perioperative pain and opioid sparing.

31.

DEFENDANT distributed hundreds of thousands of copies of an article entitled "Valdecoxib Does Not Impair Platelet Function," by Philip T. Leese, M.D., which was published in the Journal of Emergency Medicine in 2002. DEFENDANT distributed the Leese article as

1 proof that Bextra could be used for perioperative pain without causing increased bleeding after
2 surgery.

3 32.

4 DEFENDANT also distributed hundreds of thousands of copies of an article entitled
5 "The analgesic efficacy of valdecoxib vs. oxycodone/acetaminophen after oral surgery, by
6 Stephen E. Daniels, D.O., which was published in the Journal of the American Dental
7 Association (JADA) in 2002. DEFENDANT commissioned the Daniels study as part of a
8 strategy to create and disseminate medical studies that supported prescribing Bextra for
9 perioperative pain and opioid sparing. The Daniels study was not conducted by a mainstream
10 academic organization; rather DEFENDANT hired SCIREX, a contract research organization
11 owned by a large advertising company. The Daniels study was deceptively designed to produce
12 misleading study results because it compared Bextra to a single dose of a medicine that is usually
13 given in multiple doses. Although Daniels was published by Journal of the American Dental
14 Association ("JADA"), one of the journal's editors later explained that they were not told that
15 Bextra was disapproved for the treatment of acute pain. Had JADA's editors known the truth,
16 Daniels would not have been published.
17
18

19 33.

20 DEFENDANT widely disseminated the Camu, Leese, and Daniels studies to its sales
21 representatives, urged them to distribute the articles on their sales calls, and provided them with
22 discussion notes that enabled sales representatives to discuss these off-label studies during their
23 sales calls. Although the materials DEFENDANT produced for sales representatives often
24 contained a "do not detail" advisement cautioning against any discussion of the studies during
25 sales calls, the warning was illusory and widely ignored.
26

34.

1
2 DEFENDANT also attempted to hire influential medical professionals to present the
3 results of these studies in order to give a false appearance of reliability to DEFENDANT'S self-
4 generated study results.

5
6 35.

7 In 2003, the Journal of Thoracic and Cardiac Surgery published CABG I as an article
8 entitled "Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in
9 Patients Undergoing Coronary Artery Bypass Surgery" by Elisabeth Ott, M.D. This article
10 raised important concerns about the safety of high dose Bextra for treatment of acute and
11 perioperative pain and for opioid sparing uses and suggested the need for a comprehensive
12 evaluation of a large-scale trial before using Bextra to treat vulnerable patients. DEFENDANT
13 promoted Bextra for acute and perioperative pain and opioid sparing yet failed to disseminate
14 this article to the medical community and did not allow distribution of the study by
15 DEFENDANT'S sales representatives.
16

17
18 36.

19 DEFENDANT also promoted off-label uses of Bextra in medical inquiry response letters.
20 FDA regulations permit drug manufacturers to provide off-label information in response to an
21 unsolicited inquiry from a medical professional so long as the responsive material contains
22 balanced information and is not promotional. Similar to their strategy of distributing only
23 favorable off-label medical articles, DEFENDANT disclosed only favorable data about acute and
24 perioperative pain and opioid sparing indications in their responses to medical inquiries and
25 omitted negative CABG I results and the FDA denials.
26

1 **Defendant Improperly Distributed Free Samples of Bextra with the Intent to Have Samples**
2 **Used for Off-label Indications.**

3
4
5 37.

6 DEFENDANT promoted off-label use of Bextra to treat acute and perioperative pain and
7 opioid sparing by giving hundreds of thousands of 20 milligram Bextra starter samples to
8 surgeons, anesthesiologists and other surgical and pain specialists who do not customarily treat
9 severe menstrual cramps but who do treat acute and peri-operative pain. DEFENDANT intended
10 for medical specialists to use the 20 milligram samples to treat acute and perioperative pain and
11 for opioid sparing but failed to disclose the negative results from the CABG I and CABG II
12 studies and failed to disclose that FDA had rejected these indications due to concerns about their
13 safety.

14 **Defendant Employed an Enormous Sales Staff to Market Bextra for Off-Label Uses.**

15
16 38.

17 DEFENDANT relied heavily on their enormous sales staff to market Bextra for off-label
18 and FDA-denied indications. DEFENDANT produced deceptive sales messages that promoted
19 Bextra for acute and perioperative pain and opioid sparing and trained sales representatives to
20 effectively use this messaging to increase off-label sales. Sales representatives promoted
21 Bextra's off-label indications to health care providers and were encouraged to detail health care
22 providers extensively about these FDA-denied indications.

23
24 39.

25 Sales managers carefully tracked sales representatives' success in conveying
26 DEFENDANT'S messages by monitoring electronic call notes submitted by sales representatives
and accompanying them on sales calls. DEFENDANT also knew sales representatives were

1 detailing Bextra for acute and perioperative pain based on surveys conducted by consultants
2 hired by DEFENDANT to track and monitor prescribing information.

3 40.

4 DEFENDANT sought to increase Bextra sales for acute and perioperative pain and
5 opioid sparing by aggressively targeting surgeons, surgery centers, and hospitals to get Bextra
6 placed on "standing orders" and "protocols" for these indications. Surgery centers and hospitals
7 rely on standing orders and protocols for analgesic dosing regimes associated with perioperative
8 pain. DEFENDANT'S success in placing Bextra on surgical standing orders directly increased
9 Bextra sales, served as a powerful tool for promoting Bextra to other doctors and hospitals, and
10 increased the likelihood that surgical patients would remain on Bextra to treat chronic pain
11 conditions after surgery.
12

13 41.

14 DEFENDANT also obtained examples of surgical protocols and standing orders that
15 included analgesic dosing regimes for Bextra and disseminated these samples to sales
16 representatives. DEFENDANT held contests and rewarded sales representatives with
17 recognition, accolades, and cash equivalent prizes for obtaining high volume standing order
18 sales.
19

20 **Defendant Engaged in Off-Label Advertising to Consumers and Providers Using the**
21 **Pretense of Education.**

22 42.

23 Physician education programs were another integral part of DEFENDANT'S scheme to
24 promote Bextra for acute and perioperative pain and opioid sparing indications. DEFENDANT
25 hired surgeons, anesthesiologists, and other pain specialists to conduct physician education
26 programs ranging from informal luncheon presentations to Continuing Medical Education

1 programs. DEFENDANT knew off-label topics would be discussed at these programs and
2 provided speakers with presentation slides containing favorable off-label data and information
3 about Bextra.

4 43.

5 DEFENDANT'S market research indicated that more patients suffered from non-arthritis
6 pain than arthritis pain. To reach beyond the arthritis pain market, DEFENDANT developed and
7 widely used marketing materials that promoted Bextra to treat acute pain caused by sprains,
8 strains, tendonitis, and bursitis. To avoid the appearance of off-label marketing, however,
9 DEFENDANT'S sales messages used euphemisms for acute pain such as "tough pain," "flare
10 pain," "acute pain condition," and "episodic pain" and visual imagery that evoked strong and
11 powerful pain relief.
12

13 44.

14 DEFENDANT also used patient-type marketing to enhance its acute pain message for
15 Bextra. Throughout its marketing campaign, DEFENDANT consistently targeted the young
16 active "weekend warrior" patient with tough episodic pain for Bextra. In contrast, and to
17 distinguish the target market for Celebrex, DEFENDANT promoted Celebrex for the older
18 patient suffering from chronic pain.
19

20 45.

21 DEFENDANT'S marketing surveys, focus groups, and feedback from its field sales force
22 confirmed that doctors consistently perceived Bextra's strong powerful pain relief messaging as
23 targeting the acute pain market.
24

25 ///

26 ///

46.

1
2 DEFENDANT also promoted its “weekend warrior” imagery in its direct-to-consumer
3 advertising. DEFENDANT distributed hundreds of thousands of copies of a self-published
4 periodical called Perform Magazine that contained multiple images and messages promoting
5 Bextra's strong powerful pain relief. Perform Magazine was sent to subscribers of People
6 magazine and widely distributed in patient waiting rooms.

7
8 47.

9 DEFENDANT invited surgeons and other pain specialists who were likely to prescribe
10 Bextra off-label to so-called “consultant” meetings. Although DEFENDANT claimed these
11 meetings were not promotional, they conducted return on investment analysis on some attendees
12 to determine whether there was a sufficient increase in prescriptions to financially justify the
13 costs of the meetings.

14 **Defendant Gave Improper Inducements, Payments, and Gifts to Physicians.**

15
16 48.

17 To illegally promote Bextra off-label from within the medical community,
18 DEFENDANT hired surgeons, anesthesiologists, and other specialties to conduct Bextra off-
19 label dinner talks and round tables. DEFENDANT sought out and developed physician speakers
20 who were high prescribers of Bextra and supported its off-label use – these health care providers
21 were then paid to give lunch or dinner talks relating to off-label use of Bextra.

22
23 49.

24 DEFENDANT maintained a stable of recommended and paid physician-speakers that
25 sales staff could use for off-label Bextra dinner talks. Sales staff often worked with physicians
26 on their presentations, and encouraged health care providers to talk about off-label uses, even

1 though this practice is prohibited. Talks were conducted at expensive top flight restaurants.
2 DEFENDANT conducted analyses on physicians to confirm that their prescribing behavior
3 increased after speaking or after attending dinner programs.

4 50.

5 DEFENDANT rewarded doctors who were high off-label prescribers of Bextra with
6 "mentorships" in which the doctor was paid up to \$500 to allow Bextra sales representatives to
7 follow him or her around on clinical rounds and attend surgeries.
8

9 51.

10 DEFENDANT used mentorships to gain access to doctors who otherwise would not
11 allow sales representatives to visit their office. During the mentorship, the sales representatives
12 were encouraged to discuss using Bextra to treat acute and perioperative pain.

13 52.

14 DEFENDANT also cultivated off-label Bextra prescribers by rewarding certain
15 prescribers with clinical research grants and contracts.
16

17 53.

18 In addition to gifts to prescribers, DEFENDANT provided grants to certain medical
19 centers and hospitals and leveraged the resultant "goodwill" to promote off-label use of Bextra.

20 **To Enhance Their Unlawful Marketing Campaign, Defendant Concealed and**
21 **Misrepresented Bextra's Safety and Risks.**

22 54.

23 As DEFENDANT marketed Bextra to more health care providers, for more patients, and
24 for a wider assortment of illnesses and pain types, DEFENDANT consistently avoided,
25 minimized, and failed to disclose material health and safety risks. DEFENDANT deceptively
26 marketed Bextra as the most powerful non-narcotic medication without clinically reliable

1 evidence for such a claim, while omitting important information that showed Bextra was no
2 better and potentially more dangerous than traditional NSAIDs in treating pain.

3 55.

4 DEFENDANT'S decision to minimize or fail to disclose the results from CABG I, the
5 study which was the basis for the FDA's denial of Bextra for acute pain prevented doctors from
6 fully educating themselves about Bextra and created a dangerous situation where health care
7 providers were prescribing a drug without knowing all of the dangers.

8 56.

9
10 DEFENDANT also deceptively promoted Bextra's gastrointestinal safety in brochures
11 mailed directly to consumers. Although Bextra's FDA approval label cautioned that Bextra
12 could cause serious and life-threatening gastrointestinal side effects, including bleeding in the
13 stomach and intestines, DEFENDANT'S direct to consumer brochures misrepresented that, for
14 patients who take Bextra, the "stomach stays protected." DEFENDANT ran a similarly
15 deceptive advertisement in Perform magazine.

16 57.

17
18 DEFENDANT'S sales staff told health care providers that Bextra was safe and effective,
19 without affirmatively explaining side effects or adverse events. DEFENDANT'S sales
20 executives specifically told sales staff not to initiate discussion of Bextra safety.

21 58.

22 DEFENDANT also attempted to confuse health care providers to believe positive
23 Celebrex data also applied to Bextra. DEFENDANT promoted both Bextra and Celebrex at the
24 same time and their marketing materials and representations intentionally conflated research data
25

1 so that Celebrex studies were used to explain the safety and efficacy of Bextra, even though
2 Celebrex was a different drug and approved for different indications.

3 **Defendant's Unlawful Marketing Scheme Had a Powerful Effect.**

4 59.

5 DEFENDANT'S promotional scheme for Bextra was highly successful. Total Bextra
6 sales approached four billion dollars, most of which were for acute and perioperative pain and
7 opioid sparing indications and not for the 10 milligram dose treatment of pain associated with
8 rheumatoid arthritis and osteo-arthritis and the 20 milligram dose treatment for pain associated
9 with primary dysmenorrhea.
10

11 **CAUSE OF ACTION**

12 **UNLAWFUL TRADE PRACTICES**

13 **FIRST CLAIM FOR RELIEF**

14
15 **ORS 646.608(1)(e)**

16 **Count I**

17
18 60.

19 Plaintiff, STATE, realleges and incorporates each and every allegation contained in the
20 preceding paragraphs as if fully alleged herein.

21 61.

22 DEFENDANT violated ORS 646.608(1)(e) by promoting Bextra off-label for acute pain,
23 post surgery analgesia and opioid sparing without disclosing that FDA rejected DEFENDANT
24 application to promote for these indications. Each time DEFENDANT promoted Bextra for acute
25 pain, post surgery analgesia, and opioid sparing, without disclosing FDA rejected their
26 application for these indications, was a separate and distinct violation of ORS 646.608 (1)(e).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

Count II

62.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the preceding paragraphs 1 though 60 as if fully alleged herein.

63.

DEFENDANT violated ORS 646.608(1)(e) by misrepresenting the safety and efficacy of Bextra for treatment of acute pain, post surgery analgesia, and opioid sparing. Each time DEFENDANT misrepresented Bextra’s safety or efficacy for these indications was a separate and distinct violation of ORS 646.608 (1)(e).

Count III

64.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 60 as if fully alleged herein.

65.

DEFENDANT violated ORS 646.608(1)(e) by misrepresenting the gastrointestinal safety of Bextra. Each time DEFENDANT misrepresented the GI safety of Bextra was a separate and distinct violation of ORS 646.608(1)(e).

Count IV

66.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 60 as if fully alleged herein.

67.

DEFENDANT violated ORS 646.608(1)(e) by conflating information about Bextra and Celebrex to mislead doctors to believe that positive information about one drug also applied to the other. Each time DEFENDANT conflated information about Celebrex and Bextra was a separate and distinct violation of ORS 646.608(1)(e).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

Count V

68.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 60 as if fully alleged herein.

69.

DEFENDANT violated ORS 646.608(1)(e) by misrepresenting Bextra’s cardiovascular safety. Each time DEFENDANT misrepresented Bextra’s CV safety was a separate and distinct violation of ORS 646.608(1)(e).

SECOND CLAIM FOR RELIEF

ORS 646.607 (1)

Count VI

70.

Plaintiff, STATE, realleges and incorporates each and every allegation contained in the paragraphs 1 through 60 as if fully alleged herein.

71.

DEFENDANT’S deceptive promotion of unsafe high dose Bextra for off-label indications, after FDA had expressly rejected these indications because of concerns about safety, was an unconscionable tactic within the meaning of ORS 646.607 (1). Each time DEFENDANT promoted high dose Bextra for acute pain, post-surgery analgesia/opiod sparing without disclosing FDA’s rejection of these indications or providing the data that was the basis for FDA’s rejection, was a separate and distinct violation of ORS 646.607 (1).

PRAAYER FOR RELIEF

72.

WHEREFORE, Plaintiff respectfully request that a judgment be entered that:

- A. Permanently enjoins DEFENDANT from making any false, misleading or deceptive claim regarding any pharmaceutical product in advertising or promotion, including,

1 but not limited to, any false, misleading or deceptive claim regarding: the safety, effectiveness,
2 benefits or risks of the product; any medical rationale for specifying the use or continued use of
3 the product for a particular indication; the findings, existence or significance of any scientific
4 study, whether published or not, concerning the product.

5 B. Directs DEFENDANT to comply with all applicable laws and regulations relating
6 to the marketing, sale, and promotion of pharmaceutical products.

7 C. Directs DEFENDANT to pay civil penalties of \$25,000.00 for each and every
8 willful violation of ORS 646.608(1) (e) and ORS 646.607 (1).

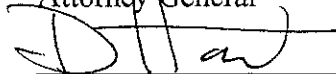
9 D. Awards Plaintiffs costs and attorneys fees, pursuant to ORS 646.632 (8);

10 E.. Grants all other relief as the Court deems appropriate.

11 Dated October 21, 2008.

12 Respectfully submitted,

13 HARDY MYERS
14 Attorney General

15 

16 David A. Hart, OSB No. 00275
17 Assistant Attorney General
18 1162 Court Street, N.E.
19 Salem, OR. 97301-4096
20 (503) 934-4400
21 david.hart@state.or.us

22 Of Attorneys for Plaintiffs
23
24
25
26