

CAUSE NO. 08-13383

FILED  
OCT 22 AM 8:54  
GARY FITZSIMMONS  
DISTRICT CLERK  
DALLAS CO., TEXAS  
DEPUTY

THE STATE OF TEXAS,  
Plaintiff,

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IN THE DISTRICT COURT OF

VS.

DALLAS COUNTY, TEXAS,

PFIZER INC,

Defendant.

1-162nd JUDICIAL DISTRICT

**PLAINTIFF'S ORIGINAL PETITION**

COMES NOW, THE STATE OF TEXAS, acting by and through GREG ABBOTT, Attorney General of Texas, complaining of PFIZER INC ("DEFENDANT" or "PFIZER") and for cause of action would show as follows:

**Discovery Control Plan**

1.1 The Attorney General intends to conduct discovery under Level 2 of Rule 190 of the Texas Rules of Civil Procedure.

**Authority**

2.1 This action is brought by Attorney General GREG ABBOTT, through his Consumer Protection & Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47, TEXAS DECEPTIVE TRADE PRACTICES-- CONSUMER PROTECTION ACT, TEX. BUS. & COM. CODE §§17.41 *et seq.* ("DTPA"), upon the grounds that DEFENDANT has engaged in false, misleading, or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by, §§17.46(a) and (b) of the DTPA.

2.2 This action is also brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §431.047, and §431.0585 of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* ("TFDCA") based upon a referral from the Texas Department of State Health Services ("TDSHS") for the drugs Celebrex and Bextra, manufactured and marketed by DEFENDANT. Section 431.047 of the TFDCA authorizes

a referral to the Attorney General to seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. This action is also brought pursuant to §431.0585 of the TFDCA that authorizes the Commissioner of Health to refer to the Attorney General to seek civil penalties in favor of the State per day per violation of §431.021 of the TFDCA pursuant to this Act.

### **DEFENDANT**

3.1 PFIZER is a Delaware corporation with its principal place of business in New York. At all relevant times, Pfizer did business in Texas selling and promoting prescription drugs, including Bextra® (“Bextra”) and Celebrex® (“Celebrex”). PFIZER may be served with process by serving its registered agent at CT Corp System, 350 North St. Paul Street, Dallas, Texas 75201.

3.2 PFIZER purchased PHARMACIA, INC. (“Pharmacia”), a Delaware corporation with its principal place of business in New Jersey, and merged the two companies’ sales forces for Bextra and Celebrex. Prior to this sale, the two companies co-marketed Bextra and Celebrex and closely coordinated all promotional efforts. PFIZER is responsible for Pharmacia’s conduct and both are collectively referred to as DEFENDANT or PFIZER.

### **Subject Matter Jurisdiction and Venue**

4.1 This Court has jurisdiction over the subject matter of this action pursuant to §17.47(b) of the DTPA and § 431.021 of the TFDCA.

4.2 Pursuant to DTPA §17.47(b) venue is proper in Dallas County because DEFENDANT has done business in Dallas County.

4.3 Venue of this action is also proper in Dallas County on the basis of § 431.047( c) and §431.0585(d) of the TFDCA by virtue of the fact that DEFENDANT is engaged in the business of offering to sell, advertising, and selling drugs in Texas.

### **Public Interest**

5.1 Because the STATE OF TEXAS has reason to believe that DEFENDANT has engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE

OF TEXAS has reason to believe that DEFENDANT has caused, and will cause, adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Consumer Protection and Public Health Division of the Office of the Attorney General of Texas believes and is of the opinion that these proceedings are in the public interest.

### **Trade or Commerce**

6.1 DEFENDANT is engaged in trade and commerce as that term is defined by §17.45(6) of the DTPA.

### **Notice Before Suit**

7.1 DEFENDANT PFIZER was informed in general of the alleged unlawful conduct described below and as may be required by §17.47(a) of the DTPA by electronic mail and certified mail on April 21, 2008.

### **Summary**

8.1 PFIZER engaged in repeated unfair and deceptive acts, methods and practices with the purpose of achieving greater sales of Celebrex and Bextra than it otherwise would have been able to achieve had they complied with the law. DEFENDANT achieved these sales in large part by misleading physicians and health professionals, consumers and others about the safety and efficacy of Bextra, and about the indications for which Bextra was approved.

8.2 DEFENDANT's unlawful marketing of Bextra began in 2001 after the U.S. Food and Drug Administration ("FDA") declined to approve Bextra for all of the uses and indications that DEFENDANT were counting on to make Bextra a financial "blockbuster." Rather than simply marketing Bextra for the more limited FDA-approved indications, DEFENDANT engaged in an aggressive, deceptive, and unlawful "off label" marketing campaign to increase sales of Bextra, a COX-2 inhibitor, to treat acute pain, perioperative pain and opioid sparing uses. These indications or uses for Bextra are referred to as "off-label" uses because they have not been approved by the FDA. Bextra's FDA-approved "on-label" use is limited to 10 milligram doses for the treatment of pain associated with rheumatoid arthritis and osteo-arthritis and 20 milligram doses for pain

associated with primary dysmenorrhea (menstrual pain).

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

8.4 DEFENDANT also commissioned and disseminated hundreds of thousands of copies of positive studies relating to off-label uses of Bextra without also providing negative studies; distributed hundreds of thousands of 20 milligram doses of Bextra to medical professionals such as orthopedic surgeons who do not generally prescribe for menstrual pain with the intent that the sample would be used off label; co-opted influential doctors to encourage off-labeling prescribing; provided meals and gifts to doctors who prescribed Bextra off-label; promoted Continuing Medical Education (“CME”) classes that encouraged off-label uses; rewarded high off-label prescribers with paid “preceptorships” and consultancies; disseminated print advertisements with text and imagery that communicated Bextra’s supposed efficacy against acute pain; and encouraged sales representatives to promote off-label uses in their sales calls. Instead of marketing Bextra safely and responsibly, DEFENDANT was driven by their narrow desire to maximize profits.

8.5 DEFENDANT also marketed and advertised Celebrex as a breakthrough treatment for pain and arthritis and misrepresented Celebrex’s cardiovascular safety by promoting Celebrex for patients as a safer and more effective alternative to traditional non-steroidal anti-inflammatories (NSAIDs).

### **Defendant’s Conduct**

#### **Background**

9.1 Nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen (Aleve®) and ibuprofen (Advil®) have been widely prescribed for many years to treat the symptoms of arthritis

and chronic and acute pain from other causes. NSAIDs are highly effective against pain and inflammation; however, they can cause gastrointestinal (GI) side effects, including serious adverse events such as obstructions, bleeds, and perforations.

9.2 Celebrex and Bextra are selective COX-2 inhibitors (“COX-2 drugs”). This class of drugs was developed in the 1990s in hope of reducing pain and inflammation; however, the scientific studies submitted to FDA for approval of COX-2 drugs were inconclusive regarding GI safety. Therefore, FDA required warnings about GI risk for Celebrex and Bextra.

9.3 The scientific rationale and justification for COX-2 drugs was safety, not efficacy. COX-2 drugs were never found to be more effective for the treatment of pain and inflammation than traditional NSAIDs.

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

9.5 In total, three COX -2 drugs have been approved for sale in the United States: Celebrex (celecoxib), Vioxx® (rofecoxib), and Bextra (valdecoxib). DEFENDANT began marketing Celebrex in early 1999. In early 2002, DEFENDANT began marketing Bextra. Ultimately, Vioxx® was withdrawn from the market in 2004, Bextra was withdrawn in 2005, and that same year, Celebrex was given a “black box” warning on its label.

9.6 DEFENDANT competed vigorously with Merck for the rapidly expanding COX-2 market. DEFENDANT’s sales representatives were paid significant bonuses to get doctors to switch patients from Vioxx® to Celebrex or Bextra.

9.7 Celebrex was disadvantaged in its competition with Vioxx® because unlike Vioxx®, Celebrex was not initially approved for the treatment of acute pain. Although eventually Celebrex was approved for this indication, the late approval impaired Celebrex’s ability to compete in the acute pain market and many doctors considered Celebrex less effective against acute pain.

#### **Bextra to Be a “Blockbuster” Painkiller, but Studies Revealed Safety Concerns.**

9.8. DEFENDANT planned to “create the next [COX-2] blockbuster” by marketing

Bextra as a “powerful agent” for both acute and chronic pain with strength equal to that of a schedule 2 narcotic. Bextra’s initial product profile identified acute pain, opioid sparing, and preemptive analgesia associated with the treatment of surgical pain as Bextra’s distinguishing qualities. By focusing on these qualities, DEFENDANT sought to supplement Celebrex's perceived weaknesses against acute pain with Bextra's strength and prevent Bextra from cannibalizing Celebrex sales. Bextra would primarily target young active patients with acute pain while Celebrex would primarily target older patients with chronic pain (e.g. – pain associated with arthritis). Bextra would compete directly against Vioxx® in the acute pain market while Celebrex would compete primarily against traditional NSAIDs including OTC drugs, for chronic pain.

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

9.10 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.

9.11 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.

9.12 In addition, 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; patients who received narcotics plus Bextra; and patients who received narcotics, Bextra, and paracoxib.

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

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

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

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

9.17 Nonetheless, beginning in 2001 after the FDA denial of certain indications and despite clear evidence of risks associated with high dosing of Bextra, DEFENDANT proceeded with its original marketing plan to market Bextra for the now FDA-disapproved indications of acute, perioperative pain and opioid sparing indications.

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

9.18 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 for off-label use. Additionally, 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.

9.19 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. ("Camu"), 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.

9.20 DEFENDANT distributed hundreds of thousands of copies of an article entitled "Valdecoxib Does Not Impair Platelet Function," by Philip T. Leese, M.D. ("Leese"), which was published in the Journal of Emergency Medicine in 2002. DEFENDANT distributed the Leese article as proof that Bextra could be used for perioperative pain without causing increased bleeding after surgery.

9.21 DEFENDANT also distributed hundreds of thousands of copies of an article entitled "The Analgesic Efficacy of Valdecoxib Versus. Oxycodone/Acetaminophen after Oral Surgery," by Stephen E. Daniels, D.O. ("Daniels"), which was published in the Journal of the American Dental Association (JADA) in 2002. DEFENDANT commissioned the Daniels study as part of a strategy to create and disseminate medical studies that supported prescribing Bextra for perioperative pain

and opioid sparing use. The Daniels study was not conducted by a mainstream academic organization; rather DEFENDANT hired SCIREX, a contract research organization owned by a large advertising company, and hired by DEFENDANT. The Daniels study was designed to produce misleading study results because it compared Bextra to a single dose of a medicine that is usually given in multiple doses. Although the Daniels study was published by Journal of the American Dental Association (“JADA”), one of the journal’s editors later explained that they were not told that Bextra was disapproved for the treatment of acute pain. Had JADA’s editors known the truth, the Daniels study would not have been published.

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

9.23 DEFENDANT also attempted to hire influential medical professionals to present the results of these studies in order to give a false appearance of reliability to DEFENDANT own self-generated and financed study results.

9.24 In 2003, the Journal of Thoracic and Cardiac Surgery published CABG I as an article entitled “Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery” by Elisabeth Ott, M.D. (“Ott”). This article raised important concerns about the safety of high dose Bextra for treatment of acute and perioperative pain and for opioid sparing uses and suggested the need for a comprehensive evaluation of a large-scale trial before using Bextra to treat vulnerable patients. DEFENDANT promoted Bextra for acute and perioperative pain and opioid sparing uses yet failed to disclose this article to the medical community and did not approve it for distribution by sales representatives.

9.25 DEFENDANT also promoted off-label uses of Bextra in medical inquiry response

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

**Defendant Improperly Distributed Free Samples of Bextra for Off-label Indications.**

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

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

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

9.28 Sales managers carefully tracked sales representatives' success in conveying DEFENDANT'S messages by monitoring electronic call notes submitted by sales representatives and accompanying them on sales calls. DEFENDANT also knew that sales representatives were detailing Bextra for acute and perioperative pain based on surveys conducted by consultants hired by DEFENDANT to track and monitor prescribing information.

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

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

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

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

9.32 DEFENDANT maintained a stable of recommended and paid physician-speakers that sales staff could use for off-label Bextra dinner talks. Sales staff often worked with physicians on their presentations, and encouraged health care providers to talk about off-label uses, even though this practice is prohibited. Talks were conducted at expensive top flight restaurants. DEFENDANT conducted analyses on physicians to confirm that their prescribing behavior increased after speaking or after attending dinner programs.

9.33 DEFENDANT rewarded doctors who were high off-label prescribers of Bextra with "preceptorships" in which the doctor was paid up to \$500 to allow Bextra sales representatives to

follow him or her around on clinical rounds and attend surgeries.

9.34 DEFENDANT used preceptorships to gain access to doctors who otherwise would not allow sales representatives to visit their office. During the preceptorship, the sales representatives were encouraged to discuss using Bextra to treat acute and perioperative pain.

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

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

**Defendant Engaged in Off-Label Advertising to Consumers and Providers.**

9.37 Physician education programs were another integral part of DEFENDANT's scheme to promote Bextra for acute and perioperative pain and opioid sparing indications. DEFENDANT hired surgeons, anesthesiologists, and other pain specialists to conduct physician education programs ranging from informal luncheon presentations to Continuing Medical Education programs. DEFENDANT knew off-label topics would be discussed at these programs and provided speakers with presentation slides containing favorable off-label data and information about Bextra.

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

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

from chronic pain.

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

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

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

9.43 As PFIZER marketed Bextra to more health care providers, for more patients, and for a wider assortment of illnesses and pain types, DEFENDANT consistently avoided, minimized, and failed to disclose material health and safety risks. DEFENDANT deceptively marketed Bextra as the most powerful non-narcotic medication without clinically reliable evidence for such a claim, and while omitting important information that showed Bextra was no better and potentially more dangerous than traditional NSAIDs in treating pain.

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

9.45 DEFENDANT also deceptively promoted Bextra's gastrointestinal safety in brochures mailed directly to consumers. Although Bextra's FDA approval label cautioned that

Bextra could cause serious and life-threatening gastrointestinal side effects, including bleeding in the stomach and intestines, DEFENDANT'S direct to consumer brochures misrepresented that, for patients who take Bextra, the "stomach stays protected." DEFENDANT ran a similarly deceptive advertisement in *Perform Magazine*.

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

9.47 DEFENDANT also attempted to confuse health care providers to believe positive Celebrex data also applied to Bextra. DEFENDANT promoted both Bextra and Celebrex at the same time and their marketing materials and representations intentionally conflated research data so that Celebrex studies were used to explain the safety and efficacy of Bextra, even though Celebrex was a different drug and approved for different indications.

9.48 FDA sent DEFENDANT a Warning Letter on January 10, 2005, indicating that five promotional pieces for Celebrex and Bextra variously: omitted material facts, including the indication and risk information; failed to make adequate provision for the dissemination of the FDA-approved product labeling; and made misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims. FDA's position was that these promotional pieces were in violation of the Federal Food, Drug, and Cosmetic Act and FDA implementing regulations, specifically 21 U.S.C.321(n), 352(a) and (n); and 21 CFR 202.1(e). Similarly, these promotional pieces constitute false advertising and also misbrand Celebrex and Bextra under the §431.021 (a) and/or (b) and (f) of the TFDCA.

## CAUSES OF ACTION

### Prohibited Acts Under the Texas Food, Drug, and Cosmetic Act

10.1 Based on the conduct alleged above in paragraphs 1.1 through 9.48, DEFENDANT has committed or caused to be committed the following acts prohibited and declared to be unlawful by § 431.001 *et seq.* of the TFDCA:

- A. Introducing or delivering for introduction into commerce a misbranded drug, in violation of § 431.021(a) of the TFDCa;
- B. Misbranding a drug in commerce, in violation of § 431.021(b) of the TFDCa, and
- C. Disseminating any false advertisement for a drug, in violation of § 431.021(f) of the TFDCa.

10.2 Each time that DEFENDANT violated §431.021 of the TFDCa is a separate and distinct violation of these provisions of the TFDCa.

#### **Violations of the Deceptive Trade Practices Act**

11.1 DEFENDANT, as alleged above in paragraphs 1.1 through 10.2, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a) of the DTPA.

11.2 Additionally, DEFENDANT, as alleged above in paragraphs 1.1 through 11.1, have violated §17.46(b) of the DTPA as follows:

- A. Causing confusion or misunderstanding as to the approval of a drug manufactured by DEFENDANT, in violation of §17.46(b)(2) of the DTPA;
- B. Representing that a drug has benefits which it does not have, in violation of §17.46(b)(5) of the DTPA;
- C. Representing that a drug is of a particular standard, quality, or grade, if they are of another, in violation of §17.46(b)(7) of the DTPA; and
- D. Failing to disclose information about a drug, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

11.3 Each time that DEFENDANT violated §17.46(a) and/or (b) of the DTPA is a separate and distinct violation of these provisions of the DTPA.

## **INJURY TO CONSUMERS**

12.1 By means of the foregoing unlawful acts and practices in paragraphs 1.1 through 11.3 above, DEFENDANT has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

## **PERMANENT INJUNCTION**

13.1 The State alleges that by reason of the foregoing, DEFENDANT should not continue to advertise, offer to sell, or sell their products in violation of the laws of Texas. The interests of the State of Texas require a permanent injunction to prohibit DEFENDANT from continuing to advertise and sell its products if they refuse or are unable to comply with standards required by the TDSHS pursuant to their authority granted by the TFDCA. The interests of the State of Texas also require a temporary and/or permanent injunction to prohibit DEFENDANT from advertising and selling their products unless DEFENDANT is in compliance with the DTPA.

13.2 Unless injunctive relief is granted, DEFENDANT will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

## **PRAYER**

14.1 WHEREFORE, Plaintiff prays that DEFENDANT PFIZER INC be cited according to law to appear and answer herein; that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining DEFENDANT PFIZER INC their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with DEFENDANT PFIZER INC from engaging in the following acts or practices:

- A. Introducing or delivering for introduction into commerce a misbranded drug;
- B. Misbranding a drug in commerce;
- C. Disseminating any false advertisement for a drug;

- D. Causing confusion or misunderstanding as to the approval of the drugs manufactured by DEFENDANT;
- F. Representing that DEFENDANT's drugs have benefits which they do not have;
- G. Representing that DEFENDANT's drugs are of a particular standard, quality, or grade, if they are of another;
- H. Failing to disclose information about a drug, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed;
- I. Promoting Bextra off-label for acute pain, post surgery analgesia and opioid sparing without disclosing that the FDA rejected DEFENDANT's application to promote for these indications;
- J. Promoting Bextra 20mg off-label as safe and effective for conditions other than primary dysmenorrhea;
- K. Misrepresenting the safety and efficacy of Bextra for treatment of acute pain, post surgery analgesia, and opioid sparing use;
- L. Misrepresenting the gastrointestinal safety of Bextra; and
- M. Conflating information to mislead doctors to believe that positive information about one drug also applied to the other.

14.2 Plaintiff further prays that this court upon final hearing order DEFENDANT PFIZER INC to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$25,000.00 per day per violation of § 431.021 of the TFDCA pursuant to § 431.0585 of the TFDCA.

14.3 Plaintiff further prays that this court, upon final hearing, order DEFENDANT PFIZER INC to destroy all products that were manufactured, adulterated, or misbranded in violation of § 431.021 of the TFDCA pursuant to of § 431.051 of the TFDCA.

14.4 Plaintiff further prays that, upon final hearing, this Court will order DEFENDANT PFIZER INC to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA pursuant to of § 17.47(c)(1) of the DTPA.

14.5 Plaintiff further prays that upon final hearing that his Court order DEFENDANT PFIZER INC to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses pursuant to § 17.47(d) of the DTPA.

14.6 Plaintiff further prays that upon final hearing that this Court order DEFENDANT PFIZER INC to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE § 402.006 (c) (Vernon 2005, Supp. 2007).

14.7 Plaintiff further prays that upon final hearing that this court order DEFENDANT PFIZER INC to pay to the Office of the Attorney General and to the Texas Commissioner of Health their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to § 431.047(d) of the TFDCA.

14.8 Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

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