SUR #35

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

IN RE: NEW YORK BEXTRA AND CELEBREX PRODUCT LIABILITY LITIGATION	Index No. 762000/2006 CASE MANAGEMENT ORDER NO. 12
THIS DOCUMENT APPLIES TO ALL CASES	

Master And Short-Form Complaints

I. Scope Of Order

1. Order Applicable To All Product Liability Plaintiffs In The New York Coordinated Bextra And Celebrex Proceeding. This Order shall apply to all plaintiffs who allegedly suffered personal injury from taking Bextra and/or Celebrex in cases currently pending in the Supreme Court of the State of New York, County of New York, and to all related product liability actions that have been or will be originally filed in, or transferred to, this Court and assigned thereto (collectively, the "Coordinated Proceeding"). This Order is binding on all parties and their counsel in all product liability cases currently pending or subsequently made part of these proceedings.

II. Master Complaints

2. Master Complaints To Serve As Underlying Basis And Foundation For All Plaintiffs' Claims. Pursuant to Case Management Order No. 1 § VII(B)(1), Plaintiffs have prepared and file herewith a Master Complaint for all claims involving the medication Bextra (the "Bextra Master Complaint") and a Master Complaint for all claims involving the medication Celebrex (the "Celebrex Master Complaint"). The Bextra Master Complaint, attached hereto as Exhibit A, and the allegations contained therein shall serve as the underlying basis and

foundation for any and all of Plaintiffs' claims related to the medication Bextra. The Celebrex Master Complaint, attached hereto as Exhibit B, and the allegations contained therein shall serve as the underlying basis and foundation for any and all of Plaintiffs' claims related to the medication Celebrex. For those Plaintiffs asserting claims relating to both Bextra and Celebrex, the Bextra Master Complaint and Celebrex Master Complaint shall serve together as the underlying basis and foundation of those Plaintiffs' claims.

III. Short-Form Complaints

3. Sample Short-Form Complaints. Plaintiffs have prepared and submit herewith three sample Short-Form Complaints: (a) a sample Short-Form Complaint for all claims involving the medication Bextra (the "Bextra Short-Form Complaint") that is attached hereto as Exhibit C; (b) a sample Short-Form Complaint for all claims involving the medication Celebrex (the "Celebrex Short-Form Complaint") that is attached hereto as Exhibit D; and (c) a sample Short-Form Complaint for all claims involving both the medications Bextra and Celebrex (the "Bextra and Celebrex Short-Form Complaint") that is attached hereto as Exhibit E.

4. Short-Form Complaints To Be Filed And Served In All Cases. Plaintiffs asserting claims involving the medication Bextra, and not Celebrex ("Bextra-only" cases), shall file and serve a Bextra Short-Form Complaint. Plaintiffs asserting claims involving the medication Celebrex, and not Bextra ("Celebrex-only" cases), shall file and serve a Celebrex Short-Form Complaint. Plaintiffs asserting claims involving both the medications Bextra and Celebrex shall file and serve a Bextra and Celebrex Short-Form Complaint.

5. In Existing Cases, Short-Form Complaints To Be Filed (Without Payment of Filing Fees) And Served Within 90 Days And Shall Take The Place Of All Prior Pleadings. In all cases in which a Summons With Notice or Complaint has been filed and served on all

Defendants prior to the date of this Case Management Order (the "Existing Cases"), Plaintiffs' counsel shall complete, file, and serve the appropriate Short-Form Complaint within 90 days of the date of entry of this Case Management Order. The Court and parties shall disregard any prior Summons With Notice or Complaints filed or served in Existing Cases, except for purposes of statutes of limitations, in which the date of filing of the appropriate Short-Form Complaint shall relate back to the date of filing of the previously filed Summons With Notice or Complaint. With regard to Existing Cases only, the service of these Short-Form Complaints on Pfizer Defendants may be made by mailing the Short-Form Complaints directly to Pfizer Defendants' counsel at the following address:

Raymond M. Williams, Esq.
Christopher M. Strongosky, Esq.
DLA Piper US LLP
1251 Avenue of the Americas
New York, New York 10020.

Service of Short-Form Complaints on non-Pfizer Defendants in Existing Cases may also be made on their respective attorneys. Neither Pfizer Defendants' counsel nor non-Pfizer Defendants' counsel consent to accept service except as provided in this paragraph.

For the filings of Short-Form Complaints related to Existing Cases, as required under this paragraph (5) of this Case Management Order No. 12, Plaintiffs shall be permitted to file those Short-Form Complaints without payment of any filing fee (so long as all filing fees were paid when the original complaints, in those Existing Cases, were filed).

6. In Future Cases, Short-Form Complaints And Summons To Be Filed And Served In Lieu Of Summons With Notice Or Complaints. In all cases in which a Summons With Notice or Complaint has not been served on all Defendants prior to the date of entry of this Case Management Order (the "Future Cases"), Plaintiffs must complete, file, and serve the appropriate

Short-Form Complaint along with a Summons as required by the New York Civil Practice Law and Rules (the "CPLR"). No other form of pleadings shall be permitted without leave from the Court. In Future Cases where a Summons With Notice or a Complaint has already been filed but not served on all Defendants, those pleadings shall be disregarded, and Plaintiffs must complete, file, and serve the appropriate Short-Form Complaint and Summons within the remaining statutorily allotted time period for service as required under the CPLR.

7. Specific Details Regarding Claims For Fraud Or Violation Of New York General Business Law § 349 To Be Stated In Plaintiff Fact Sheets. As provided for under Case Management Order No. 6 and its attachments, Plaintiffs need not plead claims for Fraud, Misrepresentation and Suppression, or Violation of G.B.L. § 349 (the Fifth and Sixth Causes of Action in the Master Complaints, respectively) with specificity in their Short-Form Complaints. Instead, Plaintiffs asserting one or both of these causes of action must set forth specific facts and details supporting them in Section II(E) of the appropriate Plaintiff Fact Sheet (i.e., Bextra, Celebrex, or Bextra and Celebrex). The allegations provided by Plaintiffs in that section shall be treated as allegations contained in a pleading and are subject to the same pleading requirements set forth under New York law and the CPLR, including CPLR 3016(b), as if offered in pleading form and as if contained in the Master Complaint or Short-Form Complaint. Defendants shall have the right to move to dismiss based upon deficiencies in a Plaintiff's response in that section of the applicable Plaintiff Fact Sheet, as described further below.

8. Claims Against Non-Pfizer Defendants Or Outside The Scope Of The Master Complaints To Be Pled Pursuant To New York Civil Practice Law And Rules And New York Law. To the extent Plaintiffs assert claims against non-Pfizer Defendants or claims otherwise outside the scope of the allegations set forth in the Bextra Master Complaint or the Celebrex

Master Complaint, their Short-Form Complaints must include factual and legal allegations sufficiently particular to comply with the pleading requirements set forth in the CPLR or as otherwise required under New York law.

IV. Non-Compliance With This Case Management Order

9. Dismissal Procedure For Non-Compliance Shall Not Require Formal Motion Practice Or Adjudication By The Court. The procedure to effectuate dismissal of any Existing or Future Case in which Plaintiffs fail to comply with the requirements for filing and serving Short-Form Complaints as set forth in paragraphs 5 and 6 above shall not require formal motion practice or adjudication by the Court, so long as the following steps are satisfied:

a. Defendants shall serve Plaintiffs' counsel (or Plaintiffs in *pro se* cases) with a letter notifying Plaintiffs' counsel that they have 20 days to complete, file, and serve a Short-Form Complaint as required by this Case Management Order or have their case dismissed without prejudice, a Notice of Motion to Dismiss pursuant to this Case Management Order, a copy of this Case Management Order, and a proposed Short Form Order identifying the case by its specific caption and index number and stating: "In accordance with Case Management Order No. 12, this case is hereby dismissed without prejudice for failure to comply with Case Management Order No. 12";

b. in the event that Plaintiffs' counsel (or Plaintiffs in *pro se* cases) do not complete, file, and serve a Short-Form complaint as required by this Case Management Order within 20 days of service of the items set forth in subparagraph (a) directly above, Defendants shall submit to the Court, with a copy to Plaintiffs' counsel (or Plaintiffs' in *pro se* cases), the proposed Short-Form Order referenced above with a cover letter indicating that the case is not compliant with this Case Management Order;

c. the Court will sign and enter the proposed Short-Form Order and, thereby, dismiss the case without prejudice; and

d. in the event that a case is dismissed without prejudice as set forth directly above in paragraphs 9(a)-(c) and later re-filed in a manner that is not compliant with this Case Management Order, then the process set forth in paragraphs 9(a)-(c) shall be repeated, except that the Notice of Motion to Dismiss and Short-Form Order shall indicate that dismissal shall be with prejudice and the resulting dismissal ordered by the Court shall be with prejudice.

V. Defendants' Rights And Obligations

10. Pfizer Defendants' Master Answers To Be Exchanged Within 30 Days Of The Date Of Entry Of This Case Management Order. Pursuant to Case Management Order No. 1 § VII(B)(2), Pfizer Defendants shall file and serve a responsive pleading to the Bextra Master Complaint (the "Bextra Master Answer") and file and serve a responsive pleading to the Celebrex Master Complaint (the "Celebrex Master Answer"). Pfizer Defendants shall serve these Master Answers on Plaintiffs' Steering Committee within 30 days of the date of entry of this Case Management Order, and those Master Answers shall be deemed applicable to all cases filed and served in this Coordinated Proceeding. Pfizer Defendants need not file specific answers to Plaintiffs' Short-Form Complaints, and to the extent that an answer is required, Pfizer Defendants' Master Answers shall constitute a general denial of all allegations contained in the Short-Form Complaints.

11. Non-Pfizer Defendants Need Not Respond To Master Complaints. Non-Pfizer Defendants named as defendants in cases subject to this Coordinated Proceeding need not respond to either the Bextra or Celebrex Master Complaints but must only file and serve

responsive pleadings corresponding to Short-Form Complaints in the specific cases in which they are named.

12. Defendants' Rights To Move To Dismiss Master Complaints, Short-Form Complaints, Plaintiff Fact Sheets, Or Any Combination Thereof. Defendants shall have the right to move to dismiss the causes of action, claims, or allegations contained in the Master Complaints, the Short-Form Complaints, Plaintiff Fact Sheets, or any combination thereof, as set forth below:

a. Motions To Dismiss Master Complaints. Pfizer Defendants shall have the right to file omnibus motions to dismiss the Bextra Master Complaint and/or the Celebrex Master Complaint or any specific causes of action, claims, or allegations set forth therein within 45 days of the date of entry of this Case Management Order and beyond that time period if so permitted under the CPLR or otherwise under New York law; further, Pfizer Defendants' filing and service of a Bextra Master Answer, a Celebrex Master Answer, a Short-Form Answer, or Defendant Fact Sheet shall not void or otherwise affect this right; and

b. Motions To Dismiss Individual Cases. Defendants shall have the right to file motions to dismiss individual cases or any specific causes of action, claims, or allegations asserted therein within 45 days of service of the Short-Form Complaint or Plaintiff Fact Sheet, whichever is later, and beyond that time if so permitted under the CPLR or otherwise under New York law; further, such motions may be based upon the allegations set forth in the corresponding Master Complaint(s), Short-Form Complaint, Plaintiff Fact Sheet, or any combination thereof; lastly, Defendants' filing and service of a Bextra Master Answer, a Celebrex Master Answer, a Short-Form Answer, or Defendant Fact Sheet shall not void or otherwise affect this right;

c. Motions To Dismiss Individual Cases After Such Cases Are Selected For Case-Specific Discovery Or Selected For Trial Consideration. Notwithstanding any other provision of this Case Management Order, Defendants shall have the right to file motions to dismiss individual cases or any specific causes of action, claims, or allegations asserted therein in cases that have been selected for case-specific discovery or for cases that have been selected for consideration for trial and designated as a case to be included in a "trial pool," pursuant to a future case management order or ruling from the Special Master or the Court governing case-specific discovery or trial selection. The failure of Pfizer Defendants to move to dismiss any or all causes of action in cases selected for case-specific discovery or trial consideration pursuant to subsection (b) above shall not be deemed a waiver of Pfizer Defendants' right to move to dismiss any or all causes of action in those cases after they are selected for case-specific discovery or trial selection. Further, such motions may be based upon the allegations set forth in the corresponding Master Complaint(s), Short-Form Complaints, Plaintiff Fact Sheet, or any combination thereof; lastly, Defendants' filing and serving of a Bextra Master Answer, a Celebrex Master Answer, a Short-Form Answer, or a Defendant Fact Sheet shall not void or otherwise affect this right; and

d. Motions To Dismiss Shall Not Stay Discovery. The filing of any motions to dismiss the Master Complaints or individual cases shall not stay discovery in this Coordinated Proceeding as a whole or in the individual cases affected by such motions.

SO ORDERED.

Dated: Dec 7, 2006

SHIRLEY WERNER KORNREICH J.S.C.

Hon. Shirley W. Kornreich, J.S.C.

Exhibit
A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

IN RE: NEW YORK BEXTRA AND CELEBREX PRODUCT LIABILITY LITIGATION	Index No. 560001/2005 **AMENDED BEXTRA MASTER COMPLAINT** **MASS TORT**

1. This Complaint is a Master Complaint filed for all Bextra plaintiffs, or if applicable, plaintiffs' spouses, children, decedents or wards represented by any plaintiffs' counsel.[1] All allegations pleaded herein are deemed pleaded in any Short-Form Complaint hereafter filed.

PARTIES

2. Details pertaining to plaintiff or plaintiffs in each action are, or will be, set forth in the Short-Form Complaint applicable to each action.

3. Defendant Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 235 East 42nd St., New York, New York 10017-5755. At all times relevant hereto, defendant Pfizer was and continues to be engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing, either directly or indirectly through third parties or related entities, the prescription drug, Bextra.

4. Defendant G.D. Searle LLC f/k/a G.D. Searle & Co. (hereinafter "Searle") is a Delaware corporation with its principal place of business in Skokie, Illinois. Searle was the

[1] Throughout this Master Complaint, the terms "plaintiff" and "plaintiffs" shall each be deemed to include the singular and the plural.

original inventor, developer, and manufacturer of Bextra, Celebrex, and parecoxib sodium. In 2000 Searle became a co-promoter of Bextra with Pfizer and has been engaged in the business of marketing and selling Bextra on a nationwide basis.

5. Defendant Pharmacia Corporation is a Delaware Corporation with its principal place of business in New Jersey. Pharmacia acquired Searle in 2000 and then in 2003 was acquired by and merged with defendant Pfizer. Searle is presently a subsidiary of Pfizer.

6. Defendants are referred to collectively herein as "defendant Pfizer" or "Pfizer."

FACTS COMMON TO ALL CAUSES OF ACTION

Overview

7. By virtue of its acquisitions of Searle and Pharmacia, as well as its own research, development, and marketing efforts, defendant Pfizer is the developer and manufacturer of three prescription drugs which it designed, manufactured, and marketed for the relief of the pain and inflammation -- Bextra (valdecoxib), Celebrex (celecoxib), and parecoxib sodium.

8. Bextra (valdecoxib), along with Celebrex (celecoxib) and parecoxib sodium, are prescription medications known as a "coxibs" which are among a group of medications called non-steroidal anti-inflammatory drugs ("NSAIDs").

9. It has been generally accepted in the scientific community since the 1970s that the a family of compounds called prostaglandins play diverse and important roles in human bodily tissues and that the COX (cyclooxygenase) enzymes plays an important role in their production.

10. It has also been accepted that prostaglandins play an important role in mediating pain and inflammation in bodily tissues and that the inhibition of the COX enzyme by traditional NSAIDs such as aspirin, ibuprofen, and naproxen is the mechanism by which pain and inflammation are reduced. It was also known, however, that the traditional NSAIDs have adverse side-effects on the gastrointestinal (GI) system, including perforations, ulcers, and

bleeding.

11. It has also been known since the early 1970s that two compounds in the prostaglandin family – prostacyclin (PGI_2) and thromboxane A_2 (TxA_2) – have potent effects on vascular homeostasis and platelet function and that disturbing the balance between them can result in pathological conditions such as thrombosis and ischaemia.

12. However, it was not until the early 1990s that it was discovered that there are two isoforms of the COX enzyme -- cyclooxygenase-1 ("COX-1") and cyclooxygenase-2 ("COX-2") -- and that each played differing roles. It was also shown that traditional NSAIDs were nonselective COX inhibitors, meaning that they inhibit the production of both COX-1 and COX-2 which in turn inhibits the production of the prostaglandins which mediate pain, inflammation, and swelling. Thus, the inhibition of prostaglandins by the inhibition of both COX-1 and COX-2 is the mechanism by which traditional NSAIDs achieve the therapeutic effect of reducing inflammation, pain, and swelling.

13. It is also known that COX-1 and COX-2 serve other functions in bodily tissues. COX-1 is found in most tissues in the body, including in the tissues lining the gastrointestinal (GI) tract and in platelets. In the GI tissues COX-1 plays an important role in protecting the tissues from injury. In the platelets COX-1 plays an important role in the production of thromboxane A_2 (TxA_2) which is involved in the aggregation (clotting) of blood platelets and the contraction of blood vessels (vasoconstriction). The inhibition of COX-1 by traditional NSAIDs therefore can result in harmful side effects to GI tissues and platelet function resulting in perforations, ulcers and bleeding.

14. COX-2 is an "inducible" enzyme, meaning that it is not normally found in most tissues until it "induced" by trauma or inflammation when it then becomes abundant in the

injured tissues. However, in the endothelial cells lining the arteries and the heart, COX-2 plays an important role in the production of prostacyclin (PGI_2). Prostacyclin is a potent anti-thrombotic because it is a vasodilator and inhibits platelet function. It therefore plays an important role in the prevention of blood clots (thrombogenesis), vasoconstriction, hypertension, and hardening of the arteries (atherogenesis).

15. The discovery of the inducible second isoform of COX-2 in the early 1990s led to the paradigm that selective inhibitors of COX-2 would be potential therapeutic agents expected to have anti-inflammatory effects similar to those of conventional NSAIDs but without the adverse side effects involving GI bleeding, perforations, and ulcers. This sparked intense competition among drug companies, including Searle, Pharmacia, and Pfizer, among others, to discover, develop, and market compounds which had the characteristics of selective COX-2 inhibition. Indeed, the selective inhibition of COX-2 is the central marketing allure of selective COX-2 inhibitors such as Bextra, Celebrex, and parecoxib sodium.

16. Bextra and Celebrex were developed and marketed by Pfizer (preceded by Searle) for oral administration at various doses in tablet form. Pfizer (preceded by Searle) also developed and sought FDA approval for an injectable COX-2 inhibitor -- parecoxib sodium -- for the management of adult acute pain. Parecoxib sodium is the injectable "prodrug" of Bextra (valdecoxib). A prodrug is an inactive precursor which only becomes active upon administration by either intravenous or intramuscular injection when it is then metabolized and converted into the active form of the drug. Thus, parecoxib sodium is metabolized into Bextra (valdecoxib) once it is injected into the body.

17. Bextra was launched in the marketplace by Pfizer after Celebrex had already become hugely successful. Pfizer sought to market Bextra as a "second generation" coxib which

was safer and more effective in the treatment of acute adult pain, peri-operative pain, rheumatoid arthritis, osteoarthritis, primary dysmenorrhea (menstrual cramps), and other conditions. Pfizer undertook an extensive campaign to market Bextra as safer and more effective than traditional, non-selective, NSAIDs and, relative to Celebrex, sought to market it as a powerful, once-a-day treatment for pain relief with improved GI tolerability and with less CV risk than traditional NSAIDs.

18. However, in designing and marketing Bextra, Pfizer intentionally ignored and/or recklessly disregarded current medical and scientific knowledge that selective inhibition of COX-2 can cause serious adverse side effects, including serious adverse cardiovascular injuries, including myocardial infarctions, strokes, heart attacks, blood clots, pulmonary emboli, hypertension, and other serious injuries.

19. Specifically, Pfizer misled the consuming public, plaintiffs, and the medical profession regarding the harmful side-effects associated with Bextra, including its serious cardiovascular risks, while overstating its benefits and falsely claiming that Bextra had a superior safety profile and superior risk/benefit profile from currently available traditional, non-selective NSAIDs.

20. Plaintiffs seek compensatory and punitive damages for injuries proximately caused by the misrepresentations and negligent and willful conduct of Pfizer in developing, manufacturing, and marketing the unreasonably dangerous prescription drug Bextra and in failing to provide adequate warnings to the medical community and the plaintiffs of its harmful effects.

Regulatory Background of Bextra

21. In October 2000, Pfizer (originally through Searle) submitted its New Drug Application (NDA 21-294) for parecoxib sodium for the treatment of preemptive or peri-

operative[2] acute pain, and for "opioid sparing" (that is, for reducing the use and adverse side-effects of opioid drugs for acute surgical pain).[3]

22. On January 16, 2001, the original New Drug Application (NDA 21-341) for Bextra (valdecoxib) was submitted to the FDA by Pfizer (originally through Searle). Pfizer sought approval to market Bextra for the prevention and treatment of acute adult pain, including peri-operative pain and opioid sparing, primary dysmenorrhea (menstrual cramping), and for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

23. In July 2001, the FDA rejected Pfizer's application for parecoxib sodium on the grounds that its safety had not been adequately established and because clinical studies revealed it was associated with serious, life-threatening injuries, including heart attacks, myocardial infarction, thrombo-embolic events, and other serious adverse events.

24. On November 16, 2001, the FDA granted new drug approval for Bextra (valdecoxib) for oral administration of 10mg/day for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis or 20mg tablets *bid* (twice per day) as needed for menstrual pain.

25. However, the FDA disapproved the use of Bextra for adult acute pain, for prevention of peri-operative pain, or for opioid sparing. The medical officer's review based his recommendation on studies which showed that Bextra had no efficacy advantage over traditional NSAIDs such as ibuprofen and naproxen and that Bextra caused hypertension and edema at doses above 10 mg and demonstrated no additional efficacy at 20mg/day. Further, Pfizer did not

[2] "Peri-operative" means "around the time of" surgery thus encompassing the pre-, intra-, and post-operative time periods.

[3] The NDA for Celebrex (celecoxib -- NDA 20-998) was filed by Searle and approved by the FDA in 1998. The NDA for Vioxx (rofecoxib -- NDA 21-042) was filed by Merck in 1998 and approved by the FDA in 1999.

obtain approval to promote Bextra as less likely than other NSAIDs to cause clinically serious GI events. As a result, the Bextra package inserts had to include a warning that its use presented "risk of GI ulceration, bleeding, and perforation."

26. Following approval, Bextra was co-promoted by Pfizer and Pharmacia until Pfizer purchased Pharmacia in 2003. Pharmacia recorded $58 million is U.S. sales of Bextra in the first quarter of 2002. By the end of October, 2002 sales of Bextra had increased to $139 million.

27. Bextra was officially launched in March/April, 2002. Pfizer then implemented a massive marketing campaign targeting doctor's offices. On April 15, 2002 nearly six thousand sales representatives from Pfizer and Pharmacia launched forays into doctor's offices to tout Bextra as the newest industry blockbuster. Pfizer's sales pitch to physicians fraudulently and misleadingly presented Bextra as more powerful than traditional NSAIDs, as presenting less risk than traditional NSAIDs regarding its gastrointestinal (GI) toxicity, and as presenting less risk than traditional NSAIDs regarding its cardiovascular (CV) toxicity.

28. Defendant Pfizer simultaneously launched a massive direct-to-consumer ("DTC") marketing campaign for Bextra. Defendant Pfizer's massive marketing campaign fraudulently and misleadingly depicted Bextra as a safer and more effective pain reliever than less expensive traditional NSAIDs. Defendant Pfizer and its representatives and agents misrepresented the safety profile of Bextra to consumers, the medical community, and healthcare providers, among others.

29. In November 2002, FDA required defendant Pfizer (through Pharmacia) to update its labeling for Bextra to include new warnings following post-marketing reports of serious adverse effects including life-threatening risks related to skin reactions -- including Stevens

Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious skin reactions.

30. In 2003 sales of Bextra were $687 million. In 2004 sales of Bextra exceeded $1.2 billion and 12.9 million prescriptions were written.

31. On October 16, 2004, FDA official Dr. Sandra Kweder, as reported in the New York Times, stated that neither Bextra nor Celebrex had been proven to be any better than older medicines like ibuprofen at guarding against stomach bleeding, a benefit often cited by these drugs, and that neither had been proved to be any better at relieving pain than older drugs.

32. In September 2004, Vioxx (rofecoxib), another COX-2 selective inhibitor, was removed from the market by Merck at the request of the FDA as a result of data showing a high risk of cardiovascular injuries.

33. On November 19, 2004, FDA official Dr. David Graham, in testimony before the Senate Finance Committee, stated that studies of Bextra showed that it increases the risks of heart attack in patients undergoing cardiac surgery and that despite these risks Bextra had never been proven to be any more effective at reducing pain or protecting the stomach than older medicines like ibuprofen that are a fraction of the price and have none of the suggested or proven risks.

34. On December 9, 2004 FDA required Pfizer to further strengthen the warnings regarding Bextra. Specifically, FDA required Pfizer to include a BLACK BOX WARNING in its labeling because of additional post-marketing evidence that Bextra was causing serious and potentially fatal skin reaction such as Stevens Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN). Pfizer was also required to add additional warnings to its labeling that Bextra was contraindicated for postoperative treatment of pain following CABG surgery because such patients had a higher risk for cardiovascular/thrombo-embolic events. This was based on a

recent study which showed that 1500 CABG patients treated with Bextra and parecoxib sodium had a higher risk for adverse cardiovascular events.

35. On January 10, 2005, the FDA issued an extensive warning letter to Pfizer regarding its promotional activities, including its direct-to-consumer ("DTC") promotional pieces. The FDA informed Pfizer that a Bextra Direct Mail Brochure was misleading regarding safety claims and inconsistent with the warnings in the Bextra package insert. The FDA also informed Pfizer that a TV Infomercial which featured both Bextra and Celebrex was misleading because it "overstates the effectiveness of the drugs while minimizing, by complete omission, the risks." The FDA further advised Pfizer that its claims to superiority over other therapies, particularly over traditional non-selective NSAIDs, was unsubstantiated.

36. On February 15 and 16, 2005, the FDA's Arthritis Advisory Committee (AAC) met to review the safety of various COX-2 inhibitors, including Bextra, Celebrex, and Vioxx. In its presentation to the committee Pfizer continued to argue that Bextra was safe and efficacious. However, the Committee, in a non-binding recommendation, voted unanimously that Bextra significantly increases the risk of cardiovascular events. The Committee further believed that more long-term studies were needed to evaluate the safety of the COX-2s.

37. The Committee also voted narrowly that the risk versus benefit profile supported continued US marketing of Bextra. However, as reported on February 25, 2005 in the New York Times, those voting in favor of continued marketing of Bextra had financial ties with Pfizer. The votes in favor of continued marketing -- despite Bextra's proven cardiovascular risks -- also came despite a warning from the AAC chairman that the evidence of cardiovascular risk "is a far larger safety signal than we have seen for any of the other drugs withdrawn [from the U.S. market] for safety reasons." Okie, *Raising the Safety Bar -- The FDA's Coxib Meeting, N Engl J*

Med, 2005;352:1283-1285.

38. On April 7, 2005 the requested Pfizer to remove Bextra from the market.

Pfizer Knew Bextra Was Unreasonably Dangerous and Not Superior to Traditional NSAIDs

39. Pfizer knew when Bextra was being developed and tested that selective COX-2 inhibitors such as Bextra pose serious cardiovascular risks for consumers. Pfizer also knew Bextra presented an additional threat to consumers with existing heart disease or cardiovascular risk factors. Pfizer knew Bextra was unreasonably dangerous based on studies performed by Pfizer on Bextra, Celebrex, and parexocib sodium, on studies conducted on competing COX-2 inhibitors, and on widely conducted basic research on COX-2 inhibitors.

40. Pfizer also knew that the initial paradigm of the functions of COX-1 and COX-2, including the "selective" inhibition of COX-2, was inaccurate and over-simplified since both COX-1 and COX-2 serve numerous other biological functions in the body.

41. Despite years of studies on selective COX-2 inhibitors, as well as the studies analyzing the risks of Bextra -- all of which showed there was an serious risk of cardiovascular injury associated with Bextra -- Pfizer failed to take appropriate action to protect the health and welfare of patients or consumers. Pfizer failed to conduct adequate pre-marketing studies, failed to conduct adequate post-marketing surveillance or pharmacovigilance, and failed to adequately or timely warn consumers and the medical profession of the risks of Bextra, opting instead to continue promoting Bextra for sale.

Medical Literature and Studies

42. Pfizer was aware of numerous articles in the published, peer-reviewed medical literature which showed that Bextra, Celebrex, parecoxib sodium, and other COX-2 inhibitors pose serious cardiovascular and related dangers.

43. Pfizer was aware prior to submitting its COX-2 inhibitors for approval by the FDA that compounds produced by the COX enzymes were involved in diverse physiological and pathological functions. They were aware that disturbing the balance between prostacyclin (PGI_2) and thromboxane A_2 (TxA_2) has adverse impacts on vascular tone, vascular homeostasis, and on platelet function. They also knew that prostacyclin (PGI_2) was anti-thrombotic and that thromboxane A_2 (TxA_2) was pro-thrombotic. They further knew that COX-2 inhibition would selectively reduce prostacyclin (PGI_2) *in vivo* thereby promoting thrombosis and other pathological conditions and therefore knew that COX-2 inhibition greatly increased the risk of cardiovascular adverse events.

44. By 1997, and prior to the submissions of the New Drug Applications (the "NDAs") for Celebrex in June 1998, for parecoxib sodium in October 2000, and for Bextra in January 2001, Pfizer was aware that selective inhibition of the COX-2 enzyme by Bextra increased the pro-thrombotic and other adverse effects of the drug, causing blood clots, heart attacks, hypertension, and other serious adverse effects in its users. Further, Pfizer knew that selective COX-2 inhibitors such as Bextra could predispose patients to myocardial infarction or thrombotic stroke.

45. For example, Pfizer was aware that in 1997 Japanese researchers had conducted a study in mice which demonstrated that selective COX-2 inhibition suppresses production of prostacyclin and therefore inhibits its critical anti-thrombotic role. Pfizer therefore was aware that COX-2 inhibition promotes thrombosis (blood clotting). Murata, et al., *Altered pain perception and inflammatory response in mice lacking prostacyclin receptor, Nature*, 1997;288:678-682.

FitzGerald/University of Pennsylvania 1999 Study

46. Pfizer was also aware in 1999 that, as reported in the Philadelphia Inquirer on

February 1, 1999, researchers at the University of Pennsylvania, including Dr. Garret FitzGerald, had raised a red flag in the published medical literature that COX-2 inhibitors might have an elevated risk of blood clots which was dangerous because it could cause heart attacks and strokes. *See*, McAdam, et al., *Systemic biosynthesis of prostacyclin by cyclooxygenase (COX)-2: The human pharmacology of a selective inhibitor of COX-2, Proc. Natl. Acad. Sci.*, 1999; 96:272-277 (citing Murata, et al., *supra*.)

47. Pfizer was further aware that the Penn researchers had stressed that due to this increased risk of blood clotting it was necessary to conduct large long-term trials in order to assess the safety and efficacy of the COX-2 inhibitors. *Id*. Despite this recommendation, Pfizer failed to conduct adequate long-term trials to assess the safety of Bextra.

48. Despite the Penn findings, Philip Needleman, Ph.D., who played an important role in conceiving of and developing Pfizer's COX-2 drugs, including Bextra, Celebrex, and parecoxib sodium, and who was then the president of G.D. Searle & Co., stated he was "not worried about the risks proposed by the Penn researchers" and falsely claimed there was "no scientific or clinical support" for Dr. FitzGerald's findings. *See*, *Philadelphia Inquirer*, Feb.1, 1999.

49. Pfizer was also aware of additional medical literature which raised the serious concern that COX-2 specific inhibitors were pro-thrombotic. Catella-Lawson, et al. *J. Pharmacol Exp Ther*, 1999;298:735-41; Hennan, et al., *Circulation*, 2001;104:820-5; FitzGerald, *COX-2 and beyond: approaches to prostaglandin inhibition in human disease, Nat Rev Drug Discov*, 2003;2:879-90.

Study 035 -- CV Dangers of Parecoxib Sodium

50. Pfizer also was aware that Bextra was unreasonably dangerous for consumers because in December 2000 the FDA medical officer who reviewed Pfizer's NDA for parecoxib sodium stated that the safety data from a CABG trial -- Study 035 -- suggested that patients treated with parecoxib sodium were at increased risk for serious adverse events including cardiovascular events such as heart attacks. Pfizer was aware that it had not adequately studied Bextra because the FDA further stated that neither the efficacy nor the safety of parecoxib sodium -- the prodrug of Bextra -- had been adequately studied.

51. Pfizer was further aware that Bextra was unreasonably dangerous because in July 2001 the FDA declined to approve the marketing of injectable parecoxib sodium, the prodrug of Bextra, for treatment of acute pain based on its concern that the CABG data from Study 035 and other study data raised the possibility that parecoxib sodium is associated with serious cardiovascular adverse events including heart attacks, myocardial infarction, thrombo-embolic events, and other injuries.

CABG 2003 Studies

52. Pfizer was aware of published literature in 2003 that an intravenous-oral parecoxib/valdecoxib regimen utilized in patients undergoing coronary artery bypass graft (CABG) surgery resulted in a higher incidence of serious cardiovascular adverse events which raised important concerns and mandated comprehensive evaluation in a large-scale trial. Ott et al., *Efficacy and safety of the cyclooxygenase inhibitors parecoxib and valdecoxib in patients undergoing coronary artery bypass surgery, J Thorac Cardiovasc Surg*, 2003;125:1481-1492.

FitzGerald/University of Pennsylvania 2004 Study

53. Pifzer was aware that an eminent researcher and cardiologist at the University of Pennsylvania, Garret FitzGerald, M.D., had concluded in a published article that COX-2

inhibitors were pro-thrombotic and that: "We now have clear evidence of an increase in cardiovascular risk that revealed itself in a manner consistent with a mechanistic explanation that extends to all coxibs.") FitzGerald, *Coxibs and Cardiovascular Disease*, *N Engl J Med*, 2004; 351:1709-1711. *See also*, Egan, et al., *COX-2-Derived Prostacyclin Confers Atheroprotection on Female Mice, Science*, 2004;306:1954-1957 (COX-2 inhibitors depress prostacyclin which elevates blood pressure, accelerates atherogenesis, and augments thrombotic response to plaque rupture).

54. Pfizer was also aware from an article published in the New York Times on November 10, 2004 that Dr. FitzGerald had conducted a study at the University of Pennsylvania which he presented at a meeting of the American Heart Association which found a significantly higher risk of heart attacks and strokes among patients taking Bextra than in those taking placebo. Dr. FitzGerald's study found that patients who took Bextra experienced heart attacks and strokes 2.19 times more frequently than patients who took placebo. Dr. FitzGerald stated that the "magnitude of the signal with Bextra is even higher than what we saw in Vioxx." He further described his data regarding Bextra as "a time bomb waiting to go off" and that Bextra, among other COX-2 inhibitors, should be used with great caution.

Wellpoint 2005 Study

55. Pfizer was further aware of the risks of Bextra from studies conducted by Wellpoint Health Networks, Inc., a health insurer, and published in February 2005 which demonstrated that Bextra, Celebrex, and Vioxx had an increased risk of heart attack, stroke, myocardial infarction and stroke. In fact, the Wellpoint Study found that participants who took Bextra had a 50% increased risk for heart attack and stroke.

Large 2005 CABG Study

56. Pfizer was aware of a large study in more than 1,600 patients regarding parecoxib

sodium and Bextra (valdecoxib) which concluded that the use of parecoxib and valdecoxib after CABG surgery was associated with an increased incidence of cardiovascular events which raised serious concerns about the use of these drugs. Nussmeier, et al., *Complications of the COX-2 inhibitors parecoxib and valdecoxib after cardiac surgery, N Engl J Med*, 2005;352:1081-91.

Other Bextra Medical Literature

57. Pfizer was aware that significant doubts had been raised about the cardiovascular safety of Bextra (valdecoxib) which "constitute a potential imminent hazard to public health and thus require action." Ray, et al., *Cardiovascular Toxicity of Valdecoxib, N Engl J Med*, 2004;351:2767. *See also*, FitzGerald, *Coxibs and Cardiovascular Disease*, *N Engl J Med*, 2004; 351:1709-1711.

58. Pfizer was aware that it had not adequately evaluated, or conducted adequate testing, regarding the cardiovascular risks of Bextra, including in long-terms studies in low-risk or high-risk populations. Furberg, et al., *Parecoxib, Valdecoxib, and Cardiovascular Risk*, *Circulation*, 2005;111:249. *See also*, Editorial, *COX-2 Inhibitors -- Lessons in Drug Safety*, *N Engl J Med*, 2005;352:1133-1135; Topol, E., *Arthritis Medicines and Cardiovascular Events -- "House of Coxibs", JAMA*, 2005;293:366-368; Drazen, J., *COX-2 Inhibitors -- A Lesson in Unexpected Problems, N Engl J Med*, 2005;352:1131-1132. As stated by Dr. Jeffrey Drazen in the New England Journal of Medicine:

> . . . had trials designed to test the question of cardiovascular toxicity been launched in 1999 and executed with urgency, substantial morbidity and perhaps a substantial number of deaths could have been prevented. As we apply new science to develop new medicines, we must not forget that our first job is to do no harm.

Drazen, J., *COX-2 Inhibitors -- A Lesson in Unexpected Problems, N Engl J Med*, 2005;352:1131-1132.

59. Pfizer further knew there were well-established options for the treatment of all the

approved indications for the COX-2 inhibitors, including Bextra, which raised serious questions regarding the justification for their use. Pfizer was aware that traditional NSAIDs, including aspirin and acetaminophen, are just as effective in relieving pain as COX-2 inhibitors, including Bextra, and do not present a superior safety or risk/benefit profile in comparison to traditional NSAIDs. Drazen, J., *COX-2 Inhibitors -- A Lesson in Unexpected Problems, N Engl J Med*, 2005;352:1131-1132.

60. The current medical literature has overwhelmingly confirmed what has now long been know about the dangers of serious cardiovascular and other injuries associated with Bextra. *See e.g.*, Andersohn, et al., *Circulation*, 2006;113:1950-1957; Graham, *JAMA*, 2006; published online September 12, 2006:E1-E4; Kearney, et al., *BMJ*, 2006;332:1302-1308.

61. These and other medical articles demonstrate that defendant Pfizer knew Bextra was unreasonably dangerous to consumers and was no safer or more effective in relieving the pain and inflammation associated with arthritis than other less-expensive, traditional NSAIDs.

Other COX-2 Studies

62. In addition to the wealth of data and literature which led to the withdrawal of Bextra in April 2005 due to its CV and other risks, defendant Pfizer knew about other data, studies, and literature which revealed a cardiovascular risk associated with COX-2 inhibitors including Bextra.

63. Pfizer was aware from the CLASS study of the cardiovascular risks associated with selective COX-2 inhibitors such as Celebrex, and was aware that COX-2 inhibitors were not safer than traditional, non-selective NSAIDs regarding either cardiovascular or gastrointestinal risks, nor more effective for pain relief.

64. Pfizer intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the data, results, risks and defects of the CLASS study. Among other things,

defendant Pfizer failed to release the study's complete twelve month results. Instead, it released only the first six months of data from the trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

65. The data from the CLASS study demonstrates that, before Celebrex was introduced to the market in January 1999, defendant Pfizer was aware that COX-2 inhibitors such as Bextra and Celebrex were not superior to traditional NSAIDs in reducing serious gastrointestinal adverse effects and caused a disproportionately and statistically significant high number of adverse cardiovascular events.

66. Pfizer further knew that its failure to include the complete data in the published CLASS study would mislead physicians and patients. Despite its knowledge that the published CLASS study was incomplete and misleading, Pfizer published the incomplete findings in the medical literature and widely distributed this misleading information in the form of reprints to physicians and the medical community in order to increase sales and profits of its COX-2 products.

67. Pfizer was further aware of medical articles which analyzed the data from CLASS and found that the annualized myocardial infarction ("MI") rate for Celebrex was significantly higher when compared with the placebo group of a meta-analysis. This raised a significant concern about the risks of cardiovascular events with COX-2 inhibitors. Mukherjee, et al., *Risk of Cardiovascular Events Associated With COX-2 Inhibitors*, *JAMA*, 2001;286:954-959.

68. Pfizer was also aware there were serious concerns and warnings from the medical and scientific communities regarding the risks associated with COX-2 inhibitors, including

Bextra, of cardiovascular events, including the risk of arterial thrombosis and increased blood pressure, particularly in patients who are already at increased risk due to other underlying conditions. Crofford, et al., *Thrombosis in Patients With Connective Tissue Diseases Treated With Specific Cyclooygenase 2 Inhibitors, Arthritis Rheum*, 2000;43:1891-6; Mukherjee, et al., *Risk of Cardiovascular Events Associated With COX-2 Inhibitors, JAMA*, 2001;286:954-959; FitzGerald, et al., *The Coxibs, Selective Inhibitors of Cyclooxygenase-2, N Engl J Med*, 2001;345:433-42; Aw, et al., *Meta-analysis of Cyclooxygenase-2 Inhibitors and Their Effects on Blood Pressure, Arch Intern Med*, 2005;165:490-496.

69. Pfizer was also aware that the APC and PreSAP studies showed an increased risk of cardiovascular injuries associated with COX-2 inhibitors. Indeed, the data from the APC study lead the NCI to suspend a Celebrex study due to a significant excess of cardiovascular injuries among participants in the study.

70. Pfizer also had knowledge of two studies conducted by Merck related to its COX-2 inhibitor Vioxx (rofecoxib) -- the Vioxx Gastrointestinal Outcomes Research (VIGOR) study and the Adenomatous Polyp Prevention (APPROVe) study. Both of these studies demonstrated that COX-2 inhibitors pose a serious risk of adverse cardiovascular events, including heart attack, stroke, myocardial infraction, blood clots, and other health risks.

71. Despite the data demonstrating the cardiovascular risks of COX-2 inhibitors from the CLASS, APC, VIGOR, and APPROVe studies, among others, Pfizer failed to adequately or timely test or evaluate the safety of Bextra. The scientific data known and available to Pfizer during and after Bextra's approval process made clear to Pfizer that Bextra caused a higher risk of cardiovascular adverse events, blood clots, stroke and/or myocardial infarctions among its consumers, and alerted Pfizer to the need to conduct additional and adequate safety studies in

appropriate patient groups.

72. Based upon readily available scientific data, Pfizer knew, or should have known, that its pre-approval testing of Bextra did not adequately represent the cross-section of individuals who were intended consumers and therefore likely to take Bextra. Therefore, Pfizer's pre-approval testing and studies were grossly inadequate. Likewise, Pfizer knew its post-marketing testing and surveillance regarding Bextra was inadequate.

73. Had Pfizer designed and conducted adequate testing and studies prior to approval and market launch, the resulting scientific data would have revealed significant increases in the incidence of strokes and myocardial infarctions among the intended and targeted population of Bextra consumers. Adequate design of studies and adequate testing would have shown that Bextra possessed serious side cardiovascular and other effects. Pfizer was under a duty to conduct appropriate post-marketing pharmacovigilance, but failed to do so, to ensure that its defectively designed product would not be placed in the stream of commerce. It also was under a duty, which it breached, to provide full and proper warnings to consumers and the medical community which accurately, fully, and timely reflected the scope and severity of symptoms of the side effects associated with Bextra.

Post-marketing Data

74. Pfizer was further aware of the risks of Bextra from post-marketing data and surveillance which demonstrated that Bextra had an increased risk of heart attack, stroke, and myocardial infarction. However, Pfizer failed to adequately review or evaluate this data, or intentionally suppressed it, in order to gain significant profits from continued Bextra sales.

75. Pfizer was further aware of adverse event reports and other post-marketing reports and information that Bextra posed an unreasonable danger to consumers of cardiovascular and other serious risks but failed to adequately evaluate or warn regarding these

reports.

Pfizer Misrepresented the Safety and Superiority of Bextra and Failed to Provide Adequate Warnings of Its Dangers.

76. Pfizer made false and misleading claims regarding the safety of Bextra, including misrepresentations regarding Bextra's CV risks and its alleged superiority in safety and efficacy in comparison to, and "over," other anti-inflammatories such as traditional NSAIDs. Specifically, Pfizer falsely represented that Bextra was a once-daily powerful option for people with rheumatoid arthritis and osteoarthritis which offered improved "GI toleration" with no increase in CV risk versus traditional NSAIDs.

77. Pfizer made further misrepresentations regarding the CV safety and superiority of Bextra in claiming that Bextra had an "established CV safety" profile, that Bextra had a superior safety-profile to traditional NSAIDs, and that Bextra had superior effectiveness to traditional non-selective NSAIDs. Pfizer further used deceptive and misleading representations of scientific data and studies to promote Bextra in its marketing and advertising. For example, Pfizer misleadingly claimed that clinical trials showed that the incidence of cardiovascular adverse events at the marketed doses was similar to placebo.

78. Pfizer made these misrepresentations in commercial advertising, direct-to-consumer ("DTC") advertising, articles, direct mail brochures, TV Infomercials, press releases, conferences, internet releases, "Dear Doctor" letters, promotions to and detailing of the medical profession, pharmacy chains, wholesalers, pharmacy benefit managers, managed care organizations, annual reports, and other marketing, advertising and promotional materials and methods.

79. Specifically, Pfizer marketed Bextra directly to doctors for use in the treatment of pain, contrary to its FDA approved labeling. In a summary document of "Final Evaluations"

from the 2002 National Consultant's Meeting for Orthopedic Surgeons organized by Defendants, participant responses to the question "which specific information presented did you find most compelling," included,

> · Valde[coxib] used as pain med.
> · Pain data - synergy of multimodal therapy
> · Safety & efficacy of Celebrex & Bextra
> · Gastrointestinal safety profile of COX-2 inhibitors
> · Although Bextra doesn't have a pain indication, it is effective in pain management
> · Use of Bextra as a pre-op adjunct and post op for management of pain…

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

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

81. The following appeared in the August 9, 2003, CHEMIST & DRUGGIST:

> Bextra is a new… Cox-2 inhibitor from 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.

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

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

83. Pfizer also marketed Bextra and Celebrex together, revealing only the positive data for each drug so that doctors would think that the positive data actually applied to both drugs. Pfizer referred to this marketing strategy as the "Halo Effect." The Halo Effect is contrary to the FDA approved labeling for both drugs in that it promoted each drug with data that had no scientific connection whatsoever to that drug. Such selective presentation of safety data was contrary to the FDA approved labeling for Bextra.

84. At all times relevant to this complaint, Pfizer's officers, directors, employees, and agents were aware of Pfizer's misrepresentations regarding the safety, efficacy, superiority of Bextra.

85. Pfizer also placed misleading articles in the medical literature in an effort to promote sales of Bextra -- including to promote "off-label" uses of Bextra -- and to mislead physicians and the medical community. For example, in 2002 Pfizer hired an outside firm, SCIREX, which was owned by one of the world's largest advertising firms, Omnicrom, to conduct a study and publish an article touting the benefits of Bextra for use in acute dental pain. This was a use which had been specifically disapproved by the FDA.

86. The article was published in the Journal of the American Dental Association: Daniels, et al., *The analgesic efficacy of valdecoxib vs. oxycodone/acetaminophen after oral surgery, J Am Dental Assoc*, 2002;133:611-621. It misleadingly concluded that Bextra was safe an effective in the treatment of acute pain following oral surgery, was an efficacious and safe alternative, and was superior to, oxycodone/acetaminophen. This article was designed and conducted by Pfizer, and was used by Pfizer salesmen, to promote and influence the use of Bextra among dentists in the treatment of an FDA non-approved use and in order to promote the off-label use of Bextra and thereby increases sales of Bextra. *See*, Petersen, *Madison Ave. Has*

Growing Role In the Business of Drug Research, NY Times, November 22, 2002. As reported in the New York Times, the independent physicians who reviewed the SCIREX article found the study inadequatley designed and its claims misleading and unsubstantiated.

87. Pfizer continued to end-run the FDA approval process by making misleading claims regarding the safety and effectiveness of Bextra and by continuing to promote Bextra for off-label uses. In fact, a Knight-Ridder analysis in May 2004 found that Pfizer sold more than half of its Bextra pills for off-label uses. In a 10-k filed with the SEC on March 10, 2004 Pfizer disclosed it was being investigated by the U.S. Justice Department regarding the marketing of Bextra for off-label uses.

88. At the time Pfizer manufactured, advertised, and distributed Bextra to physicians and consumers, it intentionally or recklessly ignored and withheld information regarding the increased risks of hypertension, stroke and myocardial infarctions. Pfizer did so because it knew that if such increased CV risks were disclosed, physicians would not prescribe Bextra, wholesalers and pharmacy chains and others would not purchase or distribute it, and, most importantly, consumers would not purchase Bextra but instead would purchase other cheaper and safer NSAIDs.

89. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a massive marketing campaign. In addition to being aggressive, Pfizer's marketing campaign, including its direct-to-consumer ("DTC") campaign and its promotional "detailing" of physicians, was fraudulent and misleading. But for this fraudulent and misleading advertising, consumers, including the plaintiffs, would not have purchased Bextra, a more costly prescriptive drug which is no safer than available alternative NSAIDs for its intended purposes.

90. At all times relevant herein, Pfizer engaged in a marketing campaign with the

intent that consumers would perceive Bextra as a safer and better drug than other NSAIDs, including its direct competitors in the COX-2 group such as Vioxx, and therefore, purchase Bextra.

91. Pfizer widely and successfully marketed Bextra throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy and safety of Bextra in order to induce widespread acceptance, use, and consumption.

92. Pfizer made misrepresentations by means of media advertisements, and statements contained in sales literature, slides, and verbal representations provided to Plaintiffs' prescribing physicians by Pfizer's representatives and agents, including drug representatives, sales personnel, detailers, and other agents and representatives of Pfizer.

93. Bextra is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. Bextra is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other nonsteroidal anti-inflammatory medicines and similar drugs on the market and is more dangerous than ordinary consumers can reasonably foresee. In particular, Bextra increases the risk of, and/or causes, cardiovascular and other serious injuries.

94. Pfizer failed to provide adequate warnings of Bextra's dangerous effects, including cardiovascular and other injuries.

95. Pfizer failed fully and adequately to inform the federal Food and Drug Administration ("FDA") of Bextra's dangerous effects, including cardiovascular and other serious injuries.

96. Pfizer made untrue, deceptive or misleading representations of material facts to

and omitted and/or concealed material facts in product packaging, labeling, medical advertising, direct-to-consumer advertising, "Dear Doctor" letters and other communications, and promotional campaigns and materials, among other methods and materials, regarding the safety and use of Bextra.

97. In addition, Pfizer downplayed and understated the serious nature of the CV risks associated with Bextra in order to increase the sales of Bextra and secure a greater share of the COX-2 market.

98. Pfizer's statements and omissions were undertaken with the intent that physicians and consumers, including plaintiffs, would rely on the Defendant's statements or omissions.

99. Pfizer knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Bextra but remained silent because Pfizer's appetite for significant future profits far outweighed its concern for the health and safety of consumers, including plaintiffs. Specifically, Pfizer actively concealed that Bextra could cause cardiovascular and other serious injuries.

100. Pfizer's practice of promoting and marketing Bextra created and reinforced a false impression as to the safety of Bextra, thereby placing consumers at risk of serious and potentially lethal effects.

101. Pfizer concealed, omitted, or minimized the side effects of Bextra or provided misinformation about adverse reactions, risks and potential harms from Bextra and succeeded in persuading consumers to purchase and ingest Bextra despite the lack of safety and the risk of adverse medical reactions, including cardiovascular events and gastrointestinal effects.

102. Pfizer was under a duty to disclose the defective and unsafe nature of Bextra to physicians, pharmacists, and consumers such as plaintiffs. Pfizer had sole access to material

facts concerning the defects, and knew that physicians, pharmacists, and users, such as plaintiffs, could not have reasonably discovered such defects.

103. Pfizer's failure to warn physicians, pharmacists, patients, and the public about the defective and unsafe nature of Bextra was reckless and without regard for the public's safety and welfare. Pfizer misled both the medical community and the public at large, including plaintiffs, by making false representations about the safety of Bextra. Pfizer downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Bextra despite available information demonstrating that Bextra was likely to cause serious and even fatal effects to users.

104. Pfizer knew or should been in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless, Pfizer continued to market Bextra by providing false and misleading information with regard to safety and efficacy.

105. Pfizer failed to provide warnings that would have dissuaded physicians from prescribing Bextra and consumers from purchasing and consuming Bextra, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Bextra.

106. Pfizer failed to provide warnings to pharmacists who dispensed Bextra and further failed to keep pharmacists informed about the serious and permanent side effects and risks associated with the use of Bextra.

107. Pfizer acted willfully, knowingly, intentionally, unconscionably, maliciously and/or with reckless indifference.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Strict Product Liability)

108. Plaintiffs repeat and incorporate by reference the allegations in paragraphs 1 through ____ of this Complaint as if fully set forth herein.

109. At all times material hereto, defendant Pfizer engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting Bextra that was defective and unreasonably dangerous to consumers including the plaintiffs.

110. The Bextra sold, distributed, supplied, manufactured and/or promoted by Pfizer was expected to reach and did reach the medical profession and community, including physicians, pharmacists, health care providers, and consumers, including plaintiffs, without substantial change in the condition in which it was manufactured and sold.

111. The Bextra sold, distributed, supplied, manufactured, and/or promoted by Pfizer was in a defective and unreasonably dangerous condition at the time it was placed into the stream of commerce.

112. Bextra was defective and unreasonably dangerous because:

(a) It contained unreasonably dangerous design defects and was not reasonably safe for its intended or reasonable purposes;

(b) Its risks and potential for causing injury to the plaintiffs, including the risk of death, exceeded its utility and benefit;

(c) It was more dangerous than reasonable available alternative medications, including other forms of anti-inflammatories and NSAIDs;

(d) It was more dangerous than an ordinary and reasonable consumer would expect and such consumer would have concluded that Bextra should not have been marketed in that condition;

(e) It was insufficiently tested to determine its hazards;

(f) It was not accompanied by adequate and timely warnings to inform the medical profession and community, including physicians, pharmacists, and other health care providers, of the risks associated with the drug.

113. Defendant Pfizer knew or should have known of the danger associated with the use of Bextra, as well as the defective nature of Bextra, but has continued to design, manufacture, sell, distribute, promote and/or supply Bextra so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Bextra.

114. Plaintiffs used the drug as directed for its intended and reasonably foreseeable purposes including to manage pain and to treat inflammation and other conditions.

115. Plaintiffs could not have discovered the defects in the drug through the reasonable exercise of care.

116. The drug was not misused by plaintiffs or materially altered or modified prior to its use.

117. If not for the aforementioned defective and unreasonably dangerous conditions of the drug, the plaintiffs would not have suffered the injuries complained of.

118. As a direct and proximate result of the defective condition of the drug, plaintiffs suffered injuries as specified in the Short-Form Complaint applicable to each separate action.

119. Pfizer's defective drug Bextra was a substantial factor in causing each plaintiff's

injuries.

120. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

SECOND CAUSE OF ACTION

(Product Liability – Failure to Warn)

121. Plaintiffs repeat and incorporate by reference the allegations in paragraphs 1 through ____ of this Complaint as if fully set forth herein.

122. At all times material hereto, defendant Pfizer was engaged in the business of manufacturing, packaging, labeling, marketing, selling, promoting, distributing and supplying its Bextra product.

123. Pfizer's Bextra product is reasonably certain to be dangerous when used in the manner that defendant specified and/or should reasonably have foreseen.

124. At all times material hereto, Pfizer was under a duty to use reasonable care to provide adequate and timely warnings of any dangers associated with its Bextra product that it knew, or in the exercise of reasonable care should have known, and which users of the product, including plaintiff, ordinarily would not discover.

125. Pfizer failed to provide adequate and timely warnings of the dangers of its Bextra product, including but not limited to:

(a) Failed to provide adequate and timely warnings of the dangers of its Bextra product to the medical profession and community, including physicians, pharmacists, and other health care providers;

(b) Failed to provide adequate and timely warnings in the labeling, including package inserts, printed or graphic materials, wrappers, containers, and other labeling, either on the product or accompanying the product;

(c) Failed to provide adequate and timely warnings to the medical profession and community, including physicians, pharmacists, and other health care providers, in its promotion, marketing, detailing, and sales of Bextra to the medical profession, including physicians, by defendant Pfizer's drug representatives and other agents and employees, and in understating or trivializing the risks, overstating the benefits, promoting indications outside the label, and diluting the import of the label in sales materials, office visits, distribution of samples, distribution of study reprints, publications, and other promotional, marketing, and sales materials and activities;

(d) Failed to provide adequate and timely warnings to the medical profession and community, including physicians, pharmacists, and other health care providers in conferences, workshops, seminars, lunch meetings, and other meetings and presentations;

(e) Failed to provide adequate and timely warnings to the plaintiffs and to the public;

(f) Failed to provide adequate and timely warnings in its advertising, including in its direct-to-consumer ("DTC") advertising;

(g) Failed to submit adequate warnings regarding the risks associated with its drug product, or to submit such warnings in a timely fashion, for consideration by the FDA;

(h) Failed to timely submit supplemental requests to the FDA for proposed labeling changes, or to timely request labeling changes or amendments, regarding risks associated with its drug product;

(i) Failed to timely submit supporting data to the FDA regarding proposed labeling changes;

(j) Failed to adequately and timely conduct post-marketing investigations, including post-marketing clinical investigations, post-marketing epidemiological and surveillance studies, and review of the scientific and medical literature and the unpublished literature;

(k) Failed to adequately and timely review and submit to the FDA adverse drug experience information and reports derived from defendants' commercial marketing experience, post-marketing clinical investigations, post-marketing epidemiological and surveillance studies, scientific and medical literature and unpublished literature;

(l) Failed to provide adequate and timely warnings to the medical profession and community, including physicians, pharmacists, and other health care providers as a result of defendant's post-marketing surveillance activities, including post-marketing adverse event reports and information.

126. Pfizer's conduct in failing to warn the medical profession and community, including physicians, pharmacists, and other health care providers, and the public and

consumers, including plaintiffs, about the serious risks associated with Bextra was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers such as plaintiffs;

127. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

THIRD CAUSE OF ACTION

(Negligence)

128. Plaintiffs repeat and re-alleges each and every allegation set forth in paragraphs 1 through _____ of this Complaint as if fully set forth herein.

129. Defendant Pfizer was under a duty to use reasonable care to design, research, test, manufacture, label, market, advertise, promote, supply, distribute and sell Bextra, including a duty to ensure that Bextra did not cause consumers of the product to suffer from unreasonably dangerous adverse side effects or serious injuries.

130. Pfizer failed to exercise ordinary or reasonable care in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Bextra into the stream of interstate commerce, in that defendant Pfizer knew or reasonably should have known that Bextra created an unreasonable risk of dangerous side effects and serious injuries in consumers of the product.

131. Pfizer knew, or in the exercise of reasonable care should have know, that Bextra would cause foreseeable injury or risk of unreasonable and dangerous side effects in the consumer if not properly designed, researched, tested, manufactured, labeled, marketed, advertised, promoted, supplied, and distributed prior to being placed into the stream of interstate commerce and being sold.

132. Pfizer was negligent in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Bextra and is liable to the plaintiffs for negligence as follows:

(a) Pfizer failed to use due care in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Bextra in order to prevent the unreasonable risks and dangers to consumers and the plaintiffs when Bextra was used for treatment;

(b) Failed to use due care in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Bextra in order to prevent the unreasonable risks and dangers to consumers and the plaintiffs when Bextra was used alone or in foreseeable combination with other drugs and medications;

(c) Failed to use due care to investigate, test, develop, or use reasonable and safer alternative designs, materials, and or manufacturing processes regarding Bextra;

(d) Failed to provide and accompany Bextra with adequate and timely warnings regarding the adverse side effects and harms associated with the use of Bextra and the frequency, comparative severity and duration of such adverse effects and harms;

(e) Failed to provide consumers and the plaintiffs with adequate and timely warnings regarding the adverse side effects and serious harms associated with the use of Bextra, including but not limited to serious cardiovascular and other injuries including heart attack, stroke, clotting, and death;

(f) Failed to provide the medical profession, including physicians, pharmacists, and health care providers, with adequate and timely warnings, training, and information regarding the unreasonable risks of adverse side effects and serious injuries associated with the use of Bextra;

(g) Failed to provide consumers, plaintiffs, and the medical profession, including physicians, pharmacists, and health care providers, with adequate and timely warnings regarding the unreasonable risks of adverse side effects and serious injuries associated with the use of Bextra after Pfizer had knowledge of the same, thereby breaching the continuing duty to warn;

(h) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance in order to properly monitor, evaluate, and determine the use and safety of Bextra for consumers and the plaintiffs prior to and after placing it into the stream of commerce;

(i) Failed to adequately conduct and meet its pharmacovigilance and other duties including failing to adequately and timely review, monitor, and investigate pre-marketing and post-marketing adverse event reports, case reports, and information, including failing to adequately and timely review adverse drug experience information and reports derived from defendants' commercial marketing experience, post-marketing clinical investigations, post-marketing epidemiological and surveillance studies, scientific and medical literature and unpublished literature;

(j) Failed to provide accurate, complete, or properly evaluated data, information, and results, in published and unpublished medical literature, articles, and reports, and to provide such literature, articles, and reports which were not misleading or false;

(k) Were otherwise careless and/or negligent.

133. Pfizer breached its duties to plaintiffs and, as a direct and proximate result of defendant Pfizer's negligence, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

134. As a direct and proximate result of defendant Pfizer's negligence, plaintiffs have paid and have become liable to pay for medical aid, expenses, medications, treatments, and other medical expenses.

135. Defendant Pfizer's aforementioned negligence was a substantial factor and proximate cause of the injuries suffered by the plaintiffs, including their physical and emotional injuries, past, present, and future medical expenses, financial expenses, and other expenses and injuries;

136. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

FOURTH CAUSE OF ACTION

(Breach of Implied Warranty)

137. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herewith.

138. At the time defendant Pfizer placed the drug into the stream of commerce it knew of the use for which the drug was intended and impliedly warranted to plaintiffs that Bextra was

merchantable and fit for the purpose intended.

139. Plaintiffs reasonably relied upon the expertise, skill, judgment and knowledge of Pfizer and upon the implied warranty that the drug was of merchantable quality and fit for use as represented by Pfizer.

140. This warranty was breached because Bextra was not safe and effective as a medication for arthritis and pain, as Pfizer had represented. The drug was not of merchantable quality but rather was unsafe and unfit for its intended use and was unreasonably dangerous.

141. As a direct and proximate result of defendant Pfizer's breach of these warranties, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

142. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

FIFTH CAUSE OF ACTION

(Breach of Express Warranty)

143. Plaintiffs repeat and incorporate by reference the allegations in paragraphs 1 through ____ of this Complaint as if fully set forth herein.

144. In the manufacturing, design, distribution, advertising, marketing, labeling and promotion of Bextra, defendant Pfizer expressly warranted Bextra to be safe and effective for the plaintiffs, consumers, and the public.

145. At the time of the making of these express warranties, Pfizer had knowledge of the purpose for which the product was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

146. Bextra does not conform to these express warranties and representations because

it is not safe or effective and may produce serious adverse side effects, including among others, heart attack, stroke, and death.

147. At all relevant times, plaintiffs were using Bextra for the purpose and in the manner intended and did not misuse the product.

148. Plaintiffs, by the use of reasonable care, would not and could not have discovered the breach and realized its danger.

149. Pfizer's breach of warranty was a substantial factor in causing plaintiffs' injuries.

150. As a direct and proximate result of Pfizer's breach of its express warranties, plaintiffs suffered profound injuries, including death, and suffered and will continue to suffer economic and non-economic loss including medical treatment and hospitalization, became liable for medical and hospital expenses, lost financial gains, was kept from ordinary activities and duties, was made to experience mental and physical pain and suffering, disability and loss of enjoyment of life, and suffered pecuniary loss among other losses and damages.

151. As a direct and proximate result of Pfizer's breach of these warranties, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

152. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

SIXTH CAUSE OF ACTION

(Fraud)

153. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through _____ of this Complaint as if fully set forth herein.

154. Defendant Pfizer, in the course of its manufacturing, marketing, sales, promotion, advertising, and distribution of Bextra, intentionally made false statements and

misrepresentations of material facts regarding the use and safety of Bextra to the public at large, including consumers, plaintiffs, the medical and scientific professions, and health care providers.

155. Pfizer's intentional misrepresentations of material facts were made for the purpose of influencing the marketing of Bextra, a product which defendant Pfizer knew to be defective as unreasonably dangerous and unsafe to the health of consumers and regarding which defendant Pfizer failed to adequately warn.

156. Pfizer's intentional misrepresentations of material facts were undertaken for the purpose of deceiving the public at large and were further made for the purpose of influencing the action of any individual who may act upon or rely upon the misrepresentations regarding the product.

157. Pfizer's intentional misrepresentations of material facts include, but are not limited to:

(a) Misrepresenting or minimizing the results and data from tests and studies showing the risks of serious heart attack, stroke, death, clotting, heart disease and other adverse cardiovascular conditions associated with Bextra;

(b) Misrepresenting or minimizing material information and facts regarding the risks of Bextra, and misrepresenting and overstating its benefits and safety profile, in order to induce the public at large, including consumers and plaintiffs, to purchase Bextra;

(c) Misrepresenting or minimizing material information and facts regarding the risks of Bextra, including misrepresenting and overstating its benefits and safety profile, in order to induce the medical and scientific

professions, including physicians, pharmacists, and health care providers, to prescribe Bextra to the public at large, including consumers and plaintiffs;

(d) Misrepresenting and making false statements in promoting unapproved dosing regimens for Bextra;

(e) Misrepresenting and making false statements and unsubstantiated comparative claims that Bextra provides mechanism-based safety characteristics that distinguish it from traditional NSAIDs and non-selective COX inhibitors and has a superior benefit/risk profile compared to available and less expensive anti-inflammatory therapies for the pain and symptoms of arthritis; and

(f) Failing to include adequate warnings regarding the cardiovascular and other risks of Bextra.

158. Pfizer made these intentional misrepresentations of material facts regarding the use and safety of Bextra to the public at large, including consumers, plaintiffs, the medical and scientific professions, and health care providers through the following means, including, but not limited to:

(a) Product labeling, including package inserts;

(b) Promotions of Bextra to physicians, pharmacists, and other health care providers by Pfizer and it's sales representatives and agents, including through direct product detailing, office visits, medical conferences and meetings, distribution of free samples, distribution of reprints of medical and other articles, professional journal advertisements, correspondence,

sales aids, wall charts, "homemade" promotional materials, and other forms of promotion and communication;

(c) In "Dear Doctor" letters and other communications with the medical and scientific communities;

(d) In published and unpublished medical and scientific literature;

(e) In public statements and promotions including in pre-approval and post-approval press releases, annual reports, articles, pre-approval and post-approval Internet and website promotional materials, correspondence; and

(f) In advertising and marketing to the public at large, consumers, and plaintiffs, including direct-to-consumer ("DTC") advertising, promotional audio conferences, television and print advertisements, television "infomercials," radio advertising, direct mail brochures, and other advertising and marketing methods, techniques, materials, and forms.

159. Pfizer marketed Bextra which it actually knew to be unsafe and without warnings of the dangers it knew to be inherent in the product.

160. Pfizer made these intentional misrepresentations and false statements of material facts in order to promote and generate increased sales of Bextra.

161. The public at large, consumers, and the plaintiffs were not aware of, or in a position to know, the falsity and misleading nature of Pfizer's intentional misrepresentations of material facts regarding the use and safety of Bextra.

162. The public at large, consumers, and the plaintiffs acted or relied upon, either directly or indirectly, Pfizer's misrepresentations regarding Bextra in agreeing to treatment, purchasing, using, and ingesting Bextra.

163. As a direct and proximate result of Pfizer's fraudulent misrepresentations, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

164. Pfizer's intentional misrepresentations of material facts regarding the use and safety of Bextra were committed with conscious and/or reckless disregard for the rights and safety of the public at large, including plaintiffs, thereby entitling plaintiffs to punitive damages.

165. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

SEVENTH CAUSE OF ACTION

(Negligent Misrepresentation and Omission)

166. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through _____ of this Complaint as if fully set forth herein.

167. Defendant Pfizer, having undertaken the manufacturing, marketing, dispensing, distribution, sale, and promotion of the prescription drug Bextra, created and were in a special relationship of trust, confidence, and privity with the public, consumers, plaintiffs, the medical and scientific professions, and health care providers and were thus under a duty to conduct appropriate and adequate studies and tests regarding the safety of Bextra and to provide accurate and complete information and warnings regarding the quality and safety of its product to them, among others.

168. Pfizer misrepresented and/or omitted material facts about the quality and safety of Bextra to the public, consumers, plaintiffs, the medical and scientific professions, and health care providers, among others. Pfizer misrepresented that Bextra was safe and effective for the treatment of osteoarthritis and rheumatoid arthritis. The representations by Pfizer were false

since the product was not safe for said purpose and was dangerous to the health of plaintiffs.

169. At the time the aforesaid representations were made, Pfizer misrepresented and/or omitted from the public, consumers, plaintiffs, the medical and scientific professions, and health care providers, material information about the propensity of Bextra to cause great harm. Pfizer negligently misrepresented claims regarding the safety and efficacy of Bextra despite the absence of sufficient scientific evidence or information to support such claims.

170. The aforementioned misrepresentations and/or omissions were made by Pfizer with the intent to induce plaintiffs to use the product, to their detriment.

171. At the time of Pfizer's misrepresentations and omissions, plaintiffs were ignorant of the falsity of these statements and reasonably believed them to be true.

172. Pfizer breached its duties to plaintiffs by providing false, incomplete and/or misleading information regarding their product. Plaintiffs reasonably believed defendant Pfizer's representations and reasonably relied on the accuracy of those representations when agreeing to treatment, and when purchasing, using, and ingesting Bextra.

173. As a direct and proximate result of one or more of these wrongful acts or omissions of defendant Pfizer, plaintiffs suffered profound injuries including death; required medical treatment and hospitalization; became liable for medical and hospital expenses; lost financial gains; were kept from ordinary activities and duties; were made to experience mental and physical pain and suffering, disability and loss of enjoyment of life; suffered pecuniary loss; and suffered other harms and injuries.

174. As a direct and proximate result of Pfizer's fraudulent misrepresentations, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

175. Defendant Pfizer's fraudulent and intentional misrepresentations, omissions and concealment of material facts regarding the use and safety of Bextra were committed with conscious and/or reckless disregard for the rights and safety of the public at large, including plaintiffs, thereby entitling plaintiffs to punitive damages.

176. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

EIGHTH CAUSE OF ACTION

(Fraudulent Misrepresentation, Concealment, and Omission)

177. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

178. Having undertaken the manufacturing, marketing, distributing and promoting of Bextra, defendant Pfizer was under a duty to provide plaintiffs, physicians, regulators and other consumers accurate and complete information regarding Bextra.

179. Pfizer fraudulently misrepresented to plaintiffs' physicians, to plaintiffs, and to other consumers that Bextra was safe when used as directed.

180. Pfizer fraudulently omitted, concealed, and suppressed material information regarding the safety risks, including the risks of heart attack, stroke, myocardial infarction, and other risks from plaintiffs' physicians, plaintiffs, the medical and scientific professions, and consumers.

181. Pfizer made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from plaintiffs and their prescribing physicians in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Bextra.

182. Pfizer also downplayed, minimized, and understated the serious nature of the risks associated with Bextra in order to increase the sales of Bextra and secure a greater share of the COX-2 and anti-inflammatory medication market.

183. Pfizer's false statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including plaintiffs, would rely on the statements and/or omissions.

184. Pfizer knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Bextra but remained silent and failed to provide adequate and timely information and warnings regarding the hazards of Bextra because Pfizer's appetite for significant future profits far outweighed its concern for the health and safety of consumers.

185. Pfizer actively concealed from plaintiffs, their prescribing physicians, and the consuming public that Bextra could cause cardiovascular and other injuries, including heart attack, stroke, clotting, and death.

186. Pfizer's practice of promoting and marketing Bextra created and reinforced a false impression as to the safety of Bextra, thereby placing consumers at risk of serious and potentially lethal effects.

187. Pfizer concealed, omitted, or minimized the side effects of Bextra or provided misinformation about adverse reactions, risks and potential harms from Bextra and succeeded in persuading consumers to agree to treatment with, and to purchase and ingest, Bextra despite the lack of safety and the risk of adverse medical reactions, including cardiovascular and other injuries, including heart attack, stroke, clotting, and death.

188. At the time of Pfizer's fraudulent misrepresentations, plaintiffs were unaware of

the falsity of the statements being made and believed them to be true.

189. Plaintiffs and their prescribing physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on such misrepresentations.

190. Pfizer had a post-sale duty to warn plaintiffs and their prescribing physicians about the potential risks and complications associated with Bextra in a timely manner but breached this duty by failing to adequately warn plaintiffs, physicians, or consumers.

191. Bextra lacked appropriate warnings, and the packaging and labels used by Pfizer were misleading, inaccurate, incomplete, and/or untimely.

192. As a direct and proximate legal result of the fraudulent acts and omissions, suppression and misrepresentations of Pfizer, plaintiffs suffered the injuries set forth in the individual Fact Sheets.

193. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentations of Pfizer, plaintiffs have paid for medical aid, treatment, attendance and medications and have suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

194. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for compensatory and punitive damages for its fraud, misrepresentation and suppression in an amount to be proved at trial.

195. Pfizer's intentional and fraudulent misrepresentations, omissions and concealment of material facts regarding the use and safety of Bextra were committed with conscious and/or reckless disregard for the rights and safety of the public at large, including plaintiffs, thereby entitling plaintiffs to punitive damages.

196. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

Ninth Cause of Action

(Violation of General Business Law § 349)

197. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

198. Plaintiffs are "persons" within the meaning of New York General Business Law § 349(h).

199. Section 349(a) of New York's General Business Law provides: "Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful."

200. Section 349(h) of New York's General Business Law empowers "[a]ny person who has been injured by reason of any violation of this section" to bring an action.

201. At all relevant times defendant Pfizer was in the business of designing, manufacturing, distributing, supplying, marketing, advertising, promoting, and selling its prescription drug product, Bextra, to consumers, including plaintiffs herein, in the State of New York.

202. Pfizer made untrue, materially deceptive or misleading representations of material facts and omitted and/or concealed material facts in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, sales, detailing, promoting, among other ways, regarding the safety and use of Bextra. Furthermore, Pfizer downplayed and/or understated the serious nature of the risks associated with Bextra in order to increase the sales of Bextra and secure a greater share of the COX-2 market.

203. Pfizer concealed, omitted, or minimized the side effects of Bextra or provided misinformation about adverse reactions, risks and potential harms from Bextra and succeeded in persuading and inducing consumers to purchase and ingest Bextra despite the lack of safety and the risk of adverse medical reactions, including serious cardiovascular and other adverse events.

204. Pfizer's practice of promoting and marketing Bextra created and reinforced a false impression as to the safety of Bextra, thereby placing consumers at risk of serious and potentially lethal effects.

205. Bextra lacked appropriate warnings, and the packaging and labels used by defendant Pfizer were misleading, inaccurate, incomplete, and/or untimely.

206. Pfizer's conduct constitutes deceptive acts or practices in the conduct of business, trade or commerce.

207. Pfizer's deceptive acts and practices took place in the context of designing, marketing, distributing, and selling a prescription medication to the public, to consumers including the plaintiffs herein, and to the medical profession and scientific community, including physicians, pharmacists, and health care providers and therefore those deceptive acts and that conduct is consumer-oriented and affects the public interest.

208. Pfizer's unlawful conduct constitutes unfair acts or practices that have the capacity to and that do deceive consumers.

209. The promotion and release of Bextra by defendant Pfizer into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts in violation of New York General Business Law § 349.

210. Pfizer acted willfully, knowingly, intentionally, unconscionably and with reckless

indifference when committing these acts of consumer fraud.

211. As a proximate result of the acts of consumer fraud set forth above, plaintiffs purchased and ingested an unsafe product, incurring monetary expense and the risk to themselves and members of their households that they would consume Bextra and thereby suffer an increased risk of harms as previously set forth herein.

212. As a direct and proximate result of the deceptive acts or practices of Pfizer, plaintiffs sustained actual damages and injuries.

213. By reason of the foregoing, defendant Pfizer is liable to each plaintiff in an amount to be proved at trial and further is liable to plaintiff for treble damages and attorneys fees.

TENTH CAUSE OF ACTION

(Violation of State Consumer Protection Acts)

214. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through _____ of this Complaint as it fully set forth herein.

215. Defendant Pfizer had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion, and sale of Bextra to Plaintiffs.

216. As a proximate result of the Pfizer's misrepresentations, plaintiffs have suffered as ascertainable loss, in an amount to be determined at trial.

217. Pfizer intended that plaintiffs rely on their materially deceptive practices and purchase Bextra as a consequence of the deceptive practices, including defendant Pfizer's misrepresentations and omissions of material fact in its marketing of Bextra contrary to its FDA approved label:

(a.) Pfizer's promotion of Bextra as a safe drug for the treatment of pain and

as having fewer side effects than comparable drugs on the market was deceptive and unlawful in that Bextra was promoted as having both cardiovascular and gastrointestinal benefits over alternative, non-selective NSAIDs, did not have such added benefits over NSAIDs, and was promoted solely for financial reasons and not due to any material increase in medical safety or efficacy over non-selective NSAIDs;

(b.) Pfizer's conduct was unfair, unlawful and deceptive in that Pfizer knew that Bextra increased the risk of adverse cardiovascular events, such as heart attack and stroke, but promoted Bextra as cardioprotective and safer than other, less expensive non-selective NSAIDs despite this knowledge and in violation of the scope of the approved FDA label;

(c.) Pfizer's conduct was unfair, unlawful and deceptive in that it touted the superiority of Bextra for GI, CV efficacy in violation of the FDA label with knowledge that it was not superior to non-selective NSAIDs in the majority of patients;

(d.) Pfizer marketed and promoted Bextra for relief of the symptoms of arthritis and other conditions without substantial or statistically significant scientific evidence for doing so and in contradiction to the FDA approved label;

(e.) Pfizer promoted the safety and efficacy of Bextra above and beyond the safety and efficacy information in its FDA approved labeling in order to induce doctors to prescribe Bextra and consumers to purchase Bextra at a price that exceeded its actual worth;

(f.) Pfizer promoted Bextra as a standard course of treatment based upon the use of reprints of articles appearing in prestigious medical journals which Pfizer knew were false and/or misleading and contrary to its FDA approved label, and which it knew would be relied on by physicians in making decisions regarding prescription of medications which would effect the health and safety of their patients;

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

218. Pfizer's actions constitute unfair or deceptive or fraudulent acts or practices in violation of various state consumer protection statutes that allow consumers to pursue claims. Plaintiffs with claims in the states identified below assert their claims pursuant to the statutes identified below:[4]

(a.) Defendant Pfizer has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b, *et seq*.;

(b.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code §2511, *et seq*.;

(c.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code §28-3901, *et seq*.;

(d.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §501.201, *et seq*.;

(e.) Defendant has engaged in unfair competition or unfair or deceptive acts or

[4] There are no equivalent state consumer protection acts in Georgia, Alabama, Mississippi or Louisiana.

practices in violation of 815 ILCS §505/1, *et seq*.;

(f.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. §24-5-0.5.1, *et seq*.;

(g.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. §367.110, *et seq*.;

(h.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. §207, *et seq*.;

(i.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code §13-101, *et seq*.;

(j.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*.;

(k.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. §445.901, *et seq*.;

(l.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §325F.67, *et seq*..;

(m.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. §358-A:1, *et seq*.;

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

(o.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §349, *et seq*.;

(p.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Defendants have engaged in unfair competition or

unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, *et seq*.;

(q.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat §1345.01, *et seq*.;

(r.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat.§201-1, *et seq*.;

(s.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. §6-13.1-1, *et seq*.;

(t.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws §37-24-1, *et seq*.;

(u.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code §47-18-101, *et seq*.;

(v.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §245 1, *et seq*.;

(w.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code §59.1-196, *et seq*.;

(x.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code §46A-6-101, *et seq*.;

(y.) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, *et seq*.

219. Plaintiffs have provided or will provide notice of this litigation to each Attorney General in each of the States requiring notice and where demand on a defendant is required.

220. As a direct, proximate and foreseeable result of defendant Pfizers' actions,

plaintiffs paid for higher priced Bextra instead of purchasing a lower-priced generic and/or no medication at all.

221. If plaintiffs had not been deceived concerning the safety and effectiveness of Bextra, they would have taken steps so as to not purchase Bextra at the prices set by defendant Pfizer.

222. Pfizer's unlawful actions caused the purchase of, or payment for Bextra by plaintiffs, and, as a result, plaintiffs paid more than they otherwise would have for NSAIDs. Further, had a reasonable plaintiff known the truth regarding defendant Pfizer's misrepresentations, plaintiffs would have used and/or paid for another less expensive, equally effective, and at least as safe NSAID, many of which were available without a prescription and therefore would not have generated unnecessary expense to plaintiffs.

223. As a direct and proximate result of Pfizer's unfair methods of competition and unfair or deceptive acts or practices, plaintiffs have suffered actual economic damage by paying for Bextra in lieu of other cheaper NSAIDs and/or to pay at an artificially inflated price.

224. By reason of the foregoing, defendant Pfizer is liable to plaintiff(s) for damages, including, where applicable punitive damages, in an amount to be proved at trial.

ELEVENTH CAUSE OF ACTION

(Wrongful Death)

225. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

226. As a result of the tortious and other acts and/or omissions of defendant Pfizer as set forth herein, decedent suffered serious emotional and bodily injuries resulting in death.

227. As a direct and proximate result of the tortious and other acts and/or omissions of

Pfizer and the wrongful death of the decedent, plaintiff(s), decedent's surviving relative(s), statutory distributee(s) and/or beneficiary(ies) has/have been deprived of future aid, income, assistance, services, companionship, society, affection, inheritance, care, guidance, and instruction, past and future financial support, and has/have suffered pecuniary losses, including, but not limited to, medical and funeral expenses, interest, and other losses.

228. Plaintiff(s), as decedent's surviving relative(s), statutory distributee(s) and/or beneficiary(ies), is/are entitled to recover damages as decedent would have if s/he were still living, as a result of the acts and/or omissions of Pfizer pled herein.

229. Plaintiff(s), as decedent's surviving relative(s), distributee(s), and/or beneficiary(ies), is/are entitled to recover punitive damages and damages for the pain and suffering caused by the acts and omissions of Pfizer as specifically pled herein.

230. By reason of the foregoing, defendant Pfizer is liable to plaintiff(s) for compensatory and punitive damages for the decedent's wrongful death in an amount to be proved at trial.

THIRTEENTH CAUSE OF ACTION

(Survival Action)

231. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

232. As a result of the actions and inactions of defendant Pfizer, decedent suffered bodily and emotional injury, including pain and suffering, prior to death.

233. Plaintiff(s), on behalf of decedent's estate, is entitled to recover damages to which decedent was or would have been entitled, including conscious pain and suffering, medical expenses, loss of earnings, funeral expenses, and other damages and losses.

234. By reason of the foregoing, defendant Pfizer is liable to plaintiff(s) for compensatory and punitive damages in an amount to be proved at trial.

FOURTEENTH CAUSE OF ACTION

(Loss of Consortium)

235. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

236. As a result of the acts of the defendant, plaintiff has been deprived of future aid, income, assistance, services, companionship, society, affection and financial support from the decedent.

237. By reason of the foregoing, defendant Pfizer is liable to plaintiff for loss of consortium and for compensatory and punitive damages in an amount to be proved at trial.

RELIEF REQUESTED

WHEREFORE, plaintiffs demand judgment against defendant Pfizer as follows:

A. Awarding each plaintiff compensatory damages against defendant Pfizer in an amount sufficient to fairly and completely compensate such plaintiff for all damages;

B. Awarding each plaintiff treble damages against defendant Pfizer so as to fairly and completely compensate each plaintiff for all damages, and to deter similar wrongful conduct in the future;

C. Awarding each plaintiff punitive damages against defendant Pfizer in an amount sufficient to punish defendant Pfizer for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding each plaintiff costs and disbursements, costs of investigations,

attorneys' fees and all such other relief available under applicable law;

E. Ordering that the costs of this action be taxed to defendant Pfizer; and

F. Awarding such other and further relief as the Court may deem just and proper.

Dated: New York, New York
November __, 2006

Attorneys for Plaintiff

Exhibit B

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

IN RE: NEW YORK BEXTRA AND CELEBREX PRODUCT LIABILITY LITIGATION	Index No. _____ **MASTER CELEBREX COMPLAINT** **MASS TORT**

1. This Complaint is a Master Complaint filed for all Celebrex plaintiffs, or if applicable, plaintiffs' spouses, children, decedents or wards represented by any plaintiffs' counsel.[1] All allegations pleaded herein are deemed pleaded in any Short-Form Complaint hereafter filed.

PARTIES

2. Details pertaining to plaintiff or plaintiffs in each action are, or will be, set forth in the Short-Form Complaint applicable to each action.

3. Defendant Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 235 East 42nd St., New York, New York 10017-5755.

4. At all times relevant hereto, defendant Pfizer was and continues to be engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing, either directly or indirectly through third parties or related entities, the prescription drug, Celebrex.

5. Defendant G.D. Searle LLC f/k/a G.D. Searle & Co. is a Delaware corporation with its principal place of business in Illinois. It was the original inventor and co-developer, with

[1] Throughout this Master Complaint, the terms "plaintiff" and "plaintiffs" shall each be deemed to include the singular and the plural.

Pfizer, of Celebrex and has been engaged in the business of marketing and selling Celebrex on a nationwide basis. Celebrex was co-promoted by Pfizer and G.D. Searle in 1999.

6. Defendant Pharmacia Corporation is a Delaware Corporation with its principal place of business in New Jersey. Pharmacia acquired G.D. Searle in 2000 and thereafter in 2003 was acquired by and merged with defendant Pfizer. G.D. Searle is presently a subsidiary of Pfizer.

7. Defendants are referred to collectively herein as "defendant Pfizer."

FACTS COMMON TO ALL CAUSES OF ACTION

8. Defendant Pfizer is the manufacturer and distributer of two prescription medications which it designed and marketed for relief of the pain and inflammation associated with arthritis -- Celebrex (celecoxib) and Bextra (valdecoxib). Both drugs are COX-2 selective non-steroidal anti-inflammatory drugs (NSAIDS) and both can cause cardiovascular (heart attack, stroke, myocardial infarction) and other serious, life-threatening injuries. This Master Complaint pertains solely to Celebrex.

9. Celebrex was initially submitted to the FDA by defendant Pfizer (through its co-promoter and co-developer, and now subsidiary, G.D. Searle) as an investigational new drug on July 13, 1995 (IND 48,395).

10. On June 29, 1998 defendant Pfizer submitted its original New Drug Application (NDA 20-998) seeking FDA approval for Celebrex (celecoxib).

11. The FDA granted new drug approval for Celebrex on December 31, 1998 for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis.

12. Defendant Pfizer publicly launched Celebrex, its new "blockbuster" drug, in January 1999. This launch was one of the largest direct-to-consumer ("DTC") marketing

campaigns ever undertaken for prescription drugs. Defendant Pfizer's massive marketing campaign fraudulently and misleadingly depicted Celebrex as a much safer and more effective pain reliever than less inexpensive traditional NSAIDs. Defendant Pfizer and its representatives and agents misrepresented the safety profile of Celebrex to consumers, the medical community, and healthcare providers, among others.

13. In April 2005, the FDA required Pfizer to include a "BLACK BOX WARNING" in its labeling for Celebrex in order to warn users of the serious cardiovascular injuries (heart attack, stroke, myocardial infarction), and other injuries associated with the use of Celebrex.

14. Bextra was also developed and marketed by defendant Pfizer. It was approved by the FDA in November 2001. However, on December 9, 2004 the FDA required defendant Pfizer to include a BLACK BOX WARNING in its labeling for Bextra because, like Celebrex, it too causes serious cardiovascular injuries (heart attack, stroke, myocardial infarction) and other adverse health effects. Ultimately, on April 7, 2005 -- at the same time it required defendant Pfizer to include a BLACK BOX WARNING for Celebrex -- the FDA requested defendant Pfizer remove Bextra from the market due to its serious cardiovascular and other adverse health effects in users.

15. Plaintiffs seek compensatory and punitive damages for injuries proximately caused by the misrepresentations and negligent and willful conduct of the defendant in manufacturing and selling the dangerous prescription drug Celebrex and in failing to provide adequate warnings of its harmful effects.

COX-2 SELECTIVE NSAIDs

16. Celebrex (celecoxib) is a prescription medication known as a "coxib" which is among a group of medications called non-steroidal anti-inflammatory drugs ("NSAIDs").

Traditional, over-the-counter NSAIDs, such as aspirin, ibuprofen, and naproxen, reduce pain, swelling, and inflammation by inhibiting the body's production of two enzymes -- cyclooxygenase-1 ("COX-1") and cyclooxygenase-2 ("COX-2"). These two enzymes play an important role in the synthesis of prostaglandins and other compounds which serve a number of functions in the body, including mediating pain, inflammation, and swelling in bodily tissues.

17. COX-1, however, also plays other important roles, including in the protection of gastrointestinal tissues such as the stomach and the intestines and in the aggregation (clotting) of blood platelets and the contraction of blood vessels (vasoconstriction). The inhibition of COX-1 by traditional NSAIDs therefore can result in harmful side effects, including perforations, ulcers and bleeding in gastrointestinal tissues. COX-2 also plays other roles, including in the prevention of the formation of blood clots (thrombogenesis), vasoconstriction, hypertension, and hardening of the arteries (atherogenesis).

18. Unlike traditional NSAIDs, Celebrex and Bextra are selective inhibitors of COX-2 only. Indeed, the selective inhibition of COX-2 is the central marketing allure of selective COX-2 inhibitors such as Celebrex. Celebrex was designed and marketed by defendant Pfizer as effective in treating the pain and inflammation of arthritis while avoiding the gastrointestinal side effects of traditional, non-selective, NSAIDs. Specifically, it was designed and marketed to target only the COX-2 enzyme and not COX-1, and thereby to reduce the pain, inflamation and swelling associated with osteoarthritis and rheumatoid arthritis[2] while allegedly avoiding the harmful gastrointestinal side effects (e.g., bleeding, ulcers) associated with the inhibition of COX-1 by traditional NSAIDs.

19. However, in designing and marketing Celebrex defendant Pfizer intentionally ignored and/or recklessly disregarded current medical and scientific knowledge that selective

[2] As well as to treat acute pain (e.g., from sprains) and dysmenorrhea (menstrual cramps).

inhibition of COX-2 can cause serious adverse side effects, including serious adverse cardiovascular injuries, including myocardial infarctions, strokes, heart attacks, blood clots, pulmonary emboli, hypertension, and other serious injuries.

20. Specifically, defendant Pfizer, misled the consuming public, plaintiffs, and the medical profession regarding the harmful side-effects associated with Celebrex while overstating its benefits and falsely claiming that Celebrex had a superior safety profile and superior risk/benefit profile from currently available traditional, non-selective NSAIDs.

PFIZER KNEW CELEBREX WAS DANGEROUS AND NOT SUPERIOR TO TRADITIONAL NSAIDs.

21. By 1997, and prior to the submission of the New Drug Application (the "NDA") for Celebrex in June 1998, defendant Pfizer was aware that selective inhibition of the COX-2 enzyme by Celebrex increased the pro-thrombotic and other adverse effects of the drug, causing blood clots, heart attacks, hypertension, and other serious adverse effects in its users. Further, defendant Pfizer knew that selective COX-2 inhibitors, such as Celebrex, could predispose patients to myocardial infarction or thrombotic stroke.

22. Based on studies performed on Celebrex and other COX-2 inhibitors, and on basic research on COX-2 selective inhibitors which had been widely conducted, defendant Pfizer knew when Celebrex was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

23. Defendant Pfizer also knew that the initial paradigm of the functions of COX-1 and COX-2, including the “selective” inhibition of COX-2, was inaccurate and over-simplified since both COX-1 and COX-2 serve numerous other biological functions in the body.

24. Despite years of studies on selective COX-2 inhibitors, as well as the new studies

specifically analyzing the risks of Celebrex, defendant Pfizer failed to take any action to protect the health and welfare of patients or consumers or to advise the medical profession, opting instead to continue promoting the drug for sale.

The CLASS Study

25. Defendant Pfizer was aware of the cardiovascular risks associated with selective COX-2 inhibitors such as Celebrex long before the FDA granted market approval in December 1998. In September 1998, defendant Pharmacia (acquired by defendant Pfizer in 2003), sponsored an allegedly independent Celebrex Long-Term Arthritis Safety Study ("CLASS"). Defendant Pfizer intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the data, results, risks and defects of the CLASS study. Among other things, defendant Pfizer failed to release the study's complete twelve month results. Instead, it released only the first six months of data from the trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

26. The data from the CLASS study demonstrates that, before Celebrex was introduced to the market in January 1999, defendant Pfizer was aware that Celebrex was not superior to traditional NSAIDs in reducing serious gastrointestinal adverse effects and caused a disproportionately and statistically significant high number of adverse cardiovascular events.

27. On August 5, 2001, an article in *The Washington Post* reported at length regarding Pfizer's failure to disclose the six months of data from the CLASS study. Specifically, the article reported that the journal in which the study was originally published, the prestigious *Journal of the American Medical Association* ("JAMA") and its editors were "flabbergasted" and "furious" that the additional data had not been disclosed.

28. On November 21, 2001 letters to the editor of JAMA from various medical doctors stated that Pfizer's failure to include the complete data in the published CLASS study raised the concern that the "unpublished data may not be widely known by physicians who prescribe celecoxib" and could "mislead physicians and patients." Hrachovec, et al., *JAMA*, 2001;286:2398-9.

29. An article in *The British Medical Journal* ("BMJ") on June 1, 2002, which reviewed the CLASS study and Pfizer's failure to include the complete data, concluded that "[p]ublishing and distributing overoptimistic data using post hoc changes to the protocol, while omitting disappointing long term data of two trials, which involved large numbers of volunteers, is misleading." Juni, *BMJ,* 2002;324:1287-8. The article further reported that 30,000 reprints of the original, incomplete and misleading CLASS study had been widely distributed to physicians and the medical community by Pfizer and "coincided with the sales of celecoxib increasing from $2623m in 2000 to $3114m in 2001." *Id*.

Medical Literature

30. Defendant Pfizer was aware of numerous articles in the published, peer-reviewed medical literature which showed that Celebrex, and other COX-2 inhibitors, posed serious cardiovascular and related dangers.

31. For example, defendant Pfizer was aware of medical articles which analyzed the data from CLASS and found that the annualized myocardial infarction ("MI") rate for Celebrex was significantly higher when compared with the placebo group of a meta-analysis. Mukherjee, et al., *JAMA*, 2001;286:954-959.

32. Defendant Pfizer was also aware there were serious concerns and warnings from the medical and scientific communities regarding the risks associated with COX-2 inhibitors,

including Celebrex, of cardiovascular events, including the risk of arterial thrombosis, particularly in patients who are already at increased risk because of other underlying conditions. Mukherjee, et al., *JAMA*, 2001;286:954-959; Crofford, et al., *Arthritis Rheum.*, 2000;43:1891-6; FitzGerald, et al., *NEJM*, 2001;345:433-42.

33. Defendant Pfizer was further aware of medical literature which raised the serious concern that COX-2 specific inhibitors such as Celebrex were pro-thrombotic. McAdam, et al., *Proc. Natl. Acad. USA*, 1999;96:272-277; Catella-Lawson, et al. *J. Pharmacol. Exp. Ther.*, 1999;298:735-41; Hennan, et al., *Circulation*, 2001;104:820-5.

34. Defendant Pfizer was also aware that it had not adequately evaluated, or conducted adequate testing, regarding the cardiovascular risks of Celebrex, including in long-terms studies in low-risk or high-risk populations. Indeed, Pfizer was aware that in its evaluation of Celebrex, "the use of small, short-term trials, the exclusion of high risk patients, and the methodologic inattention to cardiovascular events all minimized the possibility of uncovering evidence of cardiovascular harm." *See, e.g.*, Editorial, *COX-2 Inhibitors -- Lessons in Drug Safety*, *NEJM*, 2005;352:1133-1135; Topol, E., *Arthritis Medicines and Cardiovascular Events -- "House of Coxibs", JAMA*, 2005;293:366-368; Drazen, J., *COX-2 Inhibitors -- A Lesson in Unexpected Problems, NEJM*, 2005;352:1131-1132. As stated by Dr. Jeffrey Drazen in the New England Journal of Medicine:

> . . . had trials designed to test the question of cardiovascular toxicity been launched in 1999 and executed with urgency, substantial morbidity and perhaps a substantial number of deaths could have been prevented. As we apply new science to develop new medicines, we must not forget that our first job is to do no harm.

Id.

35. Defendant Pfizer was also aware from the literature that traditional NSAIDs, including aspirin and acetaminophen, are just as effective in relieving pain as COX-2 inhibitors,

including Celebrex, and do not present a superior safety or risk/benefit profile in comparison to traditional NSAIDs. *Id*. *See also*, FitzGerald, *Coxibs and Cardiovascular Disease*, NEJM, 2004; 351:1709-1711 (when the full 12-month data set from CLASS became available "it was clear celecoxib did not differ from the traditional NSAIDs in its effect on the predefined gastrointestinal end points.")

36. The current medical literature has overwhelmingly confirmed what has now long been know about the dangers of serious cardiovascular and other injuries associated with Celebrex. *See e.g.*, McGettigan, et al., *JAMA*, 2006;296:E1-E12 (meta-analysis finding increased CV risk of Celebrex at 400mg doses); Andersohn, et al., *Circulation*, 2006;113:1950-1957 (CV risk of Celebrex increased with higher doses); Brophy, et al., *Heart Online*, 2006; published online July 18, 2006:1-13 (celecoxib associated with excess risk of acute MI for current users with prior history of MI); Gislason, et al., *Circulation*, 2006;113:2906-2913(CV risk of Celebrex similar to CV risk of Vioxx); Graham, *JAMA*, 2006; published online September 12, 2006:E1-E4 (Celecoxib increases CV risk and rises at doses higher than 200 mg/d); Caldwell, et al., *J. Royal Soc. Med.*, 2006;99:132-140 (meta-analysis finding increased risk of myocardial infarction with Celebrex).

37. These and other medical articles demonstrate that defendant Pfizer knew Celebrex was unreasonably dangerous to consumers and was no safer or more effective in relieving the pain and inflammation associated with arthritis than other less-expensive, traditional NSAIDs.

The APC and PreSAP Studies

38. After the CLASS study, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. As a result, the Adenoma Prevention with Celecoxib (APC) trial was initiated in early 2000. Another trial, the Prevention of Spontaneous

Adenomatous Polyps (PreSAP) trial, was also initiated.

39. Immediately after Vioxx, the leading COX-2 competitor of Celebrex, was withdrawn by its manufacturer, Merck, from the market on September 30, 2004 as a result of its serious cardiovascular harms, defendant Pfizer issued a series of Press Releases and sent "Dear Doctor" letters to prescribing physicians in which it misleadingly claimed that the cardiovascular safety of Celebrex had been established in long-term studies, particularly in the APC and PreSAP studies.

40. For example, in a Press Release dated September 30, 2004, defendant Pfizer stated it was "confident in the long-term safety of Celebrex" because a recent FDA-sponsored study (APC) "demonstrated no increased risk of cardiac events" and therefore Celebrex "is an appropriate treatment alternative." These misleading claims were repeated in Press Releases dated October 1, 2004, October 18, 2004, and in others.

41. In reality, however, these claims were demonstrably false and misleading. First, the claims were made before the studies were completed. Second, when the APC trial was completed by the NCI, it quickly concluded that the data clearly showed a cardiovascular risk associated with Celebrex and, as a result, halted the trial.

42. As a consequence, on December 17, 2004, the National Cancer Institute suspended the use of Celebrex for all participants in the APC trial due to a significant excess of cardiovascular death, myocardial infarction (MI) and stroke. Analysis of the data by an independent Data Safety Monitoring Board (DSMB) showed a two- to three-fold increased risk of major fatal and non-fatal cardiovascular events, including myocardial infarction and stroke for participants taking the drug compared to those on a placebo. Specifically, it reported a 2.3- and 3.4-fold increased risk of cardiovascular events with the 400 mg and 800 mg daily doses of

celecoxib, respectively. Solomon, SD, et al., *Adenoma Prevention with Celecoxib (APC) Study Investigators. Cardiovascular risk associated with celecoxib in a clinical trial for colorectal adenoma prevention*, NEJM, 2005; 352:1071-80.

43. As a result of the APC findings, on December 17, 2004 FDA issued a statement confirming that the data showed Celebrex had a greater risk of cardiovascular events compared to placebo. Then, on December 23, 2004, the FDA issued a Public Health Advisory recommending limited use of COX-2 inhibitors, including Celebrex, because of the increased risk of serious cardiovascular events. It further required an evaluation of all studies involving both of Pfizer's COX-2 selective drugs, Celebrex and Bextra.

44. The published medical literature related to the APC trial clearly shows defendant Pfizer's statements regarding the findings in APC were false and misleading. The conclusion in the published medical article regarding the APC trial stated:

> Celecoxib use was associated with a dose-related increase in the composite end point of death from cardiovascular causes, myocardial infarction, stroke, or heart failure. in light of recent reports of cardiovascular harm associated with treatment with other agents in this class, these data provide further evidence that the use of COX-2 inhibitors may increase the risk of serious cardiovascular events.

Solomon, SD, et al., *Adenoma Prevention with Celecoxib (APC) Study Investigators. Cardiovascular risk associated with celecoxib in a clinical trial for colorectal adenoma prevention*, NEJM, 2005; 352:1071-80.

45. On December 17, 2004 defendant Pfizer issued a Press Release in which it conceded that the APC data "demonstrated an increased cardiovascular risk over placebo." However, it then claimed that these results were "new information" and "not consistent with the reported findings in the second study (PreSAP)."

46. This statement too is false and misleading. As reported in the published medical

literature regarding the APC and PreSAP trials, the analysis of the PreSAP data was in fact preliminary and "could not exclude a hazard ratio similar to that observed in APC." Solomon, et al., *Circulation*, 2006;114:1028-1035. More importantly, since "neither APC nor PreSAP was designed or powered to assess cardiovascular risk" the data from the two studies were combined to perform an analysis of the cardiovascular risk. *Id*. When this combined analysis was performed, the investigators observed a clear and significant increase risk of serious cardiovascular events associated with Celebrex. As the published article states:

> In summary, we observed a nearly 2-fold increased risk of the composite end point of cardiovascular death, myocardial infarction, stroke, or heart failure when combining all doses of celecoxib tested in 2 similar placebo-controlled, long-term cancer prevention trials. The observed dose-related increase in cardiovascular events and blood pressure raises the possibility that even lower dose regimens may be associated with lower overall cardiovascular hazard.

Id. Indeed, the published article states: "Celecoxib at 200 or 400 mg twice daily showed a nearly 2-fold-increased cardiovascular risk." *Id*.

The IQ5-97-02-001 Study

47. Defendant Pfizer also conducted a study, IQ5-97-02-001, to determine whether Celebrex could be used to treat Alzheimer's disease. This study, which was initiated on July 1, 1997 and completed on June 24, 1999, has never been published in the medical literature. Patients in this study took 400 milligrams of Celebrex daily. Defendant Pfizer knew this study revealed an increased risk of heart attacks, strokes and other cardiovascular events to users of Celebrex compared to placebo.

48. This trial enrolled 425 patients with mild-to-moderate Alzheimer's disease. 285 received celecoxib 200 mg twice daily and 140 received placebo. Although the article reporting the data found the findings difficult to interpret, nonetheless, over the 52 week study "there was an increase in the occurrence of thrombotic cardiovascular events (acute MI, CVA, and

peripheral thrombotic events) among patients taking celecoxib compared with placebo." Solomon, D.H., *Arthritis & Rheumatism*, 2005;52:1968-1978.

49. Notwithstanding these significant cardiovascular findings, defendant Pfizer did not publish the 1999 Alzheimer's study or submit this study to the FDA until after the FDA conducted a review of Celebrex. Further, defendant Pfizer did not advise plaintiffs, physicians, or the medical or scientific communities of this study or its findings.

50. A February 1, 2005 article in T*he New York Times* reported that this 1999 study was not disclosed publically until January 2005 when it was discovered by Public Citizen on an FDA website which had recently begun posting clinical trial results. The article further reported that the 1999 study was not submitted to the FDA until June 2001, four months after the FDA had completed a major review of the safety of Vioxx and Celebrex. The article reported that following the publication of the study by Public Citizen, defendant Pfizer acknowledged, for the first time, that the 1999 study "found that elderly patients taking the drug were far more likely to suffer heart problems than patients taking placebo." Berenson, et al., NYT, *Pfizer Says 1999 Trials Revealed Risks With Celebrex*, Feb. 1, 2005. The article further reported that two doctors who participated in the FDA's 2001 review of the safety of Celebrex stated that had they known of the 1999 study they might have recommended that Celebrex be taken with greater caution. *Id*.

The ADAPT Study

51. On December 20, 2004, the National Institutes of Health and the FDA announced the premature cessation of the Alzheimer Disease Anti-inflammatory Prevention Trial (ADAPT). This trial had been designed and initiated to assess the potential adverse cardiovascular events associated with Celecoxib. However, during the course of the trial an excess of cardiovascular risk was found in the patients assigned to naproxen versus placebo. Topol, *JAMA*, 2005;293:366-

368.

52. As it had with the APC trial, Pfizer issued false and misleading statements regarding the ADAPT findings claiming it showed there was no evidence of CV risk. However, ADAPT has never been published in the medical literature. Furthermore, due to the halting of the trial, the final data are not yet available. Moreover, since the events have not yet been adjudicated by cardiologists, it is inappropriate and misleading to draw any conclusions regarding Celebrex from ADAPT. *Id*.

FitzGerald Study

53. In an article published in the New York Times on November 10, 2004, it was reported that Dr. Garrett FitzGerald had conducted a study presented at the American Heart Association which found a significantly higher risk of heart attacks and strokes among patients taking Bextra than in those taking placebo. Dr. FitzGerald further stated that his findings indicated that Celebrex, among other COX-2 inhibitors, should be used with great caution. *See also*, FitzGerald, *Coxibs and Cardiovascular Disease*, NEJM, 2004; 351:1709-1711 (retrospective approach to the full twelve months of data from CLASS "reveals signs of increased cardiovascular risk.")

Post-marketing Data

54. Defendant Pfizer was further aware of the risks of Celebrex from post-marketing data, including studies by Wellpoint, Inc., a health insurer, which demonstrated that Celebrex had an increased risk of heart attack, stroke, myocardial infarction and stroke. However, defendant Pfizer intentionally suppressed this information in order to gain significant profits from continued Celebrex sales.

55. Defendant Pfizer was further aware of adverse event reports and other post-

marketing reports and information that Celebrex posed an unreasonable danger to consumers of cardiovascular and other serious risks.

Other COX-2 Studies

56. In addition to the wealth of data and literature which led to the withdrawal of Bextra due to its CV and other risks, defendant Pfizer knew about other data, studies, and literature which revealed a cardiovascular risk associated with COX-2 inhibitors including Celebrex. For example, defendant Pfizer had knowledge of two studies conducted by Merck related to its COX-2 inhibitor Vioxx (rofecoxib) -- Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe). Both of these studies demonstrated that COX-2 inhibitors pose a serious risk of adverse cardiovascular events, including heart attack, stroke, myocardial infraction, blood clots, and other health risks.

57. Despite the data from CLASS and its other studies, and from the VIGOR and APPROVe studies, defendant Pfizer failed to reevaluate the Celebrex data and studies. The scientific data known and available to defendant Pfizer during and after Celebrex's approval process made clear to defendant Pfizer that Celebrex would cause a higher risk of blood clots, stroke and/or myocardial infarctions among Celebrex consumers, and alerted it to the need to do additional and adequate safety studies, particularly in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events, and who are most likely to be prescribed Celebrex.

58. Based upon readily available scientific data, defendant Pfizer knew, or should have known, that its pre-approval testing of Celebrex did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take Celebrex. Therefore, defendant Pfizer’s testing and studies were grossly inadequate.

59. Had defendant Pfizer designed and conducted adequate testing and studies prior to approval and market launch, the resulting scientific data would have revealed significant increases in the incidence of strokes and myocardial infarctions among the intended and targeted population of Celebrex consumers. Adequate design of studies and adequate testing would have shown that Celebrex possessed serious side cardiovascular and other effects. Defendant Pfizer should have taken appropriate measures, but failed to do so, to ensure that its defectively designed product would not be placed in the stream of commerce. It also was under a duty, which it breached, to provide full and proper warnings which accurately and fully reflected the scope and severity of symptoms of the side effects associated with Celebrex.

PFIZER MISREPRESENTED THE SAFETY AND SUPERIORITY OF CELEBREX.

60. Defendant Pfizer made false and misleading claims regarding the safety of Celebrex, including regarding its CV risks and its alleged superiority over other anti-inflammatories including traditional NSAIDs.

61. Defendant Pfizer made these misrepresentations in, among other media and methods, press releases, commercial advertising, direct-to-consumer ("DTC") advertising, articles, conferences, internet releases, "Dear Doctor" letters, promotions to the medical profession, detailing, pharmacy chains, wholesalers, pharmacy benefit managers, managed care organizations, annual reports, and other marketing, advertising and promotional materials and methods.

62. At all times relevant to this complaint, defendant Pfizer's officers, directors, employees, and agents were aware of defendant Pfizer's misrepresentations regarding the CLASS study and other studies, and regarding Pfizer's misrepresentations regarding the safety and superiority of Celebrex.

FDA Warning Letters

63. Even before the June 1998 FDA approval of Celebrex for commercial distribution, G.D. Searle & Co. (later acquired by defendant Pfizer) was making unlawful and unsubstantiated claims regarding the safety and efficacy of Celebrex in promotional materials and press releases. Specifically, a July 16, 1997 letter from FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) advised Searle to delete all references to Celebrex on its Internet website because there was no evidence to support Searle's claim that Celebrex is safe and effective in the treatment of arthritis and that it is selective in blocking COX-2 while not interfering with COX-1.

64. After the approval of Celebrex in December 1998, defendant Pfizer continued to make misleading and unsubstantiated claims. The FDA issued three Warning Letters to defendant Pfizer (through its predecessor entity, now subsidiary, G.D. Searle) in October 1999, April 2000, and November 2000, all finding that defendant Pfizer was unlawfully making false or misleading statements concerning the safety and/or efficacy of Celebrex. The November 2000 letter cited two direct-to-consumer television advertisements that overstated the efficacy of Celebrex. The FDA ordered that defendant Pfizer (through its predecessor entity now subsidiary G.D. Searle) immediately cease distribution of the misleading ads.

65. On February 2001, and on January 10, 2005, the FDA again issued additional warning letters and reprimands to defendant Pfizer (directly or through its predecessor entity Pharmacia Corporation) stating that promotional activities, including direct-to-consumer ("DTC") promotional pieces used in marketing Celebrex were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that Celebrex had been

promoted for unapproved uses, in unapproved dosing regiments, and that the marketers had made unsupportable claims that Celebrex was safer and more effective than other NSAIDs.

Misleading Medical Articles

66. Defendant Pfizer also placed misleading articles in prestigious medical and scientific journals in order to falsely promote Celebrex and mislead physicians and the medical community. For example, a 2002 article in The British Medical Journal stated with respect to the publication in JAMA of the incomplete CLASS data that "CLASS may still be relied on by many physicians without reference to these flaws. In our experience most still believe the findings published originally. For example, most of the 58 physicians attending an osteoarthritis workshop in Berne, Switzerland, in December 2001 had not realised that CLASS was seriously biased." Juni, *BMJ* 2002;324:1287-8.

Misleading Marketing, Advertising, and Promotions

67. Defendant Pfizer's failure to conduct adequate testing and/or additional testing prior to market launch was based upon its desire to generate maximum financial gains for itself in the lucrative multi-billion dollar COX-2 inhibitor market.

68. At the time defendant Pfizer manufactured, advertised, and distributed Celebrex to consumers, it intentionally or recklessly ignored and withheld information regarding the increased risks of hypertension, stroke and myocardial infarctions because Pfizer knew that if such increased CV risks were disclosed, physicians would not prescribe Celebrex, wholesalers and pharmacy chains and others would not purchase or distribute it, and, most importantly, consumers would not purchase Celebrex, but instead would purchase other cheaper and safer NSAIDs.

69. Such an ineffective and unreasonably dangerous drug could only be widely

prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, defendant Pfizer's marketing campaign, including its direct-to-consumer ("DTC") campaign, was fraudulent and misleading. But for this fraudulent and misleading advertising, consumers, including the plaintiffs, would not have purchased Celebrex, a more costly prescriptive drug, no safer than available alternative NSAIDs for its intended purposes.

70. At all times relevant herein, Defendant Pfizer engaged in a marketing campaign with the intent that consumers would perceive Celebrex as a safer and better drug than other NSAIDs, including its direct competitors in the COX-2 group such as Vioxx, and therefore, purchase Celebrex.

71. Defendant Pfizer widely and successfully marketed Celebrex throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy and safety of Celebrex in order to induce widespread acceptance, use, and consumption.

72. Defendant Pfizer made misrepresentations by means of media advertisements, and statements contained in sales literature, slides, and verbal representations provided to Plaintiffs' prescribing physicians by defendant Pfizer's representatives and agents, including drug representatives, sales personnel, detailers, and other agents and representatives of Pfizer.

73. Celebrex is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. Celebrex is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other nonsteroidal anti-inflammatory medicines and similar drugs on the market and is more dangerous than ordinary consumers can reasonably foresee. In particular, Celebrex increases the risk of, and/or causes,

cardiovascular and other serious injuries.

74. Defendant Pfizer failed to provide adequate warnings of Celebrex's dangerous effects, including cardiovascular and other injuries.

75. Defendant Pfizer failed fully and adequately to inform the federal Food and Drug Administration ("FDA") of Celebrex's dangerous effects, including cardiovascular and other serious injuries.

76. Defendant Pfizer made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts in product packaging, labeling, medical advertising, direct-to-consumer advertising, "Dear Doctor" letters and other communications, and promotional campaigns and materials, among other methods and materials, regarding the safety and use of Celebrex.

77. In addition, defendant Pfizer downplayed and understated the serious nature of the CV risks associated with Celebrex in order to increase the sales of Celebrex and secure a greater share of the COX-2 market.

78. Defendant Pfizer's statements and omissions were undertaken with the intent that physicians and consumers, including plaintiffs, would rely on the Defendant's statements or omissions.

79. Defendant Pfizer knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Celebrex but remained silent because Pfizer's appetite for significant future profits far outweighed its concern for the health and safety of consumers, including plaintiffs. Specifically, defendant Pfizer actively concealed that Celebrex could cause cardiovascular and other serious injuries.

80. Defendant Pfizer's practice of promoting and marketing Celebrex created and

reinforced a false impression as to the safety of Celebrex, thereby placing consumers at risk of serious and potentially lethal effects.

81. Defendant Pfizer concealed, omitted, or minimized the side effects of Celebrex or provided misinformation about adverse reactions, risks and potential harms from Celebrex and succeeded in persuading consumers to purchase and ingest Celebrex despite the lack of safety and the risk of adverse medical reactions, including cardiovascular events and gastrointestinal effects.

82. Defendant Pfizer was under a duty to disclose the defective and unsafe nature of Celebrex to physicians, pharmacists, and consumers such as plaintiffs. Defendant had sole access to material facts concerning the defects, and knew that physicians, pharmacists, and users, such as plaintiffs, could not have reasonably discovered such defects.

83. Defendant Pfizer's failure to warn physicians, pharmacists, patients, and the public about the defective and unsafe nature of Celebrex was reckless and without regard for the public's safety and welfare. Defendant Pfizer misled both the medical community and the public at large, including plaintiffs, by making false representations about the safety of Celebrex. Defendant Pfizer downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Celebrex despite available information demonstrating that Celebrex was likely to cause serious and even fatal effects to users.

84. Defendant Pfizer knew or should been in possession of evidence demonstrating that Celebrex caused serious side effects. Nevertheless, defendant Pfizer continued to market Celebrex by providing false and misleading information with regard to safety and efficacy.

85. Defendant Pfizer failed to provide warnings that would have dissuaded physicians

from prescribing Celebrex and consumers from purchasing and consuming Celebrex, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Celebrex.

86. Pfizer failed to provide warnings to pharmacists who dispensed Celebrex and further failed to keep pharmacists informed about the serious and permanent side effects and risks associated with the use of Celebrex.

87. Defendant Pfizer acted willfully, knowingly, intentionally, unconscionably, maliciously and/or with reckless indifference.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Strict Product Liability

88. Plaintiffs repeat and incorporate by reference the allegations in paragraphs 1 through ____ of this Complaint as if fully set forth herein.

89. At all times material hereto, defendant Pfizer engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting Celebrex that was defective and unreasonably dangerous to consumers including the plaintiffs.

90. The Celebrex sold, distributed, supplied, manufactured and/or promoted by defendant Pfizer was expected to reach and did reach the medical profession and community, including physicians, pharmacists, health care providers, and consumers, including plaintiffs, without substantial change in the condition in which it was manufactured and sold.

91. The Celebrex sold, distributed, supplied, manufactured, and/or promoted by defendant Pfizer was in a defective and unreasonably dangerous condition at the time it was placed into the stream of commerce.

92. Celebrex was defective and unreasonably dangerous because:

(a) It contained unreasonably dangerous design defects and was not reasonably safe for its intended or reasonable purposes;

(b) Its risks and potential for causing injury to the plaintiffs, including the risk of death, exceeded its utility and benefit;

(c) It was more dangerous than reasonable available alternative medications, including other forms of anti-inflammatories and NSAIDs;

(d) It was more dangerous than an ordinary and reasonable consumer would expect and such consumer would have concluded that Celebrex should not have been marketed in that condition;

(e) It was insufficiently tested to determine its hazards;

(f) It was not accompanied by adequate and timely warnings to inform the medical profession and community, including physicians, pharmacists, and other health care providers, of the risks associated with the drug.

93. Defendant Pfizer knew or should have known of the danger associated with the use of Celebrex, as well as the defective nature of Celebrex, but has continued to design, manufacture, sell, distribute, promote and/or supply Celebrex so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Celebrex.

94. Plaintiffs used the drug as directed for its intended and reasonably foreseeable purposes including to manage pain and to treat inflammation and other conditions.

95. Plaintiffs could not have discovered the defects in the drug through the reasonable exercise of care.

96. The drug was not misused by plaintiffs or materially altered or modified prior to its use.

97. If not for the aforementioned defective and unreasonably dangerous conditions of the drug, the plaintiffs would not have suffered the injuries complained of.

98. As a direct and proximate result of the defective condition of the drug, plaintiffs

suffered injuries as specified in the Short-Form Complaint applicable to each separate action.

99. Defendant Pfizer's defective drug Celebrex was a substantial factor in causing each plaintiff's injuries;

100. By reason of the foregoing, Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

SECOND CAUSE OF ACTION
(Product Liability – Failure to Warn)

101. Plaintiffs repeat and incorporate by reference the allegations in paragraphs 1 through ____ of this Complaint as if fully set forth herein.

102. At all times material hereto, defendant Pfizer was engaged in the business of manufacturing, packaging, labeling, marketing, selling, promoting, distributing and supplying its Celebrex product.

103. Defendant Pfizer's Celebrex product is reasonably certain to be dangerous when used in the manner that defendant specified and/or should reasonably have foreseen.

104. At all times material hereto, defendant Pfizer was under a duty to use reasonable care to provide adequate and timely warnings of any dangers associated with its Celebrex product that it knew, or in the exercise of reasonable care should have known, and which users of the product, including plaintiff, ordinarily would not discover.

105. Defendant Pfizer failed to provide adequate and timely warnings of the dangers of its Celebrex product, including but not limited to:

(a) Failed to provide adequate and timely warnings of the dangers of its Celebrex product to the medical profession and community, including physicians, pharmacists, and other health care providers;

(b) Failed to provide adequate and timely warnings in the labeling, including package inserts, printed or graphic materials, wrappers, containers, and other labeling, either on the product or accompanying the product;

(c) Failed to provide adequate and timely warnings to the medical profession and community, including physicians, pharmacists, and other health care providers, in its promotion, marketing, detailing, and sales of Celebrex to the medical profession, including physicians, by defendant Pfizer's drug representatives and other agents and employees, and in understating or trivializing the risks, overstating the benefits, promoting indications outside the label, and diluting the import of the label in sales materials, office visits, distribution of samples, distribution of study reprints, publications, and other promotional, marketing, and sales materials and activities;

(d) Failed to provide adequate and timely warnings to the medical profession and community, including physicians, pharmacists, and other health care providers in conferences, workshops, seminars, lunch meetings, and other meetings and presentations;

(e) Failed to provide adequate and timely warnings to the plaintiffs and to the public;

(f) Failed to provide adequate and timely warnings in its advertising, including in its direct-to-consumer ("DTC") advertising;

(g) Failed to submit adequate warnings regarding the risks associated with its drug product, or to submit such warnings in a timely fashion, for consideration by the FDA;

(h) Failed to timely submit supplemental requests to the FDA for proposed labeling changes, or to timely request labeling changes or amendments, regarding risks associated with its drug product;

(i) Failed to timely submit supporting data to the FDA regarding proposed labeling changes;

(j) Failed to adequately and timely conduct post-marketing investigations, including post-marketing clinical investigations, post-marketing epidemiological and surveillance studies, and review of the scientific and medical literature and the unpublished literature;

(k) Failed to adequately and timely review and submit to the FDA adverse drug experience information and reports derived from defendants' commercial marketing experience, post-marketing clinical investigations, post-marketing epidemiological and surveillance studies, scientific and medical literature and unpublished literature;

(l) Failed to provide adequate and timely warnings to the medical profession and community, including physicians, pharmacists, and other health care

providers as a result of defendant's post-marketing surveillance activities, including post-marketing adverse event reports and information.

106. Defendant Pfizer's conduct in failing to warn the medical profession and community, including physicians, pharmacists, and other health care providers, and the public and consumers, including plaintiffs, about the serious risks associated with Celebrex was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers such as plaintiffs;

107. By reason of the foregoing, Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

THIRD CAUSE OF ACTION
(Negligence)

108. Plaintiffs repeat and re-alleges each and every allegation set forth in paragraphs 1 through _____ of this Complaint as if fully set forth herein.

109. Defendant Pfizer was under a duty to use reasonable care to design, research, test, manufacture, label, market, advertise, promote, supply, distribute and sell Celebrex, including a duty to ensure that Celebrex did not cause consumers of the product to suffer from unreasonably dangerous adverse side effects or serious injuries.

110. Defendant Pfizer failed to exercise ordinary or reasonable care in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Celebrex into the stream of interstate commerce, in that defendant Pfizer knew or reasonably should have known that Celebrex created an unreasonable risk of dangerous side effects and serious injuries in consumers of the product.

111. Defendant Pfizer knew, or in the exercise of reasonable care should have know, that Celebrex would cause foreseeable injury or risk of unreasonable and dangerous side effects

in the consumer if not properly designed, researched, tested, manufactured, labeled, marketed, advertised, promoted, supplied, and distributed prior to being placed into the stream of interstate commerce and being sold.

112. Defendant Pfizer was negligent in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Celebrex and is liable to the plaintiffs for negligence as follows:

(a) Failed to use due care in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Celebrex in order to prevent the unreasonable risks and dangers to consumers and the plaintiffs when Celebrex was used for treatment;

(b) Failed to use due care in the design, research, testing, manufacture, labeling, marketing, advertising, promoting, supplying, distribution, and sale of Celebrex in order to prevent the unreasonable risks and dangers to consumers and the plaintiffs when Celebrex was used alone or in foreseeable combination with other drugs and medications;

(c) Failed to use due care to investigate, test, develop, or use reasonable and safer alternative designs, materials, and or manufacturing processes regarding Celebrex;

(d) Failed to provide and accompany Celebrex with adequate and timely warnings regarding the adverse side effects and harms associated with the use of Celebrex and the frequency, comparative severity and duration of such adverse effects and harms;

(e) Failed to provide consumers and the plaintiffs with adequate and timely warnings regarding the adverse side effects and serious harms associated with the use of Celebrex, including but not limited to serious cardiovascular and other injuries including heart attack, stroke, clotting, and death;

(f) Failed to provide the medical profession, including physicians, pharmacists, and health care providers, with adequate and timely warnings, training, and information regarding the unreasonable risks of adverse side effects and serious injuries associated with the use of Celebrex;

(g) Failed to provide consumers, plaintiffs, and the medical profession, including physicians, pharmacists, and health care providers, with

adequate and timely warnings regarding the unreasonable risks of adverse side effects and serious injuries associated with the use of Celebrex after defendant Pfizer had knowledge of the same, thereby breaching the continuing duty to warn;

(h) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance in order to properly monitor, evaluate, and determine the use and safety of Celebrex for consumers and the plaintiffs prior to and after placing it into the stream of commerce;

(i) Failed to adequately conduct and meet its pharmacovigilance and other duties including failing to adequately and timely review, monitor, and investigate pre-marketing and post-marketing adverse event reports, case reports, and information, including failing to adequately and timely review adverse drug experience information and reports derived from defendants' commercial marketing experience, post-marketing clinical investigations, post-marketing epidemiological and surveillance studies, scientific and medical literature and unpublished literature;

(j) Failed to provide accurate, complete, or properly evaluated data, information, and results, in published and unpublished medical literature, articles, and reports, and to provide such literature, articles, and reports which were not misleading or false;

(k) Were otherwise careless and/or negligent.

113. Defendant Pfizer breached its duties to plaintiffs and, as a direct and proximate result of defendant Pfizer's negligence, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

114. As a direct and proximate result of defendant Pfizer's negligence, plaintiffs have paid and have become liable to pay for medical aid, expenses, medications, treatments, and other medical expenses.

115. Defendant Pfizer's aforementioned negligence was a substantial factor and proximate cause of the injuries suffered by the plaintiffs, including their physical and emotional injuries, past, present, and future medical expenses, financial expenses, and other expenses and injuries;

116. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

FOURTH CAUSE OF ACTION
(Breach of Implied Warranty)

117. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herewith.

118. At the time defendant Pfizer placed the drug into the stream of commerce, it knew of the use for which the drug was intended and impliedly warranted to plaintiffs that Celebrex was merchantable and fit for the purpose intended.

119. Plaintiffs reasonably relied upon the expertise, skill, judgment and knowledge of defendant Pfizer and upon the implied warranty that the drug was of merchantable quality and fit for use as represented by defendant Pfizer.

120. This warranty was breached because Celebrex was not safe and effective as a medication for arthritis and pain, as defendant Pfizer had represented. The drug was not of merchantable quality but rather was unsafe and unfit for its intended use and was unreasonably dangerous.

121. As a direct and proximate result of defendant Pfizer's breach of these warranties, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

122. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

FIFTH CAUSE OF ACTION
(Breach of Express Warranty)

123. Plaintiffs repeat and incorporate by reference the allegations in paragraphs 1 through ____ of this Complaint as if fully set forth herein.

124. In the manufacturing, design, distribution, advertising, marketing, labeling and promotion of Celebrex, defendant Pfizer expressly warranted Celebrex to be safe and effective for the plaintiffs, consumers, and the public.

125. At the time of the making of these express warranties, defendant Pfizer had knowledge of the purpose for which the product was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

126. Celebrex does not conform to these express warranties and representations because it is not safe or effective and may produce serious adverse side effects, including among others, heart attack, stroke, and death.

127. At all relevant times, plaintiffs were using Celebrex for the purpose and in the manner intended and did not misuse the product.

128. Plaintiffs, by the use of reasonable care, would not and could not have discovered the breach and realized its danger.

129. Defendant Pfizer's breach of warranty was a substantial factor in causing plaintiffs' injuries.

130. As a direct and proximate result of defendant Pfizer's breach of its express warranties, plaintiffs suffered profound injuries, including death, and suffered and will continue to suffer economic and non-economic loss including medical treatment and hospitalization, became liable for medical and hospital expenses, lost financial gains, was kept from ordinary activities and duties, was made to experience mental and physical pain and suffering, disability

and loss of enjoyment of life, and suffered pecuniary loss among other losses and damages.

131. As a direct and proximate result of defendant Pfizer's breach of these warranties, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

132. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

SIXTH CAUSE OF ACTION
(Fraud)

133. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through _____ of this Complaint as if fully set forth herein.

134. Defendant Pfizer, in the course of its manufacturing, marketing, sales, promotion, advertising, and distribution of Celebrex, intentionally made false statements and misrepresentations of material facts regarding the use and safety of Celebrex to the public at large, including consumers, plaintiffs, the medical and scientific professions, and health care providers.

135. Defendant Pfizer's intentional misrepresentations of material facts were made for the purpose of influencing the marketing of Celebrex, a product which defendant Pfizer knew to be defective as unreasonably dangerous and unsafe to the health of consumers and regarding which defendant Pfizer failed to adequately warn.

136. Defendant Pfizer's intentional misrepresentations of material facts were undertaken for the purpose of deceiving the public at large and were further made for the purpose of influencing the action of any individual who may act upon or rely upon the misrepresentations regarding the product.

137. Defendant Pfizer's intentional misrepresentations of material facts include, but are not limited to:

(a) Misrepresenting or minimizing the results and data from tests and studies showing the risks of serious heart attack, stroke, death, clotting, heart disease and other adverse cardiovascular conditions associated with Celebrex;

(b) Misrepresenting or minimizing material information and facts regarding the risks of Celebrex, and misrepresenting and overstating its benefits and safety profile, in order to induce the public at large, including consumers and plaintiffs, to purchase Celebrex;

(c) Misrepresenting or minimizing material information and facts regarding the risks of Celebrex, including misrepresenting and overstating its benefits and safety profile, in order to induce the medical and scientific professions, including physicians, pharmacists, and health care providers, to prescribe Celebrex to the public at large, including consumers and plaintiffs;

(d) Misrepresenting and making false statements in promoting unapproved dosing regimens for Celebrex;

(e) Misrepresenting and making false statements and unsubstantiated comparative claims that Celebrex provides mechanism-based safety characteristics that distinguish it from traditional NSAIDs and non-selective COX inhibitors and has a superior benefit/risk profile compared to available and less expensive anti-inflammatory therapies for the pain and symptoms of arthritis; and

(f) Failing to include adequate warnings regarding the cardiovascular and other risks of Celebrex.

138. Defendant Pfizer made these intentional misrepresentations of material facts regarding the use and safety of Celebrex to the public at large, including consumers, plaintiffs, the medical and scientific professions, and health care providers through the following means, including, but not limited to:

(a) Product labeling, including package inserts;

(b) Promotions of Celebrex to physicians, pharmacists, and other health care providers by defendant Pfizer and it's sales representatives and agents, including through direct product detailing, office visits, medical conferences and meetings, distribution of free samples, distribution of reprints of medical and other articles, professional journal advertisements, correspondence, sales aids, wall charts,

"homemade" promotional materials, and other forms of promotion and communication;

(c) In "Dear Doctor" letters and other communications with the medical and scientific communities;

(d) In published and unpublished medical and scientific literature;

(e) In public statements and promotions including in pre-approval and post-approval press releases, annual reports, articles, pre-approval and post-approval Internet and website promotional materials, correspondence; and

(f) In advertising and marketing to the public at large, consumers, and plaintiffs, including direct-to-consumer ("DTC") advertising, promotional audio conferences, television and print advertisements, television "infomercials," radio advertising, direct mail brochures, and other advertising and marketing methods, techniques, materials, and forms.

139. Defendant Pfizer marketed Celebrex which it actually knew to be unsafe and without warnings of the dangers it knew to be inherent in the product.

140. Defendant Pfizer made these intentional misrepresentations and false statements of material facts in order to promote and generate increased sales of Celebrex.

141. The public at large, consumers, and the plaintiffs were not aware of, or in a position to know, the falsity and misleading nature of defendant Pfizer's intentional misrepresentations of material facts regarding the use and safety of Celebrex.

142. The public at large, consumers, and the plaintiffs acted or relied upon, either directly or indirectly, defendant Pfizer's misrepresentations regarding Celebrex in agreeing to treatment, purchasing, using, and ingesting Celebrex.

143. As a direct and proximate result of defendant Pfizer's fraudulent misrepresentations, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

144. Defendant Pfizer's intentional misrepresentations of material facts regarding the

use and safety of Celebrex were committed with conscious and/or reckless disregard for the rights and safety of the public at large, including plaintiffs, thereby entitling plaintiffs to punitive damages.

145. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

SEVENTH CAUSE OF ACTION
(Negligent Misrepresentation and Omission)

146. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through _____ of this Complaint as if fully set forth herein.

147. Defendant Pfizer, having undertaken the manufacturing, marketing, dispensing, distribution, sale, and promotion of the prescription drug Celebrex, created and were in a special relationship of trust, confidence, and privity with the public, consumers, plaintiffs, the medical and scientific professions, and health care providers and were thus under a duty to conduct appropriate and adequate studies and tests regarding the safety of Celebrex and to provide accurate and complete information and warnings regarding the quality and safety of its product to them, among others.

148. Defendant Pfizer misrepresented and/or omitted material facts about the quality and safety of Celebrex to the public, consumers, plaintiffs, the medical and scientific professions, and health care providers, among others. Defendant Pfizer misrepresented that Celebrex was safe and effective for the treatment of osteoarthritis and rheumatoid arthritis. The representations by defendant Pfizer were false since the product was not safe for said purpose and was dangerous to the health of plaintiffs.

149. At the time the aforesaid representations were made, defendant Pfizer misrepresented and/or omitted from the public, consumers, plaintiffs, the medical and scientific

professions, and health care providers, material information about the propensity of Celebrex to cause great harm. Defendant Pfizer negligently misrepresented claims regarding the safety and efficacy of Celebrex despite the absence of sufficient scientific evidence or information to support such claims.

150. The aforementioned misrepresentations and/or omissions were made by defendant Pfizer with the intent to induce plaintiffs to use the product, to their detriment.

151. At the time of defendant Pfizer's misrepresentations and omissions, plaintiffs were ignorant of the falsity of these statements and reasonably believed them to be true.

152. Defendant Pfizer breached its duties to plaintiffs by providing false, incomplete and/or misleading information regarding their product. Plaintiffs reasonably believed defendant Pfizer's representations and reasonably relied on the accuracy of those representations when agreeing to treatment, and when purchasing, using, and ingesting Celebrex.

153. As a direct and proximate result of one or more of these wrongful acts or omissions of defendants, plaintiffs suffered profound injuries including death; required medical treatment and hospitalization; became liable for medical and hospital expenses; lost financial gains; were kept from ordinary activities and duties; were made to experience mental and physical pain and suffering, disability and loss of enjoyment of life; suffered pecuniary loss; and suffered other harms and injuries.

154. As a direct and proximate result of defendant Pfizer's fraudulent misrepresentations, plaintiffs suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

155. Defendant Pfizer's fraudulent and intentional misrepresentations, omissions and concealment of material facts regarding the use and safety of Celebrex were committed with

conscious and/or reckless disregard for the rights and safety of the public at large, including plaintiffs, thereby entitling plaintiffs to punitive damages.

156. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

EIGHTH CAUSE OF ACTION

(Fraudulent Misrepresentation, Concealment, and Omission)

157. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

158. Having undertaken the manufacturing, marketing, distributing and promoting of Celebrex, defendant Pfizer was under a duty to provide plaintiffs, physicians, regulators and other consumers accurate and complete information regarding Celebrex.

159. Defendant Pfizer fraudulently misrepresented to plaintiffs' physicians, to plaintiffs, and to other consumers that Celebrex was safe when used as directed.

160. Defendant Pfizer fraudulently omitted, concealed, and suppressed material information regarding the safety risks, including the risks of heart attack, stroke, myocardial infarction, and other risks from plaintiffs' physicians, plaintiffs, the medical and scientific professions, and consumers.

161. Defendant Pfizer made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from plaintiffs and their prescribing physicians in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Celebrex.

162. Defendant Pfizer also downplayed, minimized, and understated the serious nature of the risks associated with Celebrex in order to increase the sales of Celebrex and secure a

greater share of the COX-2 and anti-inflammatory medication market.

163. Defendant Pfizer's false statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including plaintiffs, would rely on the statements and/or omissions.

164. Defendant Pfizer knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Celebrex but remained silent and failed to provide adequate and timely information and warnings regarding the hazards of Celebrex because Pfizer's appetite for significant future profits far outweighed its concern for the health and safety of consumers.

165. Defendant Pfizer actively concealed from plaintiffs, their prescribing physicians, and the consuming public that Celebrex could cause cardiovascular and other injuries, including heart attack, stroke, clotting, and death.

166. Defendant Pfizer's practice of promoting and marketing Celebrex created and reinforced a false impression as to the safety of Celebrex, thereby placing consumers at risk of serious and potentially lethal effects.

167. Defendant Pfizer concealed, omitted, or minimized the side effects of Celebrex or provided misinformation about adverse reactions, risks and potential harms from Celebrex and succeeded in persuading consumers to agree to treatment with, and to purchase and ingest, Celebrex despite the lack of safety and the risk of adverse medical reactions, including cardiovascular and other injuries, including heart attack, stroke, clotting, and death.

168. At the time of defendant Pfizer's fraudulent misrepresentations, plaintiffs were unaware of the falsity of the statements being made and believed them to be true.

169. Plaintiffs and their prescribing physicians justifiably relied on and/or were

induced by the misrepresentations and/or active concealment and relied on such misrepresentations.

170. Pfizer had a post-sale duty to warn plaintiffs and their prescribing physicians about the potential risks and complications associated with Celebrex in a timely manner but breached this duty by failing to adequately warn plaintiffs, physicians, or consumers.

171. Celebrex lacked appropriate warnings, and the packaging and labels used by Pfizer were misleading, inaccurate, incomplete, and/or untimely.

172. As a direct and proximate legal result of the fraudulent acts and omissions, suppression and misrepresentations of defendant Pfizer, plaintiffs suffered the injuries set forth in the individual Fact Sheets.

173. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentations of defendant Pfizer, plaintiffs have paid for medical aid, treatment, attendance and medications and have suffered the injuries specified in the Short-Form Complaint applicable to each separate action.

174. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for compensatory and punitive damages for its fraud, misrepresentation and suppression in an amount to be proved at trial.

175. Defendant Pfizer's intentional and fraudulent misrepresentations, omissions and concealment of material facts regarding the use and safety of Celebrex were committed with conscious and/or reckless disregard for the rights and safety of the public at large, including plaintiffs, thereby entitling plaintiffs to punitive damages.

176. By reason of the foregoing, defendant Pfizer is liable to each plaintiff for damages, including punitive damages, in an amount to be proved at trial.

NINTH CAUSE OF ACTION
(Violation of General Business Law § 349)

177. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

178. Plaintiffs are "persons" within the meaning of New York General Business Law § 349(h).

179. Section 349(a) of New York's General Business Law provides:

> Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

180. Section 349(h) of New York's General Business Law empowers "[a]ny person who has been injured by reason of any violation of this section" to bring an action.

181. At all relevant times defendant defendant Pfizer was in the business of designing, manufacturing, distributing, supplying, marketing, advertising, promoting, and selling its prescription drug product, Celebrex, to consumers, including plaintiffs herein, in the State of New York.

182. Defendant Pfizer made untrue, materially deceptive or misleading representations of material facts and omitted and/or concealed material facts in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, sales, detailing, promoting, among other ways, regarding the safety and use of Celebrex. Furthermore, defendant Pfizer downplayed and/or understated the serious nature of the risks associated with Celebrex in order to increase the sales of Celebrex and secure a greater share of the COX-2 market.

183. Defendant Pfizer concealed, omitted, or minimized the side effects of Celebrex or provided misinformation about adverse reactions, risks and potential harms from Celebrex and

succeeded in persuading and inducing consumers to purchase and ingest Celebrex despite the lack of safety and the risk of adverse medical reactions, including serious cardiovascular and other adverse events.

184. Defendant Pfizer's practice of promoting and marketing Celebrex created and reinforced a false impression as to the safety of Celebrex, thereby placing consumers at risk of serious and potentially lethal effects.

185. Celebrex lacked appropriate warnings, and the packaging and labels used by defendant Pfizer were misleading, inaccurate, incomplete, and/or untimely.

186. Defendant Pfizer's conduct constitutes deceptive acts or practices in the conduct of business, trade or commerce.

187. Defendant Pfizer's deceptive acts and practices took place in the context of designing, marketing, distributing, and selling a prescription medication to the public, to consumers including the plaintiffs herein, and to the medical profession and scientific community, including physicians, pharmacists, and health care providers and therefore those deceptive acts and that conduct is consumer-oriented and affects the public interest.

188. Defendant Pfizer's unlawful conduct constitutes unfair acts or practices that have the capacity to and that do deceive consumers.

189. The promotion and release of Celebrex by defendant Pfizer into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts in violation of New York General Business Law § 349.

190. Defendant Pfizer acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

191. As a proximate result of the acts of consumer fraud set forth above, plaintiffs purchased and ingested an unsafe product, incurring monetary expense and the risk to themselves and members of their households that they would consume Celebrex and thereby suffer an increased risk of harms as previously set forth herein.

192. As a direct and proximate result of the deceptive acts or practices of defendant Pfizer, plaintiffs sustained actual damages and injuries.

193. By reason of the foregoing, defendant Pfizer is liable to each plaintiff in an amount to be proved at trial and further is liable to plaintiff for treble damages and attorneys fees.

TENTH CAUSE OF ACTION

(Violation of State Consumer Protection Acts)

194. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through _____ of this Complaint as it fully set forth herein.

195. Defendant Pfizer had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion, and sale of Celebrex to Plaintiffs.

196. As a proximate result of the defendant Pfizer's misrepresentations, plaintiffs have suffered as ascertainable loss, in an amount to be determined at trial.

197. Defendant Pfizer intended that plaintiffs rely on their materially deceptive practices and purchase Celebrex as a consequence of the deceptive practices, including defendant Pfizer's misrepresentations and omissions of material fact in its marketing of Celebrex contrary to its FDA approved label:

(a.) Defendant Pfizer's promotion of Celebrex as a safe drug for the treatment of pain and as having fewer side effects than comparable drugs on the market was deceptive and unlawful in that Celebrex was promoted as having both cardiovascular and gastrointestinal benefits over alternative, non-selective NSAIDs, did not have such added benefits over NSAIDs,

and was promoted solely for financial reasons and not due to any material increase in medical safety or efficacy over non-selective NSAIDs;

(b.) Defendant Pfizer's conduct was unfair, unlawful and deceptive in that Defendants knew Celebrex increased the risk of adverse cardiovascular events, such as heart attack and stroke, but promoted Celebrex as cardioprotective and safer than other, less expensive non-selective NSAIDs despite this knowledge and in violation of the scope of the approved FDA label;

(c.) Defendant Pfizer's conduct was unfair, unlawful and deceptive in that it touted the superiority of Celebrex for GI, CV efficacy in violation of the FDA label with knowledge that it was not superior to non-selective NSAIDs in the majority of patients;

(d.) Defendant Pfizer marketed and promoted Celebrex for relief of the symptoms of arthritis and other conditions without substantial or statistically significant scientific evidence for doing so and in contradiction to the FDA approved label;

(e.) Defendant Pfizer promoted the safety and efficacy of Celebrex above and beyond the safety and efficacy information in its FDA approved labeling in order to induce doctors to prescribe Celebrex and consumers to purchase Celebrex at a price that exceeded its actual worth;

(f.) Defendant Pfizer promoted Celebrex as a standard course of treatment based upon the use of reprints of articles appearing in prestigious medical journals which Defendants knew were false and/or misleading and contrary to its FDA approved label, and which it knew would be relied on by physicians in making decisions regarding prescription of medications which would effect the health and safety of their patients;

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

198. Defendant Pfizer's actions constitute unfair or deceptive or fraudulent acts or practices in violation of various state consumer protection statutes that allow consumers to pursue claims. Plaintiffs with claims in the states identified below assert their claims pursuant to the statutes identified below:[3]

[3] There are no equivalent state consumer protection acts in Georgia, Alabama, Mississippi or Louisiana.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(y.) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, *et seq*.

199. Plaintiffs have provided or will provide notice of this litigation to each Attorney General in each of the States requiring notice and where demand on a defendant is required.

200. As a direct, proximate and foreseeable result of defendant Pfizer's actions, plaintiffs paid for higher priced Celebrex instead of purchasing a lower-priced generic and/or no medication at all.

201. If plaintiffs had not been deceived concerning the safety and effectiveness of Celebrex, they would have taken steps so as to not purchase Celebrex at the prices set by

defendant Pfizer.

202. Defendant Pfizer's unlawful actions caused the purchase of, or payment for Celebrex by plaintiffs, and, as a result, plaintiffs paid more than they otherwise would have for NSAIDs. Further, had a reasonable plaintiff known the truth regarding defendant Pfizer's misrepresentations, plaintiffs would have used and/or paid for another less expensive, equally effective, and at least as safe NSAID, many of which were available without a prescription and therefore would not have generated unnecessary expense to plaintiffs.

203. As a direct and proximate result of defendant Pfizer's unfair methods of competition and unfair or deceptive acts or practices, plaintiffs have suffered actual economic damage by paying for Celebrex in lieu of other cheaper NSAIDs and/or to pay at an artificially inflated price.

204. By reason of the foregoing, defendant Pfizer is liable to plaintiff(s) for damages, including, where applicable punitive damages, in an amount to be proved at trial.

ELEVENTH CAUSE OF ACTION
(Wrongful Death)

205. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

206. As a result of the tortious and other acts and/or omissions of defendant Pfizer as set forth herein, decedent suffered serious emotional and bodily injuries resulting in death.

207. As a direct and proximate result of the tortious and other acts and/or omissions of defendant Pfizer and the wrongful death of the decedent, plaintiff(s), decedent's surviving relative(s), statutory distributee(s) and/or beneficiary(ies) has/have been deprived of future aid, income, assistance, services, companionship, society, affection, inheritance, care, guidance, and instruction, past and future financial support, and has/have suffered pecuniary losses, including,

but not limited to, medical and funeral expenses, interest, and other losses.

208. Plaintiff(s), as decedent's surviving relative(s), statutory distributee(s) and/or beneficiary(ies), is/are entitled to recover damages as decedent would have if s/he were still living, as a result of the acts and/or omissions of defendant Pfizer pled herein.

209. Plaintiff(s), as decedent's surviving relative(s), distributee(s), and/or beneficiary(ies), is/are entitled to recover punitive damages and damages for the pain and suffering caused by the acts and omissions of defendant Pfizer as specifically pled herein.

210. By reason of the foregoing, defendant Pfizer is liable to plaintiff(s) for compensatory and punitive damages for the decedent's wrongful death in an amount to be proved at trial.

TWELFTH CAUSE OF ACTION
(Survival Action)

211. Plaintiffs repeat and incorporate by reference each and every allegation set forth in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

212. As a result of the actions and inactions of defendant Pfizer, decedent suffered bodily and emotional injury, including pain and suffering, prior to death.

213. Plaintiff(s), on behalf of decedent's estate, is entitled to recover damages to which decedent was or would have been entitled, including conscious pain and suffering, medical expenses, loss of earnings, funeral expenses, and other damages and losses.

214. By reason of the foregoing, defendant Pfizer is liable to plaintiff(s) for compensatory and punitive damages in an amount to be proved at trial.

THIRTEENTH CAUSE OF ACTION
(Loss of Consortium)

215. Plaintiffs repeat and incorporate by reference each and every allegation set forth

in paragraphs 1 through ___ of this Complaint as if fully set forth herein.

216. As a result of the acts of the defendant, plaintiff has been deprived of future aid, income, assistance, services, companionship, society, affection and financial support from the decedent.

217. By reason of the foregoing, defendant Pfizer is liable to plaintiff for loss of consortium and for compensatory and punitive damages in an amount to be proved at trial.

RELIEF REQUESTED

WHEREFORE, plaintiffs demand judgment against defendant Pfizer as follows:

A. Awarding each plaintiff compensatory damages against defendant Pfizer in an amount sufficient to fairly and completely compensate such plaintiff for all damages;

B. Awarding each plaintiff treble damages against defendant Pfizer so as to fairly and completely compensate each plaintiff for all damages, and to deter similar wrongful conduct in the future;

C. Awarding each plaintiff punitive damages against defendant Pfizer in an amount sufficient to punish defendant Pfizer for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding each plaintiff costs and disbursements, costs of investigations, attorneys' fees and all such other relief available under applicable law;

E. Ordering that the costs of this action be taxed to defendant Pfizer; and

F. Awarding such other and further relief as the Court may deem just and proper.

Dated: New York, New York
November __, 2006

Attorneys for Plaintiff

Exhibit C

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

Plaintiff(s) - against – Defendants.	Index No. _____ **ABBREVIATED SHORT FORM COMPLAINT** Justice Shirley W. Kornreich

ABBREVIATED SHORT-FORM BEXTRA COMPLAINT AND ADOPTION BY REFERENCE

1. Plaintiff for his/her claim against the defendant states and alleges as follows and incorporates by reference the relevant portions of the Amended Master Complaint on file in *In Re: New York Bextra and Celebrex Product Liability Litigation*, Index No. 560001/05, LCP No. 0002/05, now pending in the Supreme Court of the State of New York, County of New York, before the Hon. Shirley W. Kornreich.

2. Plaintiff selects and indicates by checking off the appropriate items, those claims that are specific to his or her case. Where, pursuant to New York law, claims require specific pleading or case specific facts and individual information, plaintiff shall add and include them herein.

3. Plaintiff is an individual who resides at _____in the State of _____.

4. On or about _____ (date), Plaintiff suffered the following injury(ies) as a result of ingesting Bextra: _____

_____.

5. Plaintiff brings this action (check all that apply):

____ on behalf of himself or herself.

____ as the representative of _____.

____ as the parent and natural *guardian ad litem* of _____, a minor born on _____.

_____ as Administrator of the Estate of _____ (hereinafter "Decendent"), who was plaintiff"s _____, and who died on _____, see Letters of Administration annexed hereto as Exhibit A).

6. Plaintiff brings this action against (check all that apply):

____ Pfizer, Inc.

____ G.D. Searle LLC

____ Pharmacia Corporation

(For additional defendants, see item 12, below)

7. Plaintiff claims damages for (check all that apply):

_____ Personal Injury to himself, herself or the person represented

_____ Wrongful Death

_____ Survival Action

_____ Loss of Consortium

_____ Loss of Services

_____ Economic Loss

8. Plaintiff/Decedent purchased and/or otherwise obtained Bextra, which Plaintiff/Decedent ingested from _____to _____.

9. Plaintiffs spouse, _____, (hereinafter referred to as "Spouse") is an adult individual residing at _____ in the State of _____and claims damages as a result of:

_____ Loss of Consortium (date of marriage: _____)

____ Wrongful Death (date of death: _____)

10. The following claims asserted in the Master Complaint and the allegations with regard thereto in the Master Complaint are herein adopted by reference:

_____ First Cause of Action: Strict Products Liability

_____ Second Cause of Action: Product Liability – Failure to Warn

_____ Third Cause of Action: Negligence

_____ Fourth Cause of Acction: Breach of Implied Warranty

_____ Fifth Cause of Action: Breach of Express Warranty

_____ Sixth Cause of Action: Fraud

_____ Seventh Cause of Action: Negligent Misrepresentation and Omission

_____ Eighth Cause of Action: Fraudulent Misrepresentation, Concealment and Omission

_____ Ninth Cause of Action: Violation of General Business Law § 349

_____ Tenth Cause of Action: Violation of State Consumer Protection Acts

Specify state(s): _____

_____ Eleventh Cause of Action: Wrongful Death

____ Twelfth Cause of Action: Survival Action

____ Thirteenth Cause of Action: Loss of Consortium

11. Plaintiff asserts the following additional theories of recovery:

Against Pfizer, Inc.:

Against G.D.Searle, LLC:

Against Pharmacia Corp.:

Note: If you have include any additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pleaded by the plaintiff in a manner complying with the requirements of the New York Civil Practice Law and Rules ("CPLR").

12. Plaintiff asserts claims against the following additional defendants:

Note: If you include claims against one or more entities other than Pfizer, Inc., G.D. Searle LLC, or Pharmacia Corp., the facts supporting such claims must be specifically pleaded by the plaintiff. In addition, each claim pled against each additional defendant must be identified on a separate sheet of paper attached to this Abbreviated Short-Form Complaint.

DEMAND FOR JURY TRIAL

13. Demand is hereby made for a trial by jury.

Dated: _____

Attorneys for Plaintiff

Exhibit D

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

Plaintiff(s) - against – Defendants.	Index No. _____ **ABBREVIATED SHORT FORM COMPLAINT** Justice Shirley W. Kornreich

ABBREVIATED SHORT-FORM CELEBREX COMPLAINT AND ADOPTION BY REFERENCE

1. Plaintiff for his/her claim against the defendant states and alleges as follows and incorporates by reference the relevant portions of the Master Complaint on file in *In Re: New York Bextra and Celebrex Product Liability Litigation*, Index No._____, LCP No. _____, now pending in the Supreme Court of the State of New York, County of New York, before the Hon. Shirley W. Kornreich.

2. Plaintiff selects and indicates by checking off the appropriate items, those claims that are specific to his or her case. Where, pursuant to New York law, claims require specific pleading or case specific facts and individual information, plaintiff shall add and include them herein.

3. Plaintiff is an individual who resides at _____in the State of _____.

4. On or about _____ (date), Plaintiff suffered the following injury(ies) as a result of ingesting Celebrex: _____

_____.

5. Plaintiff brings this action (check all that apply):

____ on behalf of himself or herself.

____ as the representative of _____.

____ as the parent and natural *guardian ad litem* of _____, a minor born on _____.

_____ as Administrator of the Estate of _____ (hereinafter "Decendent"), who was plaintiff"s _____, and who died on _____, see Letters of Administration annexed hereto as Exhibit A).

6. Plaintiff brings this action against (check all that apply):

____ Pfizer, Inc.

____ G.D. Searle LLC

____ Pharmacia Corporation

(For additional defendants, see item 12, below)

7. Plaintiff claims damages for (check all that apply):

_____ Personal Injury to himself, herself or the person represented

_____ Wrongful Death

_____ Survival Action

_____ Loss of Consortium

_____ Loss of Services

_____ Economic Loss

8. Plaintiff/Decedent purchased and/or otherwise obtained Celebrex, which Plaintiff/Decedent ingested from _____to _____.

9. Plaintiffs spouse, _____, (hereinafter referred to as "Spouse") is an adult individual residing at _____ in the State of _____and claims damages as a result of:

_____ Loss of Consortium (date of marriage: _____)

____ Wrongful Death (date of death: _____)

10. The following claims asserted in the Master Complaint and the allegations with regard thereto in the Master Complaint are herein adopted by reference:

_____ First Cause of Action: Strict Products Liability

_____ Second Cause of Action: Product Liability – Failure to Warn

_____ Third Cause of Action: Negligence

_____ Fourth Cause of Acction: Breach of Implied Warranty

_____ Fifth Cause of Action: Breach of Express Warranty

_____ Sixth Cause of Action: Fraud

_____ Seventh Cause of Action: Negligent Misrepresentation and Omission

_____ Eighth Cause of Action: Fraudulent Misrepresentation, Concealment and Omission

_____ Ninth Cause of Action: Violation of General Business Law § 349

_____ Tenth Cause of Action: Violation of State Consumer Protection Acts

Specify state(s): _____

_____ Eleventh Cause of Action: Wrongful Death

____ Twelfth Cause of Action: Survival Action

____ Thirteenth Cause of Action: Loss of Consortium

11. Plaintiff asserts the following additional theories of recovery:

Against Pfizer, Inc.:

Against G.D.Searle, LLC:

Against Pharmacia Corp.:

Note: If you have include any additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pleaded by the plaintiff in a manner complying with the requirements of the New York Civil Practice Law and Rules ("CPLR").

12. Plaintiff asserts claims against the following additional defendants:

Note: If you include claims against one or more entities other than Pfizer, Inc., G.D. Searle LLC, or Pharmacia Corp., the facts supporting such claims must be specifically pleaded by the plaintiff. In addition, each claim pled against each additional defendant must be identified on a separate sheet of paper attached to this Abbreviated Short-Form Complaint.

DEMAND FOR JURY TRIAL

13. Demand is hereby made for a trial by jury.

Dated: _____

Attorneys for Plaintiff

Exhibit E

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

Plaintiff(s) - against – Defendants.	Index No. _____ **ABBREVIATED SHORT FORM COMPLAINT** Justice Shirley W. Kornreich

ABBREVIATED SHORT-FORM BEXTRA AND CELEBREX

COMPLAINT AND ADOPTION BY REFERENCE

1. Plaintiff for his/her claim against the defendant states and alleges as follows and incorporates by reference the relevant portions of the Amended Master Complaint on file in *In Re: New York Bextra and Celebrex Product Liability Litigation*, Index No. 560001/05, LCP No. 0002/05, now pending in the Supreme Court of the State of New York, County of New York, before the Hon. Shirley W. Kornreich.

2. Plaintiff selects and indicates by checking off the appropriate items, those claims that are specific to his or her case. Where, pursuant to New York law, claims require specific pleading or case specific facts and individual information, plaintiff shall add and include them herein.

3. Plaintiff is an individual who resides at _____in the State of _____.

4. On or about _____ (date), Plaintiff suffered the following injury(ies) as a result of ingesting Bextra and Celebrex: _____

_____

_____.

5. Plaintiff brings this action (check all that apply):

____ on behalf of himself or herself.

____ as the representative of _____.

____ as the parent and natural *guardian ad litem* of _____, a minor born on _____.

_____ as Administrator of the Estate of _____ (hereinafter "Decedent"), who was plaintiff's _____, and who died on _____, see Letters of Administration annexed hereto as Exhibit A).

6. Plaintiff brings this action against (check all that apply):

____ Pfizer, Inc.

____ G.D. Searle LLC

____ Pharmacia Corporation

(For additional defendants, see item 12, below)

7. Plaintiff claims damages for (check all that apply):

_____ Personal Injury to himself, herself or the person represented

_____ Wrongful Death

_____ Survival Action

_____ Loss of Consortium

_____ Loss of Services

_____ Economic Loss

8. Plaintiff/Decedent purchased and/or otherwise obtained Bextra, which

Plaintiff/Decedent ingested from _____to _____.

9. Plaintiff/Decedent purchased and/or otherwise obtained Celebrex, which Plaintiff/Decedent ingested from _____to _____.

10. Plaintiff's spouse, _____, (hereinafter referred to as "Spouse") is an adult individual residing at _____ in the State of _____and claims damages as a result of:

_____ Loss of Consortium (date of marriage: _____)

____ Wrongful Death (date of death: _____)

11. The following claims asserted in the Master Complaint and the allegations with regard thereto in the Master Complaint are herein adopted by reference:

_____ First Cause of Action: Strict Products Liability

_____ Second Cause of Action: Product Liability – Failure to Warn

_____ Third Cause of Action: Negligence

_____ Fourth Cause of Action: Breach of Implied Warranty

_____ Fifth Cause of Action: Breach of Express Warranty

_____ Sixth Cause of Action: Fraud

_____ Seventh Cause of Action: Negligent Misrepresentation and Omission

_____ Eighth Cause of Action: Fraudulent Misrepresentation, Concealment and Omission

_____ Ninth Cause of Action: Violation of General Business Law § 349

_____ Tenth Cause of Action: Violation of State Consumer Protection Acts

Specify state(s): _____

_____ Eleventh Cause of Action: Wrongful Death

____ Twelfth Cause of Action: Survival Action

____ Thirteenth Cause of Action: Loss of Consortium

12. Plaintiff asserts the following additional theories of recovery:

Against Pfizer, Inc.:

Against G.D. Searle, LLC:

Against Pharmacia Corp.:

Note: If you have include any additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pleaded by the plaintiff in a manner complying with the requirements of the New York Civil Practice Law and Rules ("CPLR").

13. Plaintiff asserts claims against the following additional defendants:

Note: If you include claims against one or more entities other than Pfizer, Inc., G.D. Searle LLC, or Pharmacia Corp., the facts supporting such claims must be specifically pleaded by the plaintiff. In addition, each claim pled against each additional defendant must be identified on a separate sheet of paper attached to this Abbreviated Short-Form Complaint.

DEMAND FOR JURY TRIAL

14. Demand is hereby made for a trial by jury.

Dated: _____

Attorneys for Plaintiff