UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE MUKASEY

[redacted] on behalf of himself and all others similarly situated,

Plaintiff,

v.

PFIZER, INC., and HENRY A. MCKINNEL,

Defendants.

04 CV 9866

Civil Action No. _____
CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff, by his attorneys, brings this action on behalf of himself and all others similarly situated, and alleges the following based upon personal knowledge as to himself and his activities, and based upon an investigation conducted by his counsel for all other matters. That investigation has included a thorough review and analysis of public documents, United States Securities and Exchange Commission ("SEC") filings, court filings, press releases, medical journal articles, patent documents and news articles concerning Pfizer, Inc. ("Pfizer" or "the Company") and the other facts as set forth herein.

NATURE OF THE ACTION

1. This is a federal class action on behalf of purchasers of the publicly-traded common stock of Pfizer between November 1, 2000 and November 10, 2004, inclusive ("the Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). These claims arise out of defendants' false and misleading statements and omissions concerning the safety and marketability of Pfizer's Celebrex and Bextra products. At all times during the Class Period, Defendants were aware of strong indicators that Celebrex and

Bextra, drugs known as "Cox-2 inhibitors", posed serious undisclosed health risks to consumers. Defendants knew or recklessly disregarded that the undisclosed health risks posed by these drugs would limit their marketability, and further knew that the potential financial liability Pfizer faced from the harms these drugs caused posed a serious threat to the Company's finances. Nonetheless, Defendants concealed these facts from the investing public, thereby damaging Plaintiff and the Class.

2. Toward the close of the Class Period, a series of factual revelations from several sources caused the market to gradually perceive the truth about Pfizer's Bextra and Celebrex products. These revelations caused Pfizer's share prices to fall from a closing price of $29.45 on November 3, 2004 to $27.15 on November 11, 2004, a drop of 8%.

JURISDICTION AND VENUE

3. This action arises under Sections 10(b) and 20(a) of the Exchange Act of 1934, as amended, 15 U.S.C. §§ 78j(b), 78(n) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

4. This Court has jurisdiction over this subject matter pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

5. Venue is proper in this district pursuant to Section 27 of the Exchange Act and 28 U.S.C. §1391(b). Pfizer was headquartered in this district at all times relevant to this action, and many of the acts charged herein, including the dissemination of materially false and misleading information in connection with the sale of a security, occurred in this district.

6. In connection with the acts alleged in this complaint, the Defendants, directly or indirectly, used means and instrumentalities of interstate commerce, including but not limited to

the mails, interstate telephone and Internet communications, and the facilities of the New York Stock Exchange.

PARTIES

7. [redacted] purchased shares of Pfizer common stock during the Class Period, and was injured thereby, as demonstrated by Plaintiff's Certification, appended hereto.

8. Defendant Pfizer, is a Delaware corporation which engaged in the development, marketing and distribution of pharmaceutical drugs worldwide. The Company is headquartered at 235 East 42nd Street, New York, New York 10017.

9. Defendant Henry A. McKinnel ("McKinnel") has been since May, 2001 Chairman of the Board and since January 2001 the Chief Executive Officer. From 1999 to May 2001 he was the President of the Company. By virtue of his positions of authority as an officer and Director of the Company, the authority over the Company's operations, accounting and public communications functions, and unfettered access to confidential Company information, Defendant McKinnel was a control person as that term is construed by the federal securities laws.

10. Defendant McKinnel was aware of and approved the materially misleading statements issued by or on behalf of Pfizer during the Class Period. McKinnel was a controlling person of Pfizer, as that term is defined by the federal securities laws, due to his ownership interests, executive position, directorial position, and relationships with other executives and employees of Pfizer, as well, as due to his direct authority over the operations, accounting and public communications functions of the Company.

11. Pfizer and McKinnel (collectively, "Defendants") are liable as direct participants in a fraudulent scheme and course of conduct that operated as fraud and/or deceit upon purchasers of Pfizer securities during the Class Period. Specifically, Defendants disseminated materially false and misleading information and concealed materially adverse facts relating to the Bextra and Celebrex products, these products' safety and marketability, and the potential liability the Company faced as a result of the undisclosed side effects each of these drugs exhibited.

CLASS ACTION ALLEGATIONS

12. Plaintiff brings this class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of a class of persons who bought Pfizer common stock during the Class Period (or their successors in interest) ("the Class"). Excluded from the Class are the Defendants named herein, members of the immediate families of the Defendants, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors in interest or assigns of any such excluded party.

13. The Class is so numerous that joinder of all members is impracticable. As of November 5, 2004, Pfizer had over 7.5 billion shares of common stock issued and outstanding, and such shares were publicly traded on the New York Stock Exchange. The exact number of members of the Class is not known at this time, but is believed to number in the thousands.

14. Plaintiff will fairly and adequately protect the interests of the members of the Class, and Plaintiff has no interests which are contrary to, or in conflict with, the interests of the Class members that he seeks to represent. Plaintiff has retained competent counsel experienced

in class action litigation under the federal securities laws to ensure such protection, and intends to prosecute this action vigorously.

15. Plaintiff's claims are typical of the members of the Class, because Plaintiff and all of the Class members sustained damages arising from the same wrongful conduct complained of herein.

16. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for the members of the Class to individually seek redress for the wrongs done to them. There will be no difficulty in the management of this action as a class action.

17. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual members in that Defendants have acted on grounds generally applicable to the entire Class. Among the questions of law and fact common to the Class are:

a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

b) whether Defendants' publicly disseminated releases and statements during the Class Period omitted and/or misrepresented material facts and whether Defendants breached any duty to convey material facts or to correct material facts previously disseminated;

c) whether Defendants participated in and pursued the common course of conduct complained of herein;

d) whether Defendants acted with scienter in omitting and/or misrepresenting material facts;

e) whether the price of Pfizer securities was artificially inflated during the Class Period as a result of the material misrepresentations and omissions complained of herein;

f) whether McKinnel was a controlling person as alleged herein; and

g) whether members of the Class have sustained damages and, if so, the proper measure of such damages.

SUBSTANTIVE ALLEGATIONS

Background

18. Pfizer, Inc. ("Pfizer") is a research based, global pharmaceutical company which develops, manufactures, and markets prescription medicines. Pfizer is based in New York and incorporated under the laws of Delaware. A major portion of Pfizer's revenue comes from the manufacture and sale of two medications: celecoxib, sold by Pfizer under the brand name Celebrex, and valdecoxib, sold by Pfizer under the brand name Bextra. Celebrex was approved by the Food and Drug Administration ("FDA") in 1998, while Bextra was approved in 2001. In 2003, sales of Celebrex totalled approximately $1.8 billion. In 2003, sales of Bextra totalled approximately $687 million.

19. Both Celebrex and Bextra are part of a family of medications known as COX-2 inhibitors used to treat chronic pain resulting from arthritis. COX-2 is an enzyme occurring naturally in the body which is thought to cause arthritis pain and inflammation. COX-2 inhibitors target this enzyme and are thereby purported to reduce the symptoms of osteoarthritis and rheumatoid arthritis.

20. The only other COX-2 inhibitor approved by the FDA – rofecoxib, sold under the brand name Vioxx by Merck – was voluntarily withdrawn from circulation by Merck in September 2004 after a clinical study meant to determine the gastrointestinal safety profile of Vioxx unintentionally revealed an increased cardiovascular risk in users following 18 months of continuous use. Cardiac problems related to the use of Cox-2 inhibitors such as Celebrex and Bextra have been documented since at least 2000. A study published in the August 29, 2000 Proceedings of the National Academy of Sciences entitled Cyclooxyyganase-2 Mediates the Cardioprotective Effects of the Late Phase of Ischemic Preconditioning in Conscious Rabbits by Dr. Ken Shinmura et al. ("NAS Study") analyzed the "late phase of ischemic preconditioning" ("Late PC") -- an adaptive response of the heart to mild cardiac events conferring resistance to subsequent cardiac problems. Late PC is beneficial for patients recovering from adverse cardiac events.

21. The NAS study determined that COX-2 plays an "essential role in the cardioprotection" afforded by Late PC, and that COX-2 inhibitors – like Celebrex and Bextra -- entirely prevented these cardioprotective effects. This article concluded that COX-2 was a "cardioprotective protein," offering beneficial cardiac effects, and that drugs blocking this cardioprotective enzyme may neutralize these cardioprotective effects.

22. This same study noted that the ability of rabbits to withstand temporary experimental coronary artery occlusion (experimental heart attack) was significantly impaired by treatment with Celebrex, as that drug "*completely block[ed] the cardioprotective effects* of late PC against both myocardial stunning and myocardial infarction." (Emphasis added). This indicated that "COX-2 activity is necessary for [Late PC] to occur."

23. The August 14, 2001 issue of Circulation contained an article entitled Effects of Selective Cyclooxygenase-2 Inhibition on Vascular Responses and Thrombosis in Canine Coronary Arteries by Dr. James K. Hennan et al. ("Circulation Study") presenting the findings of a study analyzing the effects of COX-2 inhibitors (specifically including Celebrex) on dogs recovering from circumflex coronary artery thrombosis. This article concluded that the study "raise[d] concerns regarding an *increased risk of adverse vascular events in patients receiving COX-2 inhibitors*," and that this "risk may be increased in individuals with underlying inflammatory disorders, including coronary artery disease." (Emphasis added)

24. A third study, entitled Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors, by Dr. Debabrata Mukherjee et al. was published in the August 22/29, 2001 issue of the Journal of the American Medical Association ("AMA Study"). This study noted that "*[c]urrent data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events*," and that the researcher's "*findings suggest[ed] a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors.*" (Emphasis added). This study specifically included Celebrex.

25. The AMA Study went on to conclude that "[g]iven the remarkable exposure and popularity of this new class of medications, *we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents*." (Emphasis added).

26. The Cleveland Clinic Journal of Medicine published a follow-up to the AMA Study in November, 2001 entitled COX-2 Inhibitors and Cardiovascular Risk: We Defend our Data and Suggest Caution, written by the same authors. This article noted that an "important question[]" raised by the clinical and basic data was "[s]hould COX-2 drugs be avoided in patients with coronary artery disease or its equivalents? Should they be avoided in patients at

high risk for coronary artery disease?" The article further concluded that "[u]ntil a cause-and-effect relationship between COX-2 inhibitors and cardiovascular events can be ruled out, *we should exercise caution in prescribing these agents to patients at risk for cardiovascular morbidity*." (Emphasis added)

27. Additionally, in the FDA's approval package for Bextra published on or about November 16, 2001 ("BEXTRA Approval Package"), an FDA medical officer noted specific problems with the cardiovascular safety profile of Bextra. Specifically, this officer noted that "[*t]he excess of serious cardiovascular thromboembolic [blood clots] in the valdecoxib arm of the CABG [Coronary Artery Bypass Graft] trial is of note* as the entire study population received prophylactic low dose aspirin as part of the standard of care in this setting to minimize just such events," and that "[g]iven the emerging concern over possible pro-thrombotic actions of certain agents in the COX2 class, these data are of concern." (Emphasis added).

28. This information was (and is) redacted from the publicly available version of the BEXTRA approval package. Instead, the section containing the statements in the preceding paragraph is replaced with a notation that it "[has] been removed because it contains trade secret and/or confidential information that is not disclosable." This statement has been made available as a result of a Freedom of Information Act request filed by the advocacy group Public Citizen. That lawsuit alleges the redacted section of the BEXTRA approval package was originally publicly released and was only redacted after complaints from the drug's developer.

29. There were thus at least four articles in medical journals addressing cardiac risks associated with COX-2 inhibitors, as well as information directly provided to Pfizer by the FDA informing them of this risk. Pfizer was thus plainly aware of the cardiovascular risks associated

with both Bextra and Celebrex, and of the need for further research to determine the extent of this risk, from August 2000 onwards.

Defendants' Misrepresentations

30. On November 1, 2000, Pfizer's 8-K filing with the SEC made reference to a study published in the Journal of American Medicine and claimed that this study demonstrated that "Celebrex showed a positive renal and hepatic profile with *no increase in thromboembolic or other cardiovascular-related events.*" (Emphasis added.)

31. This statement was materially false and misleading at the time it was made. In fact, clear evidence of adverse cardiac effects associated with Celebrex were found in the NAS study. The NAS study determined that COX-2 plays an "essential role in the cardioprotection" afforded by Late PC, and COX-2 inhibitors – like Celebrex and Bextra -- entirely prevented these cardioprotective effects. This article concluded that COX-2 was a "cardioprotective protein," offering beneficial cardiac effects, and that drugs blocking this cardioprotective enzyme may neutralize these cardioprotective effects.

32. On December 31, 2001, Pfizer released their 2001 Annual Report, which stated that "In addition to its outstanding GI safety profile, Celebrex has shown *no increased cardiovascular risk compared with traditional arthritis medicines, which distinguishes it from Merck's selective COX-2 inhibitor Vioxx.*" (Emphasis added.). This report further stated that "Bextra relieves OA and RA symptoms with only one 10 mg tablet per day, and *safely and effectively treats even the most severe patients.*"

33. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation

study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

34. Pfizer's March 28, 2002, 10-K SEC filing noted that "Bextra was approved by the FDA in November 2001, for the relief of pain and inflammation of osteoarthritis and adult rheumatoid arthritis and for menstrual pain. We will co-promote Bextra with Pharmacia, which discovered and developed the drug. A launch is planned in 2002."

35. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

36. Pfizer's July16, 2002 8-K filing with the SEC noted that, "Celebrex and Bextra, COX-2 specific inhibitors discovered and developed by Pharmacia and co-promoted by Pfizer and Pharmacia, continued to extend their lead over competitors. Bextra and Celebrex together currently account for 23.6 percent of audited monthly new prescriptions among U.S. non-steroidal anti-inflammatory drugs in May," and that "Bextra is off to a very good start and has already achieved a 5.6% share of new prescriptions of the NSAID market as of May."

37. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

38. Pfizer's August 13, 2002 filing with the SEC noted that "Pharmacia's worldwide sales were $807 million for Celebrex and, $89 million for Bextra in the second quarter of 2002. Pharmacia's worldwide sales for Celebrex were $1,414 million in the first six months of 2002,

$710 million in the second quarter of 2001 and $1,359 million in the first six months of 2001. Pharmacia's worldwide sales for Bextra were $147 million in the first six months of 2002."

39. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

40. Pfizer's November 13, 2002 10-Q filing with the SEC noted that "Bextra (valdecoxib), discovered and developed by our alliance partner Pharmacia, is used for relief of the pain and inflammation of OA, RA, and primary dysmenorrhea. Bextra was approved by the FDA in November 2001 and launched in the U.S. in April 2002.

41. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

42. December 31, 2002 10-K filing with the SEC stated "[w]ith Celebrex and Bextra, we can offer physicians a broad, extensive portfolio enabling them to treat a wide range of conditions from rheumatoid arthritis, to osteoarthritis, to primary dysmenorrhea (menstrual pain in adults)."

43. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

44. Pfizer's 2002 Annual Report, filed with the SEC on March 18, 2003, stated that "[t]he Celebrex launch remains the most successful new prescription product launch ever. By year-end 2002,Celebrex was receiving 22% of total arthritis prescriptions in the U.S." and that "[d]uring 2002, Pfizer and Pharmacia launched Bextra for OA, RA and primary dysmenorrhea in the U.S. Bextra provides powerful, quick-acting, 24-hour symptom relief with one convenient daily dose. By year-end 2002, Bextra was receiving 8% of total arthritis prescriptions in the U.S."

45. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the report.

46. Pfizer's January 22, 2003 8-K filing with the SEC stated that "[s]tudy results presented at the annual meeting of the American College of Rheumatology in October confirmed Bextra's improved gastrointestinal and cardiovascular safety profiles."

47. This filing specifically cited this purported "reconfirmation" of the "cardiovascular safety of Bextra" as an event which would "enhance sales of existing products and strengthen the future product portfolio."

48. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

49. Pfizer's March 27, 2003 10-K filing with the SEC stated "[w]ith Celebrex and Bextra, we can offer physicians a broad, extensive portfolio enabling them to treat a wide range

of conditions from rheumatoid arthritis, to osteoarthritis, to primary dysmenorrhea (menstrual pain in adults)."

50. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

51. In its April 22, 2003 8-K report filed with the SEC, Pfizer stated that "Bextra was launched in the U.S. in April 2002 for the relief of the pain and inflammation of OA and adult RA and for the treatment of primary dysmenorrhea. Since the launch of Bextra, U.S. physicians have dispensed approximately 9.9 million total prescriptions to more than 3.5 million arthritis and dysmenorrhea patients. In June 2003, Bextra achieved an 8.5% share of new prescriptions of the U.S. NSAID market. Celebrex and Bextra together achieved a new-prescription share of 24%."

52. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

53. In its July 25, 2003 report on Form 8-K filed with the SEC, Pfizer stated that "We [Pfizer] are continuing to demonstrate Celebrex's safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased cardiovascular risk was found*, relative to both conventional non-steroidal anti-inflammatory drugs (NSAIDs) and placebo." (Emphasis added.).

54. This report further stated that "Bextra was launched in the U.S. in April 2002 for the relief of the pain and inflammation of OA and adult RA and for the treatment of primary dysmenorrhea. Since the launch of Bextra, U.S. physicians have dispensed approximately 9.9 million total prescriptions to more than 3.5 million arthritis and dysmenorrhea patients. In June 2003, Bextra achieved an 8.5% share of new prescriptions of the U.S. NSAID market. Celebrex and Bextra together achieved a new-prescription share of 24%."

55. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

56. In its October 22, 2003 8-K filing with the SEC, Pfizer again stated that "We [Pfizer] are continuing to demonstrate Celebrex's safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased cardiovascular risk was found*, relative to both conventional NSAIDs and placebo." (Emphasis added).

57. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

58. In its October 22, 2003 8-K filing with the SEC, Pfizer again stated that "We [Pfizer] are continuing to demonstrate Celebrex's safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased*

cardiovascular risk was found, relative to both conventional NSAIDs and placebo." (Emphasis added).

59. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

60. In their January 22, 2004 8-K filing with the SEC, Pfizer again stated that "We [Pfizer] are continuing to demonstrate Celebrex's safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased cardiovascular risk was found*, relative to both conventional NSAIDs and placebo." (Emphasis added)

61. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

62. Pfizer's July 21, 2004 8-K filing with the SEC stated that an article in the May 29, 2004 issue of the Lancet "provided further evidence of the cardiovascular safety of Celebrex."

63. This was materially false and misleading for two reasons: First, at this time the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex. Second, the article actually stated that "*the increased frequency of initiation of treatment for hypertension or congestive heart failure seen in celecoxib users*, although still lower than that of rofecoxib or non-selective NSAIDs, suggests that celecoxib might not be entirely devoid of clinically important cardiovascular effects".

(Emphasis added.) This data was therefore hardly the evidence of cardiovascular safety Pfizer made it out to be.

31. Pfizer's August 10, 2004 8-K filing with the SEC contained multiple representations pertaining to the purported cardiovascular safety of Celebrex, including references to the "*established cardiovascular safety*" of Celebrex, to the "*well-documented cardiovascular safety*" of Celebrex, and asserting that there was "*no evidence of a cardiovascular safety signal for Celebrex* in long-term clinical trials of more than 6,000 patients." (Emphasis added.)

64. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

65. On September 30, 2004, Pfizer issued a press release reacting to Merck's withdrawal of Vioxx stating "Pfizer is confident in the *long-term cardiovascular safety of Celebrex*" and further asserting that "*Bextra's cardiovascular safety profile is also well established* in long-term studies." (Emphasis added.)

66. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

67. On October 1, 2004, Pfizer issued a press release stating that "[t]he evidence distinguishing the cardiovascular safety of Celebrex has accumulated over years in multiple completed studies, *none of which has shown any increased cardiovascular risk for Celebrex.*" (Emphasis added).

68. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

69. On October 15, 2004, Pfizer issued a press release stating that "[a]vailable clinical information for Bextra suggests there is *no increased risk of cardiovascular thromboembolic events* in people treated for osteoarthritis (OA) and rheumatoid arthritis (RA)." (Emphasis added).

70. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

71. On October 18, 2004, Pfizer issues a press release stating that their "strong confidence in the [cardiovascular] safety of Celebrex is based on the substantial body of experience that has accumulated over several years in multiple completed studies and ongoing trials," and that "Pfizer remains confident in the long-term cardiovascular safety of Celebrex. "These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

72. Pfizer's October 20, 2004 8-K filing with the SEC stated that "'Celebrex and Bextra continue to perform well by exceeding year-to-date sales projections,'" and that Pfizer expected this "'positive trend to continue as more doctors and patients consider Celebrex and Bextra as effective, appropriate treatments.'" This filing further stated that available clinical

information for Bextra "suggests *no increased risk of cardiovascular thromboembolic events* in patients."

73. On November 4, 2004, Pfizer issued a press release intended to reports in the Canadian press concerning the cardiovascular safety of Celebrex. This release stated that "[*t*]*he safety profile for Celebrex is well-established* and is supported by extensive clinical studies in Canada and around the world," and that "large scale clinical studies of up to four years . . . showed *no increased cardiovascular safety risk*," associated with Celebrex. (Emphasis added).

74. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

75. Defendants' foregoing statements were materially false and misleading at the time that they were made, because each misrepresented and/or omitted the material facts that there was substantial likelihood that Pfizer's Cox-2 inhibitor drugs, Celebrex and Bextra, were unsafe and had potentially dangerous cardiovascular side effects that would limit their marketability (and might result in their removal from the marketplace). As described *supra* at ¶¶ 20-29, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitor drugs in general. Defendants knew or recklessly ignored the fact that these undisclosed dangerous cardiac side effects were common to Cox-2 inhibitor drugs as a class. These severe cardiovascular side effects were likely to limit the long-term marketability of the Celebrex and Bextra products, and posed a serious threat to Pfizer in the form of massive liability to consumers harmed by the use of Bextra and Celebrex.

The Truth Is Gradually Revealed

76. On October 15, 2004, Pfizer acknowledged for the first time in a press release that Bextra might cause cardiovascular side effects, and announcing that the Company would conduct further studies to examine the safety of the drug. The press release stated in part:

> two trials in a high-risk surgery known as coronary artery bypass graft (CABG), an increase in cardiovascular events was observed in patients receiving Bextra alone or in combination with parecoxib. The first study was published last year(1) and the second study was just recently completed. Pfizer emphasized that Bextra is not approved for use in any surgical setting in the United States.
>
> Pfizer will be conducting further studies to confirm the long-term cardiovascular safety profile of Bextra in patients who require chronic treatment for arthritis with a COX-2-specific inhibitor.

77. In reaction to this announcement, CBS MarketWatch reported that Pfizer's share price was being affected by Bextra concerns, having closed down 2% at 28.50 per share.

78. Thereafter, news continued to filter into the market, as the fact gradually dawned that the same problems behind Merck's withdrawal of Vioxx were likely common throughout the Cox-2 inhibitor class of drugs, including Bextra and Celebrex. As piece after piece of the puzzle fell into place, Pfizer's shares dropped again and again in response to the news.

79. On November 4, 2004, The Calgary Herald reported:

> Celebrex, a popular pain drug touted as the safe alternative after Vioxx was pulled from drugstore shelves, is suspected of causing at least 14 deaths and numerous heart and brain side-effects, according to Health Canada.
>
> The documents include more than 100 adverse reaction reports on Celebrex in the past five years, including 19 cases of heart attack, cardiac arrest or heart failure, and five strokes. Canadian pharmacists filled about three million prescriptions for the drug last year.
>
> The data, based on voluntary reporting by doctors and others, came to light as some experts suggest Celebrex and other drugs in the

same pain-relieving class may have similar effects as Vioxx on the cardiovascular system.

* * * *

Health Canada says it is conducting a review of all the "Cox-2 inhibitor" drugs.

Dr. Jim Wright, a pharmacology professor at the University of British Columbia, said more investigation needs to be done on the Cox-2 medication and its effect on the heart.

"We should at this stage be very cautious about the use of these drugs, until such time as the answers are out there," he said. "In my opinion, we don't know for sure whether this is a class effect, but most likely it is."

He noted that Pfizer has launched a major advertising campaign in the U.S., where direct-to-consumer ads by drug companies are permitted, urging former Vioxx users to switch to Celebrex as a safe option.

Dr. Patrice Roy, Pfizer Canada's director of scientific affairs, said the Health Canada adverse reaction information is important, but far from conclusive. Several trials done on the drug have provided no evidence that Celebrex is a threat to heart health, he said.

"You have to look at the data accumulated over time," said Roy. "This drug has been studied in 30,000 patients, has been prescribed to over 40 million patients worldwide, there are studies actually sponsored by the FDA . . . and basically we haven't seen anything."

In fact, he said Pfizer recently announced a major program to investigate whether the drug has properties that could prevent heart problems by affecting inflammation of blood vessels.

The Cox-2 class of drugs, designed to treat pain caused by arthritis and other conditions, are marketed as causing fewer ulcers than other non-steroidal anti-inflammatory drugs such as Aspirin.

Four drugs in the Cox-2 class sold 7.3 million prescriptions in Canada in 2003, racking up combined sales of $475 million. Vioxx and Celebrex were by far the two most prescribed in the class, outselling Bextra and Mobicox.

Health Canada collects adverse reaction reports from doctors, drug manufacturers and others as a sort of early warning system for safety problems. But it notes the side-effects are only suspected by

the people reporting them and not proven. They also contain no information on the patients' underlying medical conditions and whether those conditions might have played a role in the adverse reaction.

Experts also believe the true number of side-effects is as much as 10 times greater than what is reported to authorities.

The department collected 111 reports on suspected cardiovascular reactions with Celebrex from January 1999 to August 2004, a period during which about 18 million prescriptions for the drug were filled.

Cardiac side-effects ranged from heightened blood pressure to congestive heart failure, cardiac arrest and stroke. The deaths occurred in people whose ages ranged from 48 to 88, although the majority were over 80.

Deaths occurred in as little as a day to months after the patient started taking Celebrex.

By comparison, there were 167 cardiac and brain adverse reaction reports filed on Vioxx in the same period, while just under 16 million prescriptions were sold in Canada. The side-effects included 63 cardiac arrests, heart attacks and heart failures, 28 cases of congestive heart failure and 11 strokes, with 22 deaths reported.

Some concern has been raised about the Cox-2 drugs generally since the Vioxx recall. One theory is that the same drug mechanism that inhibits the inflammation-causing Cox-2 enzymes also encourages blood clotting that can lead to heart attacks and other maladies.

Dr. Garret FitzGerald, a cardiologist at the University of Pennsylvania, published a paper in the New England Journal of Medicine recommending that Cox-2 drugs not be prescribed to people at risk for heart disease, and that manufacturers of the drugs still on the market provide proof they are not harmful.

Health Canada is in the process of collecting safety-related data from around the world on the Cox-2 inhibitors, said Jirina Vlk, a spokeswoman for the department.

If it concludes there is a wider problem, it could order changes to the drugs' product monographs, which outline possible side-effects

and recommended uses, or take further action, said Vlk. Health Canada has the power to force drugs from the market.

80. This news further negatively affected Pfizer's share price when President Bush's re-election was buoying other pharmaceuticals stock. In response to this news, Pfizer's share price dropped $0.39 on November 4, 2004, and another $0.27 on November 5, 2004.

81. On November 10, 2004, the New York Times further shocked the market by publishing an article which stated:

> The incidence of heart attacks and strokes among patients given Pfizer's painkiller Bextra was more than double that of those given placebos, according to preliminary results of a study presented yesterday at the American Heart Association meeting in New Orleans.
>
> The study, which pooled data from 5,930 patients taking part in 12 trials, found 2.19 times the number of heart attacks or strokes among patients given Bextra, compared with those given placebos. Merck recently withdrew Vioxx, a drug similar to Bextra, after a longer and better-controlled study showed that it doubled the risk of heart attack and stroke.
>
> "The magnitude of the signal with Bextra is even higher than what we saw in Vioxx," Dr. Garret A. FitzGerald, a cardiologist and pharmacologist at the University of Pennsylvania, said in an interview after presenting the data. "This is a time bomb waiting to go off."
>
> Susan Bro, a spokeswoman for Pfizer, said that a heart problem with Bextra appeared only in studies involving patients at very high risk for heart disease who were undergoing cardiac surgery -- a disclosure Pfizer made on Oct. 15. Other studies of Bextra involving 8,000 patients with arthritis who were followed for 6 to 52 weeks found no heart problems, she said.
>
> Dr. FitzGerald is one of the world's leading experts in COX-2 drugs, a class of medicine that includes Vioxx, Bextra and Celebrex, which is also made by Pfizer. Vioxx had sales of $2.5 billion last year, while Celebrex had sales of $1.8 billion and Bextra $687 million. Celebrex and Bextra have been on their way to bigger sales this year.

In previous studies, Dr. FitzGerald was among the first to explain why COX-2 inhibitor drugs, which were developed to cure pain without causing ulcers, might create heart troubles.

Dr. Curt Furberg, professor of public health sciences at Wake Forest University School of Medicine, helped conduct the study that Dr. FitzGerald announced yesterday. "Basically, we showed that Bextra is no different than Vioxx, and Pfizer is trying to suppress that information," Dr. Furberg said.

The new study of Bextra, however, is not nearly as persuasive as the trial that led to Vioxx's withdrawal because it is backward-looking and simply reorganizes data presented in other settings. Ms. Bro, the Pfizer spokeswoman, said the new study grouped samples that were too disparate for conclusive results.

But Dr. FitzGerald said the latest findings added to growing worries that all COX-2 inhibitors, including Bextra and Celebrex, should be used with great caution.

There is no evidence that Celebrex causes heart problems, Pfizer said.

The FitzGerald study was not the only negative development regarding Bextra. News reports yesterday noted that Pfizer said in a Nov. 5 regulatory filing that the Food and Drug Administration had rejected an application to use Bextra to treat migraines. The company said it was notified in August of the rejection.

Pfizer's stock slipped 25 cents yesterday to close at $25.99. It declined 38 cents on Monday, as investors digested the company's disclosure that it would probably add a "black box" warning -- the strongest kind -- to Bextra's label. The warning would note that, in rare instances, the drug could cause fatal skin rashes. In its Oct. 15 warning about Bextra's potential risks to patients after heart surgery, Pfizer acknowledged that it had known the results of this study for at least two months before announcing them. During that period, Pfizer representatives said publicly that the company had no evidence that either Celebrex or Bextra caused the kind of heart problems found in a large study of Vioxx.

Bextra is approved to treat arthritis pain. Unlike Vioxx, neither Bextra nor Celebrex has proved to be any safer on the stomach than older, cheaper medicines like ibuprofen or naproxen. Nor has Bextra or Celebrex been shown to alleviate pain any better than those older drugs.

> As the COX-2 controversy has continued, the Food and Drug Administration has been criticized by some researchers and medical journal editors for failing to require Vioxx's withdrawal years ago. Yesterday, Health and Human Services Secretary Tommy G. Thompson defended the F.D.A.'s handling of the Vioxx withdrawal.
>
> "You can always be a Monday morning quarterback and say, you know, this could have been done better," Mr. Thompson said. "I think the F.D.A. just does an outstanding job of protecting Americans' health."
>
> Vioxx's maker, Merck, suffered a financial blow yesterday, as the rating on its $4.9 billion in long-term debt was cut two levels, to Aa2 from Aaa, by Moody's Investors Service. The company's share price has plummeted after the withdrawal of Vioxx, which accounted for 11 percent of the company's sales last year. Hundreds of lawsuits have been filed by lawyers for patients or their survivors claiming Vioxx caused injuries or deaths.
>
> On Tuesday, Dr. FitzGerald also provided results of his further investigations into the mechanism by which COX-2 medicines may lead to heart troubles. Using mice, Dr. FitzGerald said, he found that inhibiting the COX-2 enzyme might reduce the heart protection of estrogen.

82. In direct reaction to this revelation, Pfizer's share price dropped further, to a close of $27.15 on November 11, 2004.

83. On November 18, 2004, FDA reviewer David Graham testified before the Senate Finance Committee that Bextra posed the same risks of serious, potentially life-threatening cadiovascular side effects as Merck's Vioxx, and further stated that sales of Bextra should be immediately limited or stopped. In particular, Mr. Graham stated:

> I would be looking at Bextra very, very closely. That's a cousin of Celebrex, a cousin of Vioxx. *I think that there is disturbing evidence on that drug, as well*
>
> ***
>
> [speaking of Dr. Curt Furberg, a colleague] Well, he looks at a paper that gets published on Bextra. I read the paper too, and it's

> atrocious what you can do with statistics. And when Curt looked at it, he said, "This is garbage."
>
> And he reanalyzed the data that were presented in that table (ph), and (inaudible) said, "You analyzed these data correctly, and *you see that there's a problem with Bextra*."
>
> And so, being a man who's based on evidence, who's an evidence-based scientist, what he said is: *The evidence suggests there's a problem.*
>
> ***
>
> I can tell you right now there are at least five drugs on the market today that I think need to be looked at quite seriously to see whether or not they belong there . . . [after noting one of those five was Bextra] For Bextra, I think that *we're in the same situation we are with Vioxx* in terms of needing to have good studies on cardiovascular risk, and I don't think that we have them.
>
> ***

In reaction to this news, Pfizer's share price continued to drop over the next several sessions, falling to a close of $26.79 on November 24, 2004.

84. On December 9, 2004, Reuters reported that the FDA was adding a new cardiovascular safety warning to Bextra's label, stating in part:

> Pfizer Inc.'s painkiller Bextra will come with a new warning about the possibility of heart attacks and blood clots in patients who have just had heart bypass surgery, the U.S. Food and Drug Administration said on Thursday. The FDA said it still considers the drug beneficial when taken for approved uses, such as relieving arthritis pain.
>
> "FDA believes that, based on what we know now, the overall benefit of Bextra outweighs the risk when used in properly selected patients as directed in the approved labeling," the FDA said in a statement posted on its Web site.
>
> A Pfizer study of more than 1,500 patients who had just had heart bypass surgery found that patients treated with Bextra for pain were more likely to have heart attacks, strokes and blood clots in the legs or lungs than others who took a placebo, the agency said.

> Bextra is not approved for treating pain following heart bypass surgery. The new warning specifically urges doctors not to use the drug in that setting.
>
> The updated Bextra label also includes a stronger warning, now highlighted in a black box, about the the possibility of a rare, potentially fatal skin reaction known as Stevens-Johnson Syndrome. As of November, the FDA had received 87 reports of that condition and other skin reactions. Thirty-six of the patients were hospitalized and four died, the FDA said.
>
> Bextra is getting close attention from regulators because it is in the same family of drugs as Merck & Co. Inc.'s arthritis pill Vioxx, which was pulled from the market Sept. 30 after a study showed the drug doubled the chances of heart attacks and strokes when used for more than 18 months. Both drugs are so-called COX-2 inhibitors.
>
> Bextra, which was launched in 2001, had sales last year of $687 million.
>
> Pfizer spokeswoman Mariann Caprino said the company had no comment on the heart warning. "There's no new information in the label. It's all been previously shared with the medical community," she said.
>
> Pfizer announced in October that two small clinical trials of Bextra showed heart bypass patients had an increased risk of stroke and heart attack. The company also said at the time it was adding the skin-related warning to the drug's packaging.
>
> The FDA is planning a public advisory committee meeting in February to discuss safety concerns with Bextra and other COX-2 inhibitors, including another Pfizer painkiller, Celebrex.
>
> Pfizer shares fell 13 cents, or 0.47 percent, to close at $27.37 on the New York Stock Exchange.

85. In reaction to this latest news, Pfizer's shares dropped again, falling to a close of $27.09 on December 10, 2004.

CAUSATION ALLEGATIONS

86. Pfizer's common stock was traded on the New York Stock Exchange at all relevant times. As described *supra,* Defendants' material misrepresentations and omissions had

the effect of creating and maintaining an artificially inflated price for Pfizer's securities. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting the false public perception of Pfizer and Celebrex and Bextra.

87. Defendants had a duty to promptly disseminate accurate and truthful information with respect to Pfizer's financial and operational condition or to cause and direct that such information be disseminated and to promptly correct any previously disseminated information that was misleading to the market. As a result of their failure to do so, the price of Pfizer's stock was artificially inflated during the Class Period, damaging Plaintiff and the Class.

88. Defendants' false and misleading statements and omissions in their press releases and other public statements directly caused losses to the Class. On the strength of these false statements, misrepresentations and material omissions in its press releases, announcements and other public statements concerning its financial condition, the Company's stock was artificially inflated to a Class Period high of $48.06 per share on December 20, 2000, and remained artificially inflated until the end of the Class Period. Thereafter, the stock fell to $26.79 on November 24, 2004, thereby inflicting substantial damages on Plaintiff and the Class.

89. Until shortly before Plaintiff filed this Complaint, he was unaware of all of the facts, as described herein, and could not have reasonably discovered the Defendants' fraudulent scheme by the exercise of reasonable diligence.

DEFENDANTS ACTED WITH SCIENTER

90. Each misrepresentation and/or omission of material fact alleged herein was made with reckless disregard for, or knowledge of its false and misleading nature. At all relevant times, each Defendant knew the material facts regarding the Cox-2 inhibitor class-wide risk of

severe cardio-vascular side effects and the impact such side-effects could have on the Company and the Company's sales of its Celebrex and Bextra products. Thus, the misrepresentations and omissions complained of herein were made with the Defendants' knowledge, or with deliberate recklessness.

91. Defendant McKinnel had the opportunity to commit and participate in the fraud described herein. Defendant McKinnel was the Chief Executive Officer of Pfizer, and thus controlled the Company's press releases, corporate reports, SEC filings and communications with analysts.

92. Defendants had the motive to commit and participate in the fraud. The Company wished to continue to market these drugs and garner the revenues and earnings from their sales, and McKinnel wished to continue to receive his compensation based on these revenues and earnings.

93. As set forth at ¶¶ 20-29, *supra*, Defendants were on notice at all times during the Class Period about the class-wide deleterious and dangerous cardiovascular effects of Cox-2 inhibitors drugs, including Celebrex and Bextra. Thus, Defendants knew or recklessly disregarded the negative facts alleged herein at all relevant times. Nevertheless, Defendants acted to suppress and conceal the truth about Celebrex and Bextra from consumers and from investors, and actively misrepresented the safety of these products throughout the Class Period.

FRAUD ON THE MARKET ALLEGATIONS

94. At all relevant times, the market for Pfizer common stock was an efficient market for the following reasons, among others:

a) At all relevant times during the Class Period, Pfizer's common stock was listed and actively traded on the New York Stock Exchange, a highly efficient National Market,

with approximately 7.5 billion shares of common stock issued and outstanding as of November 5, 2004, and an average daily trading volume of over 30 million shares of Pfizer stock exchanged during the Class Period;

b) As a registered and regulated issuer of securities, Pfizer filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information described in this Complaint;

c) Several financial analysts covered and reported on Pfizer's developments, including analysts with Morgan Stanley, CIBC World Markets, Friedman Billings Ramsey & Co., Oppenheimer & Co., and others.

95. As a result of the above, the market for Pfizer securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the securities' prices. Under these circumstances, all purchasers of Pfizer securities during the Class Period suffered similar injury through their purchase of securities at prices which were artificially inflated by the Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

INAPPLICABILITY OF STATUTORY SAFE HARBOR

96. The statutory safe harbor for certain forward-looking statements does not apply to the misrepresentations and omissions alleged in this complaint. Many of the statements were not specifically identified as "forward-looking statements" when made. To the extent that there were any properly identified forward-looking statements, there were no meaningful cautionary statements identifying the important then-present factors that could and did cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statement pleaded

herein, Defendants are liable nonetheless because at the time each of the misrepresentations was made, the particular speaker(s) knew that the statement was false or misleading at that time.

97. Any warnings or other cautionary language contained in the press releases and other public statements described herein were generic, "boilerplate" statements of risk that would affect any similar company, and misleadingly contained no factual disclosure of any of the problems with the Company which placed the ability of the Company to accurately depict its own financial situation into serious question. As such, any forward-looking statements complained of herein were not accompanied by meaningful cautionary language.

98. Any relevant purported risk disclosures were, in fact, false and misleading in and of themselves, by virtue of the fact that the events which the risk disclosures purported to warn against as contingencies had frequently already become a reality or a certainty.

COUNT I

(Violations of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated thereunder against all Defendants)

99. Plaintiff incorporates by reference and realleges all preceding paragraphs as though fully set forth herein.

100. During the Class Period, Defendants engaged in a plan, scheme and course of business which operated as a fraud upon Plaintiff and Class Members, and made various untrue statements of material fact and omitted to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading to Plaintiff and other Class Members as set forth above. The purpose and effect of this scheme was to induce Plaintiff and the members of the Class to purchase the Company's securities during the Class Period at artificially inflated prices.

101. By reason of the foregoing, Defendants knowingly or recklessly violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they themselves or a person whom they controlled: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and other members of the Class in connection with their purchases of the Company's common stock during the Class Period.

102. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the representations described above, Plaintiff and other members of the Class relied, to their detriment, directly on the misstatements or the integrity of the market both as to price and as to whether to purchase these securities. Plaintiff and the other members of the Class would not have purchased Pfizer stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' false and misleading statements and omissions. At the time of the purchase of Pfizer securities by Plaintiff and the other members of the Class, the fair market value of said securities was substantially less than the prices paid. Plaintiff and the other members of the Class have suffered substantial damages as a result.

COUNT II

(Violations of § 20(a) of The Exchange Act)

103. Plaintiff incorporates by reference and realleges all preceding paragraphs as though fully set forth herein.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 15, 2004