IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MONTANA BOARD OF INVESTMENTS; TEACHER RETIREMENT SYSTEM OF TEXAS; CALIFORNIA PUBLIC EMPLOYEES' RETIREMENT SYSTEM; CALIFORNIA STATE TEACHERS' RETIREMENT SYSTEM; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA; ARIZONA STATE RETIREMENT SYSTEM; CAISSE DE DÉPÔT ET PLACEMENT DU QUÉBEC; THRIVENT LARGE CAP GROWTH PORTFOLIO (f/k/a Lutheran Brotherhood Employees' Equities Fund); THRIVENT LARGE CAP GROWTH PORTFOLIO (f/k/a/ Growth Portfolio); THRIVENT LARGE CAP GROWTH PORTFOLIO (f/k/a Investors Growth Portfolio); THRIVENT FINANCIAL FOR LUTHERANS FOUNDATION (f/k/a Lutheran Brotherhood Foundation); THRIVENT FINANCIAL FOR LUTHERANS (f/k/a Lutheran Brotherhood); THRIVENT LARGE CAP STOCK FUND (f/k/a Lutheran Brotherhood Fund); THRIVENT LARGE CAP GROWTH FUND (f/k/a Lutheran Brotherhood Growth Fund); THRIVENT LARGE CAP VALUE FUND (f/k/a Lutheran Brotherhood Value Fund); THRIVENT LARGE CAP VALUE PORTFOLIO (f/k/a Value Portfolio); THRIVENT LARGE CAP VALUE PORTFOLIO (f/k/a Equity Income Portfolio); THRIVENT LARGE CAP GROWTH FUND (f/k/a The AAL Aggressive Growth Fund); THRIVENT LARGE CAP GROWTH FUND (f/k/a The AAL Technology Stock Fund); THRIVENT LARGE CAP GROWTH PORTFOLIO (f/k/a AAL Aggressive Growth Portfolio); THRIVENT BALANCED FUND (f/k/a The AAL Balanced Fund); THRIVENT LARGE CAP STOCK FUND (f/k/a The AAL Capital

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

Growth Fund); THRIVENT LARGE CAP VALUE FUND (f/k/a The AAL Equity Income Fund); THRIVENT LARGE CAP STOCK PORTFOLIO (f/k/a Capital Growth Portfolio); THRIVENT PARTNER TECHNOLOGY PORTFOLIO (f/k/a Technology Stock Portfolio); THRIVENT LARGE CAP INDEX FUND-I (f/k/a The AAL Large Company Index Fund); THRIVENT LARGE CAP INDEX FUND (f/k/a The AAL Large Company Index Fund II); THRIVENT BALANCED PORTFOLIO (f/k/a Balanced Portfolio); AND THRIVENT LARGE CAP INDEX PORTFOLIO (f/k/a Large Company Index Portfolio); AMERICAN CENTURY MUTUAL FUNDS, INC. - GROWTH FUND; AMERICAN CENTURY MUTUAL FUNDS, INC. - SELECT FUND; AMERICAN CENTURY MUTUAL FUNDS, INC. - ULTRA FUND; AMERICAN CENTURY MUTUAL FUNDS, INC. - BALANCED FUND; AMERICAN CENTURY MUTUAL FUNDS, INC. - CAPITAL VALUE FUND; AMERICAN CENTURY MUTUAL FUNDS, INC. - FUNDAMENTAL EQUITY FUND; AMERICAN CENTURY MUTUAL FUNDS, INC. - CAPITAL GROWTH FUND; AMERICAN CENTURY VARIABLE PORTFOLIOS, INC. - VP BALANCED FUND; AMERICAN CENTURY VARIABLE PORTFOLIOS, INC. - VP VALUE FUND; AMERICAN CENTURY VARIABLE PORTFOLIOS, INC. - VP INCOME & GROWTH FUND; AMERICAN CENTURY VARIABLE PORTFOLIOS, INC. - VP ULTRA FUND; AMERICAN CENTURY VARIABLE PORTFOLIOS, INC. - VP LARGE COMPANY VALUE FUND; AMERICAN CENTURY WORLD MUTUAL FUNDS, INC. - GLOBAL GROWTH FUND; AMERICAN CENTURY WORLD MUTUAL FUNDS, INC. - LIFE SCIENCES FUND; AMERICAN CENTURY CAPITAL

PORTFOLIOS, INC. - EQUITY INCOME FUND; AMERICAN CENTURY CAPITAL PORTFOLIOS, INC. - VALUE FUND; AMERICAN CENTURY CAPITAL PORTFOLIOS, INC. - EQUITY INDEX FUND; AMERICAN CENTURY CAPITAL PORTFOLIOS, INC. - LARGE COMPANY VALUE FUND; AMERICAN CENTURY STRATEGIC ASSET ALLOCATIONS, INC. - STRATEGIC ALLOCATION: CONSERVATIVE FUND; AMERICAN CENTURY STRATEGIC ASSET ALLOCATIONS, INC. - STRATEGIC ALLOCATION: MODERATE FUND; AMERICAN CENTURY STRATEGIC ASSET ALLOCATIONS, INC. - STRATEGIC ALLOCATION: AGGRESSIVE FUND; AMERICAN CENTURY QUANTITATIVE EQUITY FUNDS, INC. - INCOME AND GROWTH FUND; AMERICAN CENTURY QUANTITATIVE EQUITY FUNDS, INC. - EQUITY GROWTH FUND; AMERICAN CENTURY TOTAL RETURN EQUITY; AMERICAN CENTURY INVESTMENT MANAGEMENT, INC. – PIGSLG; PITT COUNTY MEMORIAL HOSPITAL; MARY REYNOLDS BABCOCK FOUNDATION; DOMINICAN CONVENT OF OUR LADY OF THE ROSARY; FRANCISCAN SISTERS OF THE ATONEMENT INC.; CONGREGATION OF THE SISTERS OF ST. JOSEPH OF SPRINGFIELD INC.; SISTERS OF SAINT URSULA OF THE BLESSED VIRGIN; ELI BROWN & SONS, INC.; BOYD DE BROSSARD; THE DOLPHIN TRUST; SHARON B. DRAGER, MD P.C. PROFIT SHARING PLAN; LW & JW, LLC; PRESENTATION CAPITAL ASSET PROGRAM II; ELEANOR MILLER ALGER TTEE FBO JANE MILLER ROSS; JANE MILLER ROSS; MR. ROBERT GRAFF; JUDY LEY ALLEN; ST. THOMAS CHURCH GENERAL FUND A/C #2; KAISER PERMANENTE

RETIREMENT PLAN; SISTERS OF THE HOLY CROSS INC.; FRANCISCAN SISTERS OF THE POOR FDN INC.; ANDREW JAY - HOON KIM LLC; LOS ANGELES DEPT. WATER & POWER EMPLOYEE RETIREMENT; TEAMSTERS LOCAL 500 SEVERANCE TRUST FUND; JOSEPH G. TIMPONE IRA ROLLOVER; THE JOINT INVESTMENT COMMITTEE OF THE CITY OF WICHITA RETIREMENT SYSTEMS; NORAMCO QUALITY FUNDS USA – ALGER; ALGER SPECTRA FUND, INC.; THE ALGER INSTITUTIONAL FUNDS - ALGER LARGE CAP GROWTH INSTITUTIONAL FUND; THE ALGER INSTITUTIONAL FUNDS - ALGER CAPITAL APPRECIATION INSTITUTIONAL FUND; THE ALGER FUNDS - ALGER GREEN FUND; THE ALGER INSTITUTIONAL FUNDS - ALGER BALANCED INSTITUTIONAL FUND; THE ALGER FUNDS - ALGER CAPITAL APPRECIATION FUND; THE ALGER FUNDS - ALGER GROWTH & INCOME FUND; THE ALGER FUNDS - ALGER HEALTH SCIENCES FUND; THE ALGER FUNDS - ALGER LARGE CAP GROWTH FUND; THE ALGER PORTFOLIOS - ALGER GROWTH & INCOME PORTFOLIO; THE ALGER PORTFOLIOS - ALGER LARGE CAP GROWTH PORTFOLIO; THE ALGER PORTFOLIOS - ALGER BALANCED PORTFOLIO; THE ALGER PORTFOLIOS - ALGER CAPITAL APPRECIATION PORTFOLIO; ALGER SICAV - THE ALGER AMERICAN ASSET GROWTH FUND; ALGER SICAV - ALGER U.S. LARGECAP FUND; JANUS FUND; JANUS TWENTY FUND; JANUS GROWTH AND INCOME FUND; JANUS WORLDWIDE FUND; JANUS BALANCED FUND; JAD INTECH RISK-MANAGED GROWTH FUND; JAD INTECH RISK-MANAGED CORE FUND; INTECH U.S. CORE FUND; JANUS

RESEARCH FUND; JAD LARGE CAP GROWTH FUND; JAD GROWTH & INCOME FUND; JANUS FORTY FUND; JAD BALANCED FUND; JAD RESEARCH CORE FUND; JAD WORLDWIDE FUND; JANUS RESEARCH CORE FUND; JAS LARGE CAP GROWTH PORTFOLIO; JANUS ASPEN WORLDWIDE PORTFOLIO; JANUS ASPEN BALANCED PORTFOLIO; JANUS GLOBAL LIFE SCIENCES FUND; JANUS ORION FUND; JCF US ALL CAP GROWTH FUND; JCF US BALANCED FUND; JCF US TWENTY FUND; JCF GLOBAL LIFE SCIENCES FUND; JCF US RESEARCH FUND; JCF INTECH US RISK MANAGED CORE FUND; JCMLLC - INTECH RISK-MANAGED GLOBAL CORE; INTECH U.S. LARGE CAP VALUE FUND SEED ACCOUNT; JANUS INSTITUTIONAL SELECT GROWTH PORTFOLIO; INTECH US ENHANCED PLUS FUND LLC; INTECH US BROAD LARGE CAP GROWTH FUND LLC; JANUS INSTITUTIONAL LARGE CAP GROWTH PORTFOLIO; COLLEGE RETIREMENT EQUITIES FUND - STOCK ACCOUNT; TIAA-CREF MUTUAL FUNDS - EQUITY INDEX FUND (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF MUTUAL FUNDS - GROWTH & INCOME FUND (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF MUTUAL FUNDS - GROWTH EQUITY FUND (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF MUTUAL FUNDS - SOCIAL CHOICE EQUITY FUND (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF ASSET MANAGEMENT COMMINGLED FUNDS TRUST I - ANALYSTS PORTFOLIO FUND; TIAA-CREF ASSET MANAGEMENT COMMINGLED FUNDS TRUST I – LARGE-CAP VALUE FUND; TIAA-CREF ASSET MANAGEMENT COMMINGLED FUNDS TRUST I - LARGE-CAP GROWTH

FUND; TIAA SEPARATE ACCOUNT VA-1 - STOCK INDEX ACCOUNT; TIAA-CREF FUNDS - TIAA-CREF EQUITY INDEX FUND; TIAA-CREF FUNDS - TIAA-CREF GROWTH & INCOME FUND; TIAA-CREF FUNDS - TIAA-CREF GROWTH EQUITY FUND; TIAA-CREF FUNDS - TIAA-CREF LARGE-CAP VALUE FUND; TIAA-CREF FUNDS - TIAA-CREF LARGE-CAP VALUE INDEX FUND; TIAA-CREF FUNDS - TIAA-CREF S&P 500 INDEX FUND; TIAA-CREF FUNDS - TIAA-CREF SOCIAL CHOICE EQUITY FUND; TIAA-CREF LIFE FUNDS - GROWTH & INCOME FUND; AND TIAA-CREF LIFE FUNDS - GROWTH EQUITY FUND,

PLAINTIFFS,

v.

PFIZER INC.; HENRY A. McKINNELL; JOHN L. LaMATTINA; KAREN L. KATEN; JOSEPH M. FECZKO; AND GAIL CAWKWELL,

DEFENDANTS.

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I. INTRODUCTION

Montana Board of Investments, Teacher Retirement System of Texas, California Public Employees' Retirement System, California State Teachers' Retirement System, The Regents of the University of California, Arizona State Retirement System, Caisse de dépôt et placement du Québec, Thrivent Funds (as defined herein), American Century Funds (as defined herein), Alger Management Funds (as defined herein), Janus Funds (as defined herein), and TIAA-CREF Funds (as defined herein) (collectively, "Plaintiffs") by their undersigned counsel, for their Complaint against Pfizer Inc. ("Pfizer" or the "Company"), Pfizer's former Chairman and Chief Executive Officer, Henry A. McKinnell ("McKinnell"), its former Senior Vice President and President of Pfizer Global Research and Development, John L. LaMattina ("LaMattina"), its former Vice Chairman and President - Pfizer Human Health, Karen L. Katen ("Katen"), its former Chief Medical Officer, Joseph M. Feczko ("Feczko"), and its former Medical Director for Celebrex and Global Markets, Gail Cawkwell ("Cawkwell") (collectively, the "Individual Defendants," and together with Pfizer, "Defendants"), allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters.

Plaintiffs' information and belief as to allegations concerning matters other than themselves and their own acts is based upon their counsel's review and analysis of, among other things (i) documents filed publicly by Pfizer and certain affiliates thereof with the United States Securities and Exchange Commission (the "SEC"); (ii) press releases, news articles, and other public statements issued by or concerning Pfizer and its representatives, co-promoters, and affiliates; (iii) research reports issued by financial analysts concerning Pfizer's securities and business; (iv) information concerning investigations by federal and state governmental agencies; (v) information concerning investigations by foreign regulatory authorities; (vi) testimony given

before the Arthritis Advisory Committee and Drug Safety and Risk Management Committee of the United States Food and Drug Administration (the "FDA"); (vii) publications concerning the pharmaceutical industry and epidemiological study; (viii) discussions with consulting experts; (ix) the August 31, 2009 guilty plea by Pfizer subsidiary, Pharmacia & Upjohn Company, in *United States of America v. Pharmacia & Upjohn Company, Inc.*, Criminal No. 09 CR 10258-DPW (D. Mass.), as well as the October 9, 2009 Sentencing Memorandum and the deferred prosecution agreement between Pfizer and the United States Department of Justice (the "DOJ"); (x) documents and information, including internal emails produced by Pfizer, deposition testimony provided by its former officers and employees, and court filings in related cases brought against Defendants, including the action captioned *In re Pfizer Inc. Securities Litigation*, Case No. 04-CV-9866 (LTS) (HBP) (S.D.N.Y.) (the "Pfizer Securities Class Action"); and (xi) documents and information disclosed in other litigations naming Pfizer or its subsidiaries or affiliates as defendants or nominal defendants, including *In re: Bextra and Celebrex Marketing and Sales Practices, and Product Liability Litigation*, No. 05-CV-01699 (N.D. Cal.) and *Alaska Electrical Pension Fund, et al. v. Pharmacia Corp., et al.*, No. 03-CV-01519 (D.N.J.) (the "Pharmacia Securities Class Action").[1] Plaintiffs believe that substantial additional evidentiary support for the allegations herein exists and will continue to be revealed after Plaintiffs have a reasonable opportunity to conduct discovery.

II. NATURE AND SUMMARY OF THE ACTION

1. This action concerns a fraud perpetrated by Pfizer and its top executives to misrepresent and conceal the significant cardiovascular risks of the Company's best-selling pain-

[1] On September 7, 2012, Plaintiffs timely requested exclusion from the Pfizer Securities Class Action, and bring the instant claims in their individual capacities.

relieving drugs, Celebrex (celecoxib) and Bextra (valdecoxib), in a calculated effort to win market share and reap billions of dollars in profits.

2. Defendants, including Pfizer, McKinnell, LaMattina, Katen, Feczko, and Cawkwell, made, issued and approved over seventy patently false and misleading statements during the period October 31, 2000 to October 19, 2005 (the "Relevant Period"), regarding the purported cardiovascular safety of Celebrex and Bextra. Defendants consistently publicized Celebrex and Bextra as highly effective and entirely safe drugs from a cardiovascular perspective. As detailed below, Defendants blatantly misled investors and the public in a number of ways regarding the serious cardiovascular side-effects of Celebrex and Bextra. Defendants affirmatively misrepresented and suppressed the results of over a dozen clinical studies, a wealth of epidemiological data, and various other information demonstrating that these drugs were associated with serious cardiovascular risk, including heart attack, stroke and death. Defendants' misstatements and omissions resulted in years of blockbuster sales, domination of the multi-billion dollar "COX-2" market, and artificial inflation in Pfizer's stock price. When the truth about the cardiovascular risks of Celebrex and Bextra was ultimately revealed, Bextra was pulled from the market, a "black box" warning was slapped on Celebrex, sales of the drugs dramatically declined, and Plaintiffs lost billions of dollars as Pfizer's stock price plummeted by approximately thirty percent.

3. Celebrex and Bextra are non-steroidal anti-inflammatory drugs ("NSAIDs") that belong to a class of drugs known as Cyclooxygenase 2 ("COX-2") inhibitors. COX-2 inhibitors selectively inhibit the COX-2 enzyme, which is involved in inflammation, while sparing the COX-1 enzyme, which protects the stomach's natural protective mucus lining. COX-2 inhibitors were developed as an alternative to traditional NSAIDs, such as aspirin, ibuprofen (Advil) and

naproxen (Aleve), which inhibit both the COX-1 and COX-2 enzymes and can cause toxicity in the digestive tract and kidney problems in long term use. Following the discovery of COX-2 in the early 1990s, pharmaceutical companies raced to develop the first specific COX-2 inhibitor drug. Analysts predicted that COX-2 inhibitors had the potential to make traditional NSAIDs obsolete, and that the company that won the race to market would earn billions of dollars in profits.

4. Celebrex, the first selective COX-2 inhibitor approved by the FDA, had the most successful drug launch in history. Following its approval in 1998 as a treatment for pain from arthritis and menstruation, Celebrex generated revenues of over $1.4 billion in 1999, $2.6 billion in 2000, $3.1 billion in 2001, $3.1 billion in 2002, $2.5 billion in 2003, and $3.3 billion in 2004. Bextra, which was approved by the FDA in November 2001 and marketed by Pfizer as the "power" option for acute pain, also had a widely successful debut. Bextra generated revenues of $470 million in 2002, $875 million in 2003, and over $1.2 billion in 2004. By 2004, these two drugs alone accounted for nearly 10% of Pfizer's total worldwide revenue, or over $4.5 billion.

5. Defendants achieved these extraordinary results by consistently misrepresenting Celebrex and Bextra as completely free of any cardiovascular risks. In press releases, newspaper articles, advertisements, television shows, annual and quarterly reports, and conference calls with securities analysts, Defendants repeatedly touted the allegedly superior cardiovascular safety profile of Celebrex and Bextra. By way of example, Pfizer issued nearly a dozen press releases between 2001 and 2004 trumpeting "Celebrex's strong efficacy, excellent tolerability, and a proven safety profile." Multiple Pfizer press releases declared that "Celebrex showed no increase in thromboembolic events or other cardiovascular-related events." This was true, the

Company claimed, “even among non-aspirin users” and even as “compared with the traditional NSAID comparators.”

6. Repeatedly, Pfizer and its representatives claimed that Celebrex demonstrated “no signal” and “no evidence” of cardiovascular risk. For example, during an October 17, 2001 earnings conference call, Defendant Katen declared: “We have not seen any problems with cardiovascular safety with Celebrex” and “There’s never been a cardiovascular issue raised around Celebrex.” On a July 25, 2003 quarterly conference call, Katen similarly proclaimed that: “An independent analysis that included our entire Celebrex arthritis clinical trial database, found no evidence in increased cardiovascular risk for Celebrex, relative to both conventional, non-psoriatal anti-inflammatory drugs and placebo.”

7. Pfizer and its representatives also made many similar representations about Bextra’s purported cardiovascular safety. For example, in a November 19, 2001 press release, Pfizer emphasized that, “[i]n controlled arthritis trials, the use of BEXTRA at the recommended dose has not been associated with any increased risk of cardiovascular or renal complications versus NSAIDs studied.” Similarly, in an October 28, 2002 press release, Pfizer touted Bextra as an effective and safe form of pain reliever: “Analyses of pooled study results for the COX-2 specific inhibitor BEXTRA . . . underscored its improved upper gastrointestinal (GI) safety as well as its cardiovascular safety profile.”

8. In particular, Pfizer aggressively marketed the purported comparative safety of its COX-2 franchise relative to Merck & Co., Inc.’s (“Merck”) well-known COX-2 drug, Vioxx. Although sales of Celebrex and Bextra quickly reached “blockbuster” status, Pfizer was eager to take market share from Merck. In February 2001, the FDA held hearings to consider the cardiovascular safety of Celebrex and Vioxx. The hearings – which were tainted by Pfizer’s

misleading submission that omitted adverse results of several Celebrex studies – resulted in a cardiovascular warning for Vioxx, but not for Celebrex. This purported difference in cardiovascular safety profiles between Celebrex and Vioxx gave Pfizer a powerful marketing edge over Vioxx, and Pfizer brazenly exploited the difference for years thereafter. Pfizer routinely asserted in press releases, SEC filings, and elsewhere that Celebrex had a "superior" safety profile ***specifically*** as compared to Vioxx.

9. Furthermore, at the same time Pfizer and its representatives hyped the purported safety and efficacy of Celebrex and Bextra, they also underscored to investors the drugs' commercial importance to the Company. Repeatedly, for example, Pfizer boasted that Celebrex was "the most successful drug launch in the history of the pharmaceutical industry" and "the #1 branded non-steroidal anti-inflammatory drug (NSAID) and the #1 Cox-2-specific inhibitor in the world," having "the broadest range of approved indications."

10. Unbeknownst to investors, at the same time that Defendants were engaged in a media blitz touting the superiority of Celebrex and Bextra, Defendants were in possession of an abundance of adverse, nonpublic information demonstrating a variety of cardiovascular risks associated with the drugs. Far from having "no evidence" of cardiovascular risk, as Defendants consistently maintained, it is now clear that information concerning the cardiovascular risks of Celebrex and Bextra was well known by Pfizer, since at least as early as 1999, but concealed and misrepresented to the public. Indeed, from 1999 through 2005, Pfizer and the Individual Defendants were in possession of the results of over a dozen completed clinical studies demonstrating increased cardiovascular risk for Celebrex and Bextra.

11. In the late 1990s, for example, Defendants learned of the "Fitzgerald Hypothesis," which theorized that COX-2 inhibitors as a class may elevate cardiovascular risk. While Pfizer

publicly discredited the Fitzgerald Hypothesis, internally Pfizer was in possession of a cardiovascular events analysis that confirmed its validity. This "July 14, 1999 Cardiovascular Events Analysis," which was prepared by Pfizer's Co-Promoter (first Searle and then Pharmacia) in the commercialization of Celebrex and Bextra revealed statistically significant increases for all cardiovascular events for patients using Celebrex compared to a placebo, and statistically significant differences between Celebrex and traditional NSAIDs for certain cardiovascular events. It was never published.

12. Similarly, in 1999, Searle completed and provided Pfizer with a study examining the effects of Celebrex on the progression of Alzheimer's disease. This study, which was known as the "Alzheimer's 001 Study," began in 1997 and was the longest-term, placebo-controlled study relating to Celebrex. In addition to its long duration (52 weeks), the Alzheimer's 001 Study was important because of the enormous potential of the Alzheimer's market. The Alzheimer's 001 Study, however, did not demonstrate cardiovascular safety. Instead, it revealed statistically significant increases in cardiovascular risk, including: (i) thirty serious cardiovascular adverse events in the Celebrex group compared to three such events in the placebo group; (ii) ten cardiovascular-related deaths in the Celebrex group versus two in the placebo group; (iii) a statistically significant increase in blood pressure in the Celebrex group; and (iv) statistically significant differences for certain cardiovascular-related body systems between treatment groups. Following the study, Pfizer quietly dropped its plans to pursue an indication for Celebrex for the treatment of Alzheimer's disease.

13. In March 2000, a large clinical trial known as the "Celecoxib Long-Term Arthritis Safety Study" or the "CLASS Study" was completed. The CLASS Study was designed to compare the incidence of significant upper gastrointestinal events associated with Celebrex with

those in one of two traditional NSAIDs, ibuprofen and diclofenac, in both osteoarthritis and rheumatoid arthritis patients. The CLASS Study revealed a statistically significant result of nine heart attacks in a Celebrex subgroup versus none for diclofenac. Pfizer did not publish this subgroup analysis in the medical literature during the Relevant Period. Further, Pfizer purposefully distorted the overall CLASS Study results by releasing only the favorable results from the first six months of the study and concealing the unfavorable results from the remainder of the study, which lasted approximately thirteen months. An internal Pfizer email candidly states, with regard to the medical community's favorable view of the reported CLASS results, ***"[t]hey swallowed our story, hook, line, and sinker . . . ."*** [2]

14. One month after the CLASS Study, in April 2000, a large clinical trial was completed that compared Celebrex to diclofenac and naproxen in the treatment of osteoarthritis of the knee and hip. The so-called "SUCCESS Study" was poorly named, as it revealed a statistically significant 10 to 1 increase in heart attacks for patients taking Celebrex versus those taking the two traditional arthritis medicines studied. Even adjusting for the differences in the enrollment patients taking Celebrex versus traditional arthritis medicines, there was a 5 times increase in heart attacks in the Celebrex group. Again, Pfizer did not publish the results of this SUCCESS Study during the Relevant Period. Instead, the SUCCESS Study (along with other studies) was ***"embargoed"*** during the Relevant Period as Pfizer knew the increased risk for heart attacks seen in the study would raise questions.

15. By 2005, Pfizer had in its possession cardiovascular safety data from at least 41 placebo-controlled, completed clinical trials of Celebrex. In May 2005, Pfizer performed a pooled meta-analysis of all of these studies. ***The May 2005 pooled analysis showed a***

[2] All emphasis added unless otherwise noted. All references to "ECF Nos." refer to docket entries in the Pfizer Securities Class Action, unless otherwise noted.

statistically significant, <u>seven times</u> increased cardiovascular risk for Celebrex patients versus patients taking a placebo.

16. Even more startling, the May 2005 pooled analysis reached its conclusion of seven times statistical significance without considering the findings of numerous additional studies and epidemiological data demonstrating increased cardiovascular risk. For example, the pooled meta-analysis did not take into account the adverse trials that did not have completed study reports as of October 31, 2004. In addition, the pooled analysis did not include studies by certain government regulators, such as a 2003 report provided to Pfizer by a representative (or "Rapporteur") of a European regulator that detailed "a clear signal" for increased risk of heart attacks in Celebrex-treated patients compared to traditional arthritis medicines. Nor did the pooled analysis include the epidemiological study of claims data prepared by Aetna, a national health insurer and managed health care provider, provided to Pfizer in November 2004, which showed a statistically significant increase in heart attacks among Celebrex users versus those receiving other NSAIDs or no treatment at all. Finally, and also by way of example, the May 2005 pooled meta-analysis found a seven times, statistically significant increased risk for "any myocardial thromboembolic event" even without including a long-term, placebo-controlled trial of Celebrex in cancer patients (known as the "APC Study," discussed further below) that was halted in December 2004 because of a dramatic increase in cardiovascular death and stroke among participants.

17. With respect to Bextra, which Pfizer developed as a complement to Celebrex, Pfizer's internal clinical trial database also contained numerous completed studies demonstrating cardiovascular risk. For example, Study 016 – a six week double-blind, randomized, placebo-controlled study completed in 1998 and designed to determine the efficacy of Bextra in

rheumatoid arthritis patients – demonstrated twelve serious adverse cardiovascular events (including six heart attacks) in Bextra patients versus none in patients taking a placebo or naproxen. Likewise, Study 047 – a large, 6-month safety study of high dose Bextra compared to naproxen (a traditional arthritis medicine) – demonstrated that the incidence of hypertension was significantly increased in the Bextra group versus a comparison naproxen group. Finally, Studies 060 and 061, which were completed in 2000 and also compared the use of Bextra in rheumatoid arthritis patients versus naproxen, revealed six incidences of serious myocardial, endocardial or pericardial episodes and valve disorders in four patients, one in each Bextra treatment group. Commenting on the Study 060 study results before a September 2000 Valdecoxib (Bextra) Strategic Summit, a Pfizer physician wrote in an internal email, ***"[t]here is clearly an increased incidence of MI [heart attacks] with valdecoxib compared to placebo and NSAIDs."***

18. Concerned that the adverse cardiovascular findings from these Bextra studies would negatively impact sales of both Bextra and Celebrex, Pfizer chose not to publish their results. In February 2002, for example, the "Bextra Publications Working Group" voted to ***"embargo"*** publication of Study 047 because the "***publication of these data [047] would be damaging to the product***." Defendants also concealed the results of a study in patients with chronic cancer pain (known as the "040 Cancer Pain Study"), which revealed a nearly 2 to 1 increase in serious adverse events for patients taking Bextra versus placebo, including a statistically significant increase in deaths and peripheral edema in Bextra-treated patients. The results were forwarded to Defendant Cawkwell, among others, with instructions ***"not [to] discuss more widely at this time."***

19. Pfizer also concealed the results of the "CABG-1 Study," a clinical safety study that compared the use of Bextra (both in tablet and injectable form) to placebo in post-coronary

artery bypass graft surgery patients. This study, which was completed in June 2000, revealed a cardiovascular safety signal – *viz.*, statistically significant increases in death, myocardial infarction, cerebrovascular accident, pulmonary embolism and deep vein thrombosis for Bextra patients compared to placebo. Pfizer employees were instructed to conceal the negative Bextra data from investors. In a 2001 email commenting on a "Q and A book for the shareholder's meeting," a senior physician in Pfizer's worldwide clinical department wrote ***"Do you have cardiovascular problems like Vioxx? - an[swer]: do not disclose[.]"***

20. Defendants clearly understood the import of this adverse safety data. Indeed, Pfizer used the adverse cardiovascular findings of the CABG-1 Study as negotiating leverage to drive down the price Pfizer was to pay Pharmacia for Celebrex and Bextra under the parties' Co-Promotion Agreement. This is reflected in an August 2001 "talking points" memo to Defendant McKinnell that discusses, *inter alia,* Pfizer's belief that the drug could not earn an acute pain indication as a result of the negative results, including Bextra's ***"life-threatening adverse events."***

21. In August 2001, the FDA requested that Pfizer perform a follow-up study, the "CABG-2 Study," to explain the cardiovascular safety signals seen in CABG-1. It was critical that CABG-2 yield clean results if Bextra was to earn an acute pain indication and compete with Merck's Vioxx, which was already approved for use in treating acute pain. Pfizer management, including Defendant Cawkwell, was well aware that a repeat of the adverse cardiovascular safety signal from CABG-1 would mean the acute pain indication would be ***"DOA [i.e., dead on arrival]***." Although Pfizer enacted several study design changes to decrease the likelihood that the CABG-2 Study would produce a cardiovascular safety signal, the CABG-2 Study resulted in a "significantly higher" incidence of cardiovascular thromboembolic adverse events compared to

a placebo. The "topline" results of CABG-2 were reported to Pfizer management, including Defendants Cawkwell and Feczko, and the study results were later sent to the FDA on March 17, 2004. However, consistent with its custom and practice, Pfizer did not discuss them publicly.

22. On September 30, 2004, Merck publicly announced that it was voluntarily and immediately withdrawing Vioxx from markets worldwide after an ongoing trial confirmed that its COX-2 inhibitor increases cardiovascular risk, including heart attack and stroke. The withdrawal of Vioxx was a major event that shook up the pharmaceutical industry and caused Merck's stock price to plummet by nearly 27% in a single day. A week later, on October 6, 2004, *The New England Journal of Medicine* published an editorial that questioned the safety of all COX-2 drugs, including Celebrex and Bextra.

23. Vioxx's withdrawal should have alerted Pfizer to disclose immediately the cardiovascular dangers of Celebrex and Bextra that the Company had been hiding for years. However, rather than come clean, Pfizer attempted to capitalize on Vioxx's withdrawal in an effort to further dominate the COX-2 market and grab billions in additional sales. Thus, on the same morning that Merck announced the withdrawal of Vioxx, Pfizer's CEO, Defendant McKinnell, sent an email regarding "VIOXX Withdrawal" that instructed senior Pfizer management to seize on the absence of their biggest COX-2 competitor as a marketing opportunity. ***"We need to move immediately to avoid collateral damage and to exploit what could be a major opportunity,"*** McKinnell wrote. ***"How to handle Bextra is an interesting problem. I suggest we focus on Celebrex,"*** the CEO added. Within forty-five minutes, Pfizer embarked on a media campaign, announcing that employees had scoured the Company's internal databases and that Celebrex, unlike Vioxx, was not associated with any increased cardiovascular risk.

24. At 9:31 a.m. on September 30, 2004, the same day that Merck withdrew Vioxx from the market, Pfizer released a statement reaffirming that none of its Celebrex studies had ever shown any increased cardiovascular risk. Pfizer issued another press release the following day that forcefully repeated the claim that no completed Celebrex study had ever shown any increased cardiovascular risk. "The 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***, the world's most prescribed arthritis and pain relief brand," the Company reaffirmed. "Bextra's cardiovascular safety profile is also well established in long-term studies," Pfizer further represented.

25. Remarkably, McKinnell also directed Pfizer management, including Defendants Katen, LaMattina and Feczko, to publicize that Celebrex might actually ***reduce*** cardiovascular risk. Thus, for example, during an October 20, 2004 earnings conference call, Defendant Feczko maintained that "a lot of the epidemiological studies" in the Company's possession "actually showed a trend toward some kind of beneficial effects seen on vasculature." During a November 10, 2004 episode of the *Nightly Business Report*, Defendant McKinnell emphatically denied any "cloud of uncertainty" about the safety and effectiveness of Celebrex and Bextra, and claimed that Pfizer's "current information" actually showed that Celebrex might be "protective of the heart." Upon learning that Pfizer was spreading the idea that Celebrex might alleviate heart risks, Pharmacia's former Chief Safety Officer, who worked extensively on matters relating to the cardiovascular safety of Celebrex and Bextra, sent an email to a Pfizer employee strongly condemning the "cardio-protective" claim:

> Regrettably, the situation is such that unless you play your cards well you will lose Bextra for sure, and possibly Celebrex. Unfortunately, I just don't see Mitch [Gandleman, Pfizer spokesperson] handling this well. At least I hope that he

stops making an ***asshole of himself (and the company) by making public statements saying that they plan to prove celebrex is cardioprotective.***

26. By December 2004, Pfizer began to lose control over its hidden study information documenting Celebrex's increased cardiovascular risks. On December 17, 2004, the National Institute of Health announced that a long-term, placebo-controlled trial of Celebrex in cancer patients (the "APC Study") had been halted due to a dramatic increase in cardiovascular death and stroke among Celebrex users. Again, rather than admit that it had been concealing evidence of increased cardiovascular risk – including completed study results which Pfizer had in its possession since 1999 and 2000 and aggregate study data showing a seven times statistically significant increased cardiovascular risk for Celebrex versus placebo – Pfizer publicly maintained that the increased cardiovascular risk seen in this terminated cancer study was an isolated event and that none of its prior studies had revealed any cardiovascular risk signals.

27. Significantly, just a few months earlier, following Merck's withdrawal of Vioxx, Pfizer received an inquiry from the FDA seeking additional information relating to Celebrex's cardiovascular side effects, in particular, the findings of the Alzheimer's 001 Study. At the time, the results of Alzheimer's 001 Study had only been provided to the Data Safety Monitoring Committee ("DSMC"), an independent safety committee that reviews clinical trial data. After Vioxx was pulled from the market, the DSMC physicians urged Pfizer to get the results of the Alzheimer's 001 Study in print so they could be factored into the medical assessment of Celebrex. Pfizer had previously ignored this advice, but in late December 2004, following the FDA inquiry, Pfizer reluctantly began preparing a supplement to the original Alzheimer's 001 Study report submitted to the FDA in June 2001. It was Pfizer's plan to supplement the report with additional information about the study, but to retain the original false conclusion that Celebrex was safe and well tolerated in the Alzheimer's study population. The independent

physicians on the DSMC would not have it, and on Christmas Eve 2004, the DSMC "reminded" Pfizer about the cardiovascular safety concerns that had been seen in the study in 1999 (over 5 years earlier) and that the cardiovascular safety results remained unpublished.

28. Concerned that the DSMC might go public with its concerns over the unpublished Alzheimer's 001 Study results, Pfizer changed the supplemental report it had been planning to submit to the FDA. The final supplemental report, filed with the FDA on January 5, 2005, acknowledged that there were statistically significant increases for cardiovascular events in the study, and conceded that the safety and tolerability of Celebrex compared to placebo in the study population ***"cannot be decisively concluded."*** Even still, Pfizer failed to fully disclose the known cardiovascular safety risks of the Company's COX-2 franchise. Moreover, despite the intense scrutiny and heightened public interest surrounding cardiovascular risk and COX-2 inhibitors at this time, Pfizer did not disclose to the public that it had filed a supplemental FDA report.

29. Instead, in late January 2005, Pfizer quietly posted the five-year-old, previously unpublished cardiovascular results of the Alzheimer's 001 Study in a study "synopsis" on a new industry-specific web site. Pfizer's surreptitious posting of the study "synopsis" did not work. It was soon discovered by a health advocacy group and ultimately brought to light in a *The New York Times* exposé, published in early February 2005, detailing how Pfizer had hid the results since 1999. Dr. Sidney M. Wolfe, who discovered the revised Alzheimer's 001 Study "synopsis" on the internet, and who had spoken at the February 2001 FDA Advisory Committee hearings that resulted in a cardiovascular warning for Vioxx but not Celebrex, was quoted in *The New York Times* article as stating, ***"'It's a clear signal that I would have loved to have known about four years ago.'"***

30. Through the end of the Relevant Period in October 2005, Defendants continued to misrepresent the cardiovascular safety profile of Celebrex and Bextra, claiming that the studies showing increased cardiovascular risk for the two drugs were isolated or aberrations. Pfizer continued to hide the substantial other evidence of cardiovascular risk it had in its possession for years.

31. When the truth about the drugs' cardiovascular safety profiles was revealed, Bextra (like Vioxx) was removed from the market and Celebrex was given a "black box warning" – the FDA's gravest warning – regarding its cardiovascular risks. Revenues from Celebrex fell from approximately $2.3 billion for the first nine months of 2004 to $1.3 billion for the same period in 2005, a decline of 45%. Bextra's revenues for the first three quarters declined by more than $925 million, from 2004 to 2005. Combined, Celebrex's and Bextra's revenues for the first nine months of 2005 fell by almost $2 billion compared to the first nine months of 2004, a decline of over 60%. As a result, from the close of trading on October 6, 2004 through October 20, 2005, the day Pfizer announced third quarter earnings, Pfizer's stock fell from $31.18 per share to $21.90, a decline of $9.28 per share or approximately 30%, erasing approximately $74 billion in market capitalization.

32. In the wake of Defendants' misconduct, a wave of government investigations and civil lawsuits were brought against Pfizer and its executives and affiliates. In the fall of 2004, for example, the U.S. Department of Justice commenced an investigation into Pfizer's "off-label" marketing of Bextra to treat acute pain – *i.e.*, after the FDA had denied such an indication based on various undisclosed safety studies, including the CABG-1 Study, which showed Bextra's significant cardiovascular side effects.

33. On August 31, 2009, a Pfizer subsidiary agreed to plead guilty to a criminal felony charge of violating the Food, Drug and Cosmetic Act, admitting that it intentionally, and with the intent to deceive and defraud, marketed Bextra for uses and dosages that were not approved by the FDA. To settle the pending criminal charges, Pfizer also agreed to pay a fine of ***$1.195 billion***, which, according to the DOJ, was ***"the largest criminal fine ever imposed in the United States for any matter."***

34. At the plea hearing, the prosecuting U.S. Attorney stated that Defendants' misconduct was ***"across the corporation*** and so many people were involved, and the astonishing number of e-mails that had 20 people on it, all of whom ***should have known that [their conduct] was improper."*** She further stated that "we certainly think that in this case there were real human beings that ***knew what they were doing was illegal and did it anyway***" and that "many of them were following direct instructions from managers above them." The sentencing memorandum similarly stated that ***"the illegal conduct was pervasive throughout the company"*** and that the ***"corporate culture contributed to causing the conduct and allowing it to continue."***

35. In addition to pleading guilty to a felony and paying a total of $1.3 billion in criminal fines regarding the illegal promotion and sales practices of Bextra, Pfizer agreed to pay ***another $1 billion*** to settle civil claims by the government that the Company had violated the False Claims Act, including prohibited off-label use and dosage promotions, and violations of the Federal anti-kickback statute, with respect to thirteen different drugs. According to the DOJ, this was ***"the largest civil fraud settlement in history against a pharmaceutical company."***

36. On top of these landmark federal criminal and civil fines totaling approximately ***$2.3 billion***, Pfizer also was forced to pay an additional ***$894 million*** to state governments and

private litigants to settle the bulk of personal injury litigation and state government probes surrounding Celebrex and Bextra.

37. Today, Bextra is no longer sold and Pfizer's Celebrex website states under the heading "Important Safety Information:" Celebrex ***"may increase . . . the chance of a heart attack or stroke that can lead to death."***

III. JURISDICTION AND VENUE

38. The claims asserted herein arise under Sections 10(b), 20(a) and 20(A) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

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

40. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. §§ 1391(b), (c) and (d). Many of the acts and omissions alleged herein, including the preparation and dissemination to the public of materially false and misleading information, occurred in substantial part in this District. Pfizer maintained its corporate headquarters and principal executive offices in this District throughout the Relevant Period.

41. In connection with the acts and conduct alleged herein, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including (among other things) the United States mails, interstate telephone communications, and the facilities of national securities exchanges and markets.

IV. THE PARTIES

A. Plaintiffs

42. Montana Board of Investments ("Montana BOI") is a plaintiff in this action. Montana BOI is charged with investment and management of funds of the State of Montana

through Montana's Unified Investment Program, which includes public employee pension funds and trust funds. As of June 30, 2011, Montana BOI had $13.5 billion in net assets under management. Plaintiff Montana BOI purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

43. Teacher Retirement System of Texas ("Texas Teachers") is a plaintiff in this action. Texas Teachers provides retirement and related benefits for those employed by the public schools, colleges and universities supported by the State of Texas. As of June 30, 2012, Texas Teachers had approximately $108 billion in net assets under management. Plaintiff Texas Teachers purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

44. California Public Employees' Retirement System ("CalPERS") is a plaintiff in this action. CalPERS is the largest state public pension fund in the United States with $238.5 billion in assets under management as of August 31, 2012. CalPERS manages retirement benefits for more than 1.6 million California public employees, retirees and their families. CalPERS is an arm of the State of California, operating pursuant to the California Constitution (Article 16, Section 17) and the California Government Code. Plaintiff CalPERS purchased shares of common stock of Pfizer during the Relevant Period and suffered damages as a result of the violations pled herein.

45. California State Teachers' Retirement System ("CalSTRS") is a plaintiff in this action. CalSTRS is the largest teachers' retirement fund in the United States, with over 856,000 members and over $152 billion in assets under management as of March 31, 2012. Plaintiff CalSTRS purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

46. The Regents of the University of California ("The Regents of UC") is a plaintiff in this action. The Regents of UC is a 26-member board, established by Article IX, Section 9 of the California Constitution that governs the University of California and manages its retirement, endowment, and cash assets. These investments provide benefits to current and retired employees and support the university's mission of education, research, and public service. The Regents of UC currently manages a portfolio totaling approximately $72 billion. Plaintiff The Regents of UC purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

47. Arizona State Retirement System ("Arizona SRS") is a plaintiff in this action. Arizona SRS is an agency of the State of Arizona that provides retirement benefits, long-term disability benefits and other benefits to employees of the state, counties, municipalities, universities, community colleges, school districts and other political entities. As of June 30, 2012, Arizona SRS had $28.3 billion in assets under management and 538,776 members. Plaintiff Arizona SRS purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

48. Caisse de dépôt et placement du Québec ("La Caisse") is a plaintiff in this action. La Caisse manages institutional funds, primarily from public and private pension and insurance funds in Quebec. La Caisse is one of the largest institutional funds managers in Canada and North America with over $204 billion of assets under management as of December 31, 2011. Plaintiff La Caisse purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

49. Thrivent Financial for Lutherans ("Thrivent Financial") is a faith-based, not-for-profit membership organization with nearly 2.5 million members. Thrivent Financial is also a

Fortune 500 financial services organization with over $75 billion in assets under management as of December 31, 2011. The following Thrivent Financial for Lutherans funds and/or accounts are plaintiffs in this action: Thrivent Large Cap Growth Portfolio (f/k/a Lutheran Brotherhood Employees' Equities Fund); Thrivent Large Cap Growth Portfolio (f/k/a Growth Portfolio); Thrivent Large Cap Growth Portfolio (f/k/a Investors Growth Portfolio); Thrivent Financial for Lutherans Foundation (f/k/a Lutheran Brotherhood Foundation); Thrivent Financial for Lutherans (f/k/a Lutheran Brotherhood); Thrivent Large Cap Stock Fund (f/k/a Lutheran Brotherhood Fund); Thrivent Large Cap Growth Fund (f/k/a Lutheran Brotherhood Growth Fund); Thrivent Large Cap Value Fund (f/k/a Lutheran Brotherhood Value Fund); Thrivent Large Cap Value Portfolio (f/k/a Value Portfolio); Thrivent Large Cap Value Portfolio (f/k/a Equity Income Portfolio);Thrivent Large Cap Growth Fund (f/k/a The AAL Aggressive Growth Fund); Thrivent Large Cap Growth Fund (f/k/a The AAL Technology Stock Fund); Thrivent Large Cap Growth Portfolio (f/k/a AAL Aggressive Growth Portfolio); Thrivent Balanced Fund (f/k/a The AAL Balanced Fund); Thrivent Large Cap Stock Fund (f/k/a The AAL Capital Growth Fund); Thrivent Large Cap Value Fund (f/k/a The AAL Equity Income Fund); Thrivent Large Cap Stock Portfolio (f/k/a Capital Growth Portfolio); Thrivent Partner Technology Portfolio (f/k/a Technology Stock Portfolio); Thrivent Large Cap Index Fund-I (f/k/a The AAL Large Company Index Fund); Thrivent Large Cap Index Fund (f/k/a The AAL Large Company Index Fund II); Thrivent Balanced Portfolio (f/k/a Balanced Portfolio); and Thrivent Large Cap Index Portfolio (f/k/a Large Company Index Portfolio) (collectively, "Thrivent Funds"). Plaintiffs Thrivent Funds purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

50. American Century Investment Management, Inc. ("American Century") is a leading investment manager serving investment companies, pooled investment vehicles, charitable organizations, investment professionals, foundations, endowments, and institutions worldwide. As of September 7, 2012, American Century had over $123 billion in assets under management. The following American Century Investment Management funds and/or accounts are plaintiffs in this action: American Century Mutual Funds, Inc. - Growth Fund; American Century Mutual Funds, Inc. - Select Fund; American Century Mutual Funds, Inc. - Ultra Fund; American Century Mutual Funds, Inc. - Balanced Fund; American Century Mutual Funds, Inc. - Capital Value Fund; American Century Mutual Funds, Inc. - Fundamental Equity Fund; American Century Mutual Funds, Inc. - Capital Growth Fund; American Century Variable Portfolios, Inc. - VP Balanced Fund; American Century Variable Portfolios, Inc. - VP Value Fund; American Century Variable Portfolios, Inc. - VP Income & Growth Fund; American Century Variable Portfolios, Inc. - VP Ultra Fund; American Century Variable Portfolios, Inc. - VP Large Company Value Fund; American Century World Mutual Funds, Inc. - Global Growth Fund; American Century World Mutual Funds, Inc. - Life Sciences Fund; American Century Capital Portfolios, Inc. - Equity Income Fund; American Century Capital Portfolios, Inc. - Value Fund; American Century Capital Portfolios, Inc. - Equity Index Fund; American Century Capital Portfolios, Inc. - Large Company Value Fund; American Century Strategic Asset Allocations, Inc. - Strategic Allocation: Conservative Fund; American Century Strategic Asset Allocations, Inc. - Strategic Allocation: Moderate Fund; American Century Strategic Asset Allocations, Inc. - Strategic Allocation: Aggressive Fund; American Century Quantitative Equity Funds, Inc. - Income and Growth Fund; American Century Quantitative Equity Funds, Inc. - Equity Growth Fund; American Century Total Return Equity; and American Century Investment Management,

Inc. - PIGSLG (collectively, "American Century Funds"). Plaintiffs American Century Funds purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

51. Fred Alger Management, Inc. ("Alger Management") is a pioneer of growth-style investment management with over $16 billion in assets under management as of June 2012. The following Alger Management funds and/or accounts are plaintiffs in this action: Pitt County Memorial Hospital; Mary Reynolds Babcock Foundation; Dominican Convent of Our Lady of the Rosary; Franciscan Sisters of the Atonement Inc.; Congregation of the Sisters of St. Joseph of Springfield Inc.; Sisters of Saint Ursula of the Blessed Virgin; Eli Brown & Sons, Inc.; Boyd De Brossard; The Dolphin Trust; Sharon B. Drager, MD P.C. Profit Sharing Plan; LW & JW, LLC; Presentation Capital Asset Program II; Eleanor Miller Alger Ttee FBO Jane Miller Ross; Jane Miller Ross; Mr. Robert Graff; Judy Ley Allen; St. Thomas Church General Fund A/C #2; Kaiser Permanente Retirement Plan; Sisters of the Holy Cross Inc.; Franciscan Sisters of the Poor Fdn Inc.; Andrew Jay - Hoon Kim LLC; Los Angeles Dept. Water & Power Employee Retirement; Teamsters Local 500 Severance Trust Fund; Joseph G. Timpone IRA Rollover; The Joint Investment Committee of the City of Wichita Retirement Systems; Noramco Quality Funds USA – Alger; Alger Spectra Fund, Inc.; The Alger Institutional Funds - Alger Large Cap Growth Institutional Fund; The Alger Institutional Funds - Alger Capital Appreciation Institutional Fund; The Alger Funds - Alger Green Fund; The Alger Institutional Funds - Alger Balanced Institutional Fund; The Alger Funds - Alger Capital Appreciation Fund; The Alger Funds - Alger Growth & Income Fund; The Alger Funds - Alger Health Sciences Fund; The Alger Funds - Alger Large Cap Growth Fund; The Alger Portfolios - Alger Growth & Income Portfolio; The Alger Portfolios - Alger Large Cap Growth Portfolio; The Alger Portfolios - Alger Balanced

Portfolio; The Alger Portfolios - Alger Capital Appreciation Portfolio; Alger SICAV - The Alger American Asset Growth Fund; and Alger SICAV - Alger U.S. Largecap Fund (collectively, "Alger Management Funds"). Plaintiffs Alger Management Funds purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

52. Janus Capital Management LLC ("Janus") provides investment management services to investment companies, pooled investment vehicles, pension and profit sharing plans, charitable organizations, corporations and other businesses, state or municipal government entities, investment advisers, insurance companies, and high net worth individuals. Janus is a wholly owned operating subsidiary of Janus Capital Group, one of the largest mutual fund complexes in the United States with nearly $158.2 billion in assets under management as of September 30, 2012. The following Janus funds and/or accounts are plaintiffs in this action: Janus Fund; Janus Twenty Fund; Janus Growth and Income Fund; Janus Worldwide Fund; Janus Balanced Fund; JAD INTECH Risk-Managed Growth Fund; JAD INTECH Risk-Managed Core Fund; INTECH U.S. Core Fund; Janus Research Fund; JAD Large Cap Growth Fund; JAD Growth & Income Fund; Janus Forty Fund; JAD Balanced Fund; JAD Research Core Fund; JAD Worldwide Fund; Janus Research Core Fund; JAS Large Cap Growth Portfolio; Janus Aspen Worldwide Portfolio; Janus Aspen Balanced Portfolio; Janus Global Life Sciences Fund; Janus Orion Fund; JCF US All Cap Growth Fund; JCF US Balanced Fund; JCF US Twenty Fund; JCF Global Life Sciences Fund; JCF US Research Fund; JCF INTECH US Risk Managed Core Fund; JCMLLC - INTECH Risk-Managed Global Core; INTECH U.S. Large Cap Value Fund Seed Account; Janus Institutional Select Growth Portfolio; INTECH US Enhanced Plus Fund LLC; INTECH US Broad Large Cap Growth Fund; and Janus Institutional Large Cap Growth Portfolio

(collectively, "Janus Funds"). Plaintiffs Janus Funds purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

53. College Retirement Equities Fund and the TIAA-CREF Funds are investment companies that issue variable annuities and mutual funds of varying classes. They are part of a group of a related entites branded collectively as "TIAA-CREF." As a group, these entities serve, principally but not necessarily exclusively, those in the academic, medical, cultural, governmental and research fields plan for retirement. As of March 31, 2012, TIAA-CREF had approximately $487 billion in assets under management. The following funds and/or accounts are plaintiffs in this action: College Savings Growth Fund; College Retirement Equities Fund - Equity Index Account; College Retirement Equities Fund - Global Equities Account; College Retirement Equities Fund - Growth Account; College Retirement Equities Fund - Social Choice Account; College Retirement Equities Fund - Stock Account; TIAA-CREF Mutual Funds - Equity Index Fund (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF Mutual Funds - Growth & Income Fund (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF Mutual Funds - Growth Equity Fund (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF Mutual Funds - Social Choice Equity Fund (f/k/a TIAA-CREF Institutional Mutual Funds); TIAA-CREF Asset Management Commingled Funds Trust I - Analysts Portfolio Fund; TIAA-CREF Asset Management Commingled Funds Trust I – Large-Cap Value Fund; TIAA-CREF Asset Management Commingled Funds Trust I - Large-Cap Growth Fund; TIAA Separate Account VA-1 - Stock Index Account; TIAA-CREF Funds - TIAA-CREF Equity Index Fund; TIAA-CREF Funds - TIAA-CREF Growth & Income Fund; TIAA-CREF Funds - TIAA-CREF Growth Equity Fund; TIAA-CREF Funds - TIAA-CREF Large-Cap Value Fund; TIAA-CREF Funds - TIAA-CREF Large-Cap Value Index Fund; TIAA-CREF Funds - TIAA-CREF S&P 500

Index Fund; TIAA-CREF Funds - TIAA-CREF Social Choice Equity Fund; TIAA-CREF Life Funds - Growth & Income Fund; and TIAA-CREF Life Funds - Growth Equity Fund (collectively, "TIAA-CREF Funds"). Plaintiffs TIAA-CREF Funds purchased Pfizer common stock during the Relevant Period and suffered damages as a result of the violations pled herein.

B. Defendants

1. Defendant Pfizer

54. Defendant Pfizer is a research-based global pharmaceutical company that discovers, develops, manufactures, and markets prescription medicines for humans and animals, as well as consumer healthcare products. In its public filings, Pfizer describes itself as "the world's largest research-based biomedical and pharmaceutical company." At all relevant times herein, Pfizer distributed or directed the distribution of pharmaceuticals to all fifty states and the District of Columbia, as well as in numerous countries around the world. Pfizer conducts its business directly, as well as through over 350 subsidiary entities, including Pharmacia Corporation. Pfizer is headquartered in New York, with its principal place of business at 235 East 42nd Street, New York, New York.

55. Pfizer is the successor-in-interest of G.D. Searle & Co. ("Searle") and Pharmacia Corporation ("Pharmacia"). Searle created two drug compounds, celecoxib (brand name: Celebrex) and vadecoxib (brand name: Bextra). On February 18, 1998, Searle and its parent company, Monsanto Company ("Monsanto"), and Pfizer entered into a U.S. Collaboration Agreement and Global Agreement to develop, commercialize, and promote Celebrex and Bextra (collectively, the "Co-Promotion Agreement"). On December 19, 1999, Searle's parent company, Monsanto, merged with Pharmacia. As a result of the merger, Pharmacia acquired the rights to Celebrex and Bextra, and succeeded to the rights of Searle in its Co-Promotion Agreement with Pfizer. On or about April 16, 2003, Pfizer acquired Pharmacia, including all of

Searle's and Pharmacia's interest in Celebrex and Bextra and its rights under the Co-Promotion Agreement, in a stock-for-stock transaction valued at $60 billion.

56. Unless otherwise stated, Searle, Monsanto, and Pharmacia are referred to herein, collectively and individually, as "Co-Promoter." In addition, Searle, Monsanto, Pharmacia and Pfizer are sometimes collectively referred to herein as "Pfizer."

2. The Individual Defendants

57. Defendant McKinnell was Pfizer's Chairman of the Board from May 2001 to December 2006 and served as its Chief Executive Officer from January 2001 to July 2006. In addition, McKinnell served as President of Pfizer Pharmaceuticals Group, the principal operating division of the Company, from January 1997 to April 2001; as Chief Operating Officer from May 1999 to December 2000; as Executive Vice President from 1992 to 1999; and in various other positions within the Company from 1971 to 1992. During the Relevant Period, Defendant McKinnell served on a number of committees comprised of Pfizer's most senior executives, including the Executive Leadership Team, the Development Planning Committee, and the Global Development Review Committee.

58. Defendant LaMattina was the Senior Vice President and President of Pfizer Global Research and Development from October 2003 until December 2007. Defendant LaMattina joined Pfizer in 1977 and held various positions of increasing responsibility in research and development before becoming Senior Vice President and President of Pfizer Global Research and Development. In April 2001, Defendant LaMattina became Vice President of Pfizer Inc.; Executive Vice President – Pfizer Global Research and Development; and President – Worldwide Research. In May 2002, Defendant LaMattina became Vice President of Pfizer Inc.; Executive Vice President – Pfizer Global Research and Development; and President Worldwide Research and Technology Alliances. During the Relevant Period, Defendant

LaMattina served on committees comprised of Pfizer's most senior executives, including Pfizer's Leadership Team, Development Planning Committee and the Global Development Review Committee.

59. Defendant Katen was appointed Vice Chairman and President – Pfizer Human Health in March 2005. As Vice Chairman of Pfizer and a senior executive officer, Ms. Katen reported directly to Defendant McKinnell. Defendant Katen joined Pfizer in 1974 and moved up the ranks to top senior executive positions. She was President of Pfizer's U.S. Pharmaceuticals Group from June 1995 to July 2002; Senior Vice President of Pfizer Inc. from May 1999 to April 2001; and Executive Vice President and President of Pfizer Global Pharmaceuticals, the Company's worldwide pharmaceutical organization, from April 2001 to March 2005. During the Relevant Period, Defendant Katen served on committees comprised of Pfizer's most senior executives, including Pfizer's Executive Committee, Development Planning Committee and the Global Development Review Committee.

60. Defendant Feczko was Pfizer's President of Worldwide Development and Executive Vice President of Pfizer Global Research and Development during the Relevant Period. He was named Chief Medical Officer on February 24, 2005, and remained in that position through the end of the Relevant Period. As President of Worldwide Development and Chief Medical Officer, Feczko reported directly to Defendants LaMattina and Katen. During the Relevant Period, Defendant Feczko served on committees comprised of Pfizer's most senior executives, including the Development Planning Committee, the Global Development Review Committee, and Pfizer's Leadership Team.

61. Defendant Cawkwell was the Medical Director of Major Markets, Celebrex, from December 2000 to February 2001. From February 2001 to June 2003, she was Medical Director,

Valdecoxib. From June 2003 through the end of the Relevant Period, she served as Medical Team Leader and Full Development Team Leader, Celecoxib.

62. Defendants McKinnell, LaMattina, Katen, Feczko and Cawkwell are collectively referred to herein as the "Individual Defendants."

63. The Individual Defendants were each members of key joint committees consisting of Pfizer and Co-Promoter employees, which were charged with overseeing the development and commercialization of Celebrex and Bextra. These committees included the Joint Executive Management Committee, the Joint Operations Committee, the Valdecoxib Joint Product Team, and the Bextra Publications Working Group. Through their participation on these joint committees, as well as their roles at the Company, they knew, and had access to, information concerning the undisclosed cardiovascular side effects of both drugs. The responsibilities of these committees are detailed below in Section VII.E.

64. The Individual Defendants are liable for the materially false and misleading statements and omissions of material fact pleaded herein. As set forth more fully below, the Individual Defendants possessed the power and authority to control the contents of the false and misleading statements issued by Pfizer, and whether and how to communicate them. The Individual Defendants themselves made several of the false and misleading statements at issue, and all of the Individual Defendants were involved in preparing, drafting, reviewing and/or disseminating the false and misleading statements issued by Pfizer alleged herein to be misleading, approved or ratified these statements and, therefore, adopted them as their own. The Individual Defendants were also provided with copies of these statements prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be

corrected. As a result, the false and misleading statements asserted herein can be attributed to the Individual Defendants explicitly and/or implicitly from the surrounding circumstances.

65. Further, Defendant McKinnell signed the Company's SEC filings during the Relevant Period, and certain of these SEC filings contained certifications signed by Defendant McKinnell pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Consequently, McKinnell is responsible for the truthfulness and accuracy of Pfizer's public reports, press releases and other statements concerning, among other things, the medical and commercial viability of Celebrex and Bextra and the Company's financial results. Defendant McKinnell is primarily liable for the materially false and misleading representations and omissions of material facts contained within these statements.

66. In addition, under the rules and regulations promulgated by the SEC under the Exchange Act, including Regulation S-K Item 303, the Individual Defendants had a duty to report all trends, demands or uncertainties that were reasonably likely to impact Pfizer's revenues, expenses, and previously reported financial information, such that it would be indicative of future operating results. As detailed below, the Individual Defendants' misrepresentations and omissions during the Relevant Period violated these requirements and obligations as well as their duties and obligations pursuant to the Exchange Act.

67. By virtue of their high-level positions within Pfizer, the Individual Defendants directly participated in the management of the Company, were directly involved with the Company's day-to-day operations, and were privy to confidential non-public information concerning Celebrex, Bextra, and the operations of Pfizer. Among other things, the Individual Defendants attended management and/or board of directors meetings, and had access to internal Company documents, reports and other information, including adverse non-public information

regarding Pfizer's business, operations, products and future prospects, and non-public information concerning Celebrex and Bextra.

68. Because of their high-level positions with the Company, and their access to material non-public information, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were materially false and misleading. Each of the Individual Defendants knew or recklessly disregarded the fact that the false and misleading statements and omissions complained of herein would adversely affect the integrity of the market for Pfizer's stock, would cause the price of Pfizer's common stock to become artificially inflated, and would expose Celebrex and Bextra users to a significant risk of injury or death. Each of the Individual Defendants acted knowingly or in such a reckless manner as to constitute a fraud and deceit upon Plaintiffs.

V. PFIZER DEVELOPS CELEBREX AND BEXTRA AS A SAFE ALTERNATIVE TO TRADITIONAL NSAIDS

A. The Safety Risks Associated With Traditional, Non-Selective NSAIDs

69. Traditional nonsteroidal, anti-inflammatory drugs, such as aspirin, ibuprofen (Advil), and naproxen (Aleve), are effective in reducing pain and inflammation, and are widely used to treat persons suffering from arthritis, muscle pain, and other inflammatory conditions. Traditional NSAIDs work by inhibiting the cyclooxygenase enzyme, which catalyzes the formation of prostacyclin and thromboxane, two prostaglandins that naturally exist in the body. Prostacyclin and thromboxane have opposite effects: prostacyclin widens blood vessels and inhibits blood clotting; in contrast, thromboxane narrows blood vessels and promotes blood clotting. These two chemicals normally exist in the body in a natural balance referred to as homeostasis.

70. Long-term use of traditional NSAIDs can cause gastrointestinal ("GI") and renal (kidney) problems. Adverse GI effects caused by traditional NSAIDs include nausea, indigestion, and, in more severe cases, gastric perforation, ulceration and bleeding. Adverse renal effects include salt and fluid retention, and high blood pressure. According to the December 8, 2010 sworn testimony of Dr. Philip Needleman, head of Research & Development at Searle and, later, Pharmacia, traditional "NSAIDs are the biggest single cause of drug-induced hospitalizations and caused 16,500 deaths a year in over 100,000 severe hospitalizations from the GI side effects."[3]

B. Discovery Of The COX-2 Enzyme Raises Hopes For A Selective NSAID That Is Safer Than Traditional Pain Killers

71. For many years, scientists only recognized one form of the cyclooxygenase enzyme. This form, now known as COX-1, is naturally present in the stomach lining, where it helps play a protective role in preventing erosion of the stomach lining by the stomach's own acid.

72. In the early 1990s, scientists discovered a second form of the COX enzyme, referred to as COX-2. Unlike COX-1, this enzyme is not normally present in the stomach and only appears in the stomach when there is inflammation, and at the site of the inflammation. Following the discovery of the COX-2 enzyme, scientists concluded that COX-2, but not COX-1, was primarily involved with pain and inflammation.

73. Traditional NSAIDs inhibit both the COX-1 and COX-2 enzymes – in this respect, they are "non-selective." Following the discovery of the COX-2 enzyme, scientists realized that traditional NSAIDs relieved pain and inflammation by inhibiting COX-2, but caused GI and renal problems by inhibiting COX-1. This discovery raised hopes that a drug

[3] *See* 12/8/10 Deposition Tr. of Dr. Philip Needleman at 38:22-39:1.

could be developed that would selectively inhibit the COX-2 enzyme, but not COX-1, and thereby provide the relief from pain and inflammation provided by traditional NSAIDs while simultaneously avoiding the safety risks associated with traditional NSAIDs.

74. Pfizer, as well as numerous other pharmaceutical companies and Wall Street analysts, appreciated early that a drug that selectively inhibited the COX-2 enzyme (and not the COX-1 enzyme) could have the potential for enormous commercial success. These drug companies and analysts recognized that patients suffering from diseases that cause chronic pain and inflammation, such as arthritis, would benefit from a painkiller that did not have the side effects associated with traditional NSAIDs.

75. As a result of this market opportunity, a race emerged among the major U.S. pharmaceutical companies to create the first COX-2 inhibitor, with Pfizer/Searle and Merck the major competitors. As one October 21, 1997 *Bloomberg* report explained, "[w]ith a potential market of $5 billion at stake," Pfizer/Searle and Merck "are running a tight race to get a new type of painkiller to market, with both of them in final clinical tests with osteoarthritis patients." The report quoted research analyst, David Maris of Aros, who stated that these drugs "have the potential to make all other non-steroidal anti-inflammatory drugs obsolete." As noted in a December 21, 1998 report by the Chemical Markets Reporter, a weekly trade publication, it "remains a toss-up as to which [Searle/Pfizer or Merck] will have a better position in the marketplace."

C. Pfizer Enters The Race For The First COX-2 Inhibitor

76. Beginning in the late 1990s, and continuing through the Relevant Period, Pfizer faced a serious problem impacting its future financial stability: the patents for a number of its major drugs were set to expire in the upcoming years. Pfizer faced looming patent expiration dates for some of its best-selling drugs, including Diflucan, Zithromax, Novasc, and Zoloft.

Defendants knew that, once Pfizer's patents on these drugs expired, generic versions of the drugs would enter the market and draw market share away from Pfizer. Accordingly, Pfizer urgently needed to identify, develop, and commercialize drugs with fresh patents to offset for this expected decline in future revenues.

77. As reflected in the chart below, when the first of Pfizer's COX-2 inhibitors, Celebrex, reached the market in 1999, Pfizer's next five major patents set to expire accounted for $7.8 billion or 39% of Pfizer's revenue from all of its pharmaceuticals business, and over 32% of the Company's revenue from all of its 33 major human pharmaceutical brands sold during the Relevant Period.

Pfizer Drug	Patent Expiration	1999 Revenue (in millions)
Accupril	2002	$514
Diflucan	2004	$989
Zithromax	2005	$1,309
Norvasc	2006	$2,991
Zoloft	2006	$1,997
Total		**$7,800**

78. In order to identify and commercialize new blockbuster drugs to offset the anticipated decrease in revenues from these patent expirations, Pfizer joined forces with Searle, a pharmaceutical company that had identified two potential COX-2 candidates – celecoxib (Celebrex) and valdecoxib (Bextra). On February 18, 1998, Pfizer entered into two agreements with Searle and Monsanto, collectively referred to as the Co-Promotion Agreement. The Co-Promotion Agreement, which was executed by Defendant McKinnell on behalf of Pfizer, contemplated that Pfizer would jointly develop and commercialize Searle's two COX-2 candidates.

79. Pursuant to the terms of the Co-Promotion Agreement, Pfizer made a lump-sum payment to Searle of $85 million and agreed to pay an additional $230 million upon the achievement of certain milestones. Also part of the Co-Promotion Agreement, Pfizer committed to devote substantial time and resources to the development of Celebrex and Bextra. In particular, Pfizer agreed to devote "substantially equal efforts and resources [as its Co-Promoter] to the marketing, promotion, and detailing" of the COX-2s.[4] In consideration for this commitment and payment, the Co-Promoter agreed to provide Pfizer a percentage of future sales on Celebrex and Bextra.

80. The Co-Promotion Agreement provided Pfizer with the unfettered right to review "all pre-clinical and clinical data and all Product NDA, IND, or other regulatory filings" for Celebrex and Bextra. It states that, "[p]romptly following the completion of Phase II, [the Co-Promoter] shall … provide Pfizer with all material clinical data and the opportunity to review other clinical data, non-clinical data and regulatory communications resulting from Phase II, together with all final study reports relating thereto and a Phase III development plan."[5]

81. The Co-Promotion Agreement also gave Pfizer the right (and the obligation) to review and approve all press releases or other public statements made by its Co-Promoter relating to jointly marketed COX-2 drugs, including Celebrex or Bextra. On this subject, the Co-Promotion Agreement stated, among other things, that "[n]either party shall originate any news release or public announcement, written or oral, relating to the Agreements without the prior written approval of the other party except as otherwise required by Law."[6] Accordingly, by

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[4] *See* 2/18/98 U.S. Collaboration Agreement (Celecoxib), bearing Bates No. DEFS 509082-121 (attached to ECF No. 328 in the Pharmacia Securities Class Action).
[5] *See* 2/18/98 Global Agreement, bearing Bates No. DEFS 00508894-9080 (attached to ECF No. 328 in the Pharmacia Securities Class Action).
[6] *See* 2/18/98 U.S. Collaboration Agreement (Celecoxib), bearing Bates No. DEFS 509082-121 (attached to ECF No. 328 in the Pharmacia Securities Class Action).

announcing the Co-Promotion Agreement, Defendants assured investors that subsequent statements made by either Pfizer or its Co-Promoter relating to Celebrex or Bextra were jointly approved and issued by both companies.

82. On this subject, Susan Yarin, Pfizer's former Director of Media Relations, testified as follows:

> Q: How did you represent Pfizer in regard to the co-promoter [sic] agreement and working with Pharmacia [i.e, Pfizer's Co-Promoter]?
> **A. The co-promote agreement required that both companies agree upon anything that was done, in other words, one company would not put out an ad or press release or anything independent of the other company. So when something was initiated by Pharmacia, my role was to take it and vet it through Pfizer**.
>
> * * *
>
> Q. Any press release that Pharmacia issued regarding Celebrex or Bextra, Pfizer would have had the opportunity to review, correct?
> **A. Yes.**
>
> * * *
>
> Q. Pfizer also had the opportunity to provide input regarding those press release [sic], is that correct?
> **A. Yes.**
>
> Q. What input did you provide with respect to Celebrex or Bextra press releases that Pharmacia issued, if you can recall?
> **A. Review of content and insuring that the press release received review, appropriate review, on the Pfizer side.**
>
> Q. Did you personally review the content of the press releases relating to Celebrex and Bextra?
> **A. They usually came into me first; I would generally look at them, yes, they came into me first.**
>
> Q. And then what would you do with them?
> **A. They would be vetted through a series of people in different capacities, but the most important was putting them through a review committee comprised of legal, medical, regulatory colleagues, who would look at them to make sure that they reflected accurate information.**
>
> Q. Is that part of the process that you described a moment ago relating to ensuring that they received appropriate review?
> **A. Yes.**[7]

[7] *See* 10/11/11 Tr. of S. Yarin Deposition at 20:25-23:20 (objections omitted) (quoted at ECF No. 420 at 20).

83. In addition, Pfizer and its Co-Promoter regularly issued joint press releases and used the same public relations firm to disseminate public statements about Celebrex and Bextra. Further, in concert with Pharmacia, Pfizer referred questions about certain press releases specifically to Dr. Steven Geis (a Pharmacia physician who Pfizer later hired as a consultant and expert witness). In short, under the Co-Promotion Agreement, Pfizer had and exercised the authority to control the content of statements jointly made by Pfizer and Searle, and later, Pfizer and Pharmacia, about Celebrex and Bextra.

84. As part of the Co-Promotion Agreement, Pfizer and its Co-Promoter agreed to establish joint committees composed of senior executives from each company tasked with overseeing the day-to-day development and commercialization of Celebrex and Bextra, including the Joint Executive Management Committee, the Joint Operations Committee, the Joint Valdecoxib Joint Product Team, and the Joint Bextra Publications Working Group. As set forth more fully below (*e.g.*, ¶¶335-59), members of these groups, which included each of the Individual Defendants, reviewed and discussed information concerning Celebrex's and Bextra's undisclosed cardiovascular safety risks.

85. On February 18, 1998, Pfizer issued a press release announcing the Co-Promotion Agreement. In its press release, Defendant McKinnell assured investors that "Celecoxib promises to bring relief to millions who suffer from arthritis and represents a major medical and commercial opportunity for both Searle and Pfizer." Searle and Pfizer's COX-2s would be safe for chronic use, in contrast with "all currently available NSAIDs [which] can cause adverse effects [that] limit their usefulness." Pfizer represented to the public and investors that its COX-2 inhibitors would have the benefits of traditional NSAIDs, but without their safety risks.

D. Pfizer Successfully Launches Celebrex In 1999

86. Pfizer and Searle won the race to bring the first COX-2 inhibitor to market. Pfizer obtained FDA approval of Celebrex on December 31, 1998, three months before Merck received FDA approval for Vioxx. Shortly thereafter, Celebrex was available by prescription for use in treating pain and inflammation caused by osteoarthritis and adult rheumatoid arthritis. Later, on October 22, 2001, Pfizer announced that the FDA had approved Celebrex for the treatment of acute adult pain or pain after surgery, and primary dysmenorrhea (painful menstrual cramps).

87. Investors and analysts closely followed the launch of Celebrex and its impact on Pfizer's business and financial results. In August 21, 1998, for example, analysts at Gruntal Investment Research (now part of Stifel Financial) rated Pfizer shares a "Strong Buy" based largely on expectations regarding Celebrex's blockbuster potential. Under the heading, "Celebra - Pfizer's Next Possible Blockbuster with $3 Billion Peak Sales Potential," analysts at the independent investment firm noted that: "We believe [Celebrex] has blockbuster, multi-billion dollar sales potential in the large $12 billion pain and inflammation market. We expect Pfizer to continue its strong track record in the co-marketing of products through its current co-marketing deal for Celebra with Monsanto's G. D. Searle pharmaceutical unit . . . ."

88. As of December 1, 1998, according to a report in the *Associated Press*, "[a]nalysts predict[ed] that tens of millions of people will take cox 2 inhibitors to relieve a variety of kinds of pain." By May 22, 1999, expectations had become even greater, with "[a]nalysts say[ing] Vioxx and Celebrex each have sales potential of more than $2 billion annually," according to a report published by *The Record*.

89. Celebrex had a widely successful launch. By 2000, Celebrex was already among a select group of only eight Pfizer human pharmaceutical products with sales of over $1 billion. As Dr. Philip Needleman stated at his December 8, 2010 deposition in the Pfizer Securities Class

Action, Celebrex's launch was one of "***the most successful launches of all times.***"[8] Market competition, however, remained intense, with Merck looking to capture market share by showing that its drug, Vioxx, was safer than Celebrex. As noted in one May 24, 1999 *Reuters* article, "competition between the two compounds promises to be fierce as they are the first in a class of COX-2 inhibitors, designed to treat pain ***without harmful side effects***."

E. Pfizer Successfully Launches Bextra In 2001

90. On November 16, 2001, Pfizer and its Co-Promoter obtained FDA approval for their second COX-2 inhibitor, Bextra. The FDA approved Bextra to treat osteoarthritis, rheumatoid arthritis, and menstrual symptoms. The FDA rejected Pfizer and its Co-Promoter's request for approval, however, of an indication that would allow Pfizer to promote Bextra to treat acute pain.[9]

91. Investors welcomed the news of Bextra's approval. According to a November 20, 2001 report in *The Star Ledger*, the FDA's approval of Bextra "appear[ed] to separate [Pharmacia's] arthritis drugs from Merck's ***in terms of cardiovascular concerns,*** analysts said." As *The Pharmaletter* similarly reported that day, "Bextra could have the differentiating marketing message it needs to be seen as a genuine next-generation drug that can continue the success of the class to date" and "is likely to garner market share from Vioxx." According to the same report, a research analyst from Leerink Swann & Co. estimated that the entire "COX-2 inhibitor franchise will achieve sales of $3.06 billion for full-year 2001, rising 20% to $3.67 billion in 2002 and 17% to $4.27 billion in 2003." Breaking out the numbers, a December 21, 2001 Credit Suisse analyst report "project[ed] 2002 sales for Bextra of $520 million and 2003 sales of $1.23 billion."

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[8] *See* 12/8/10 Deposition Tr. of Dr. Philip Needleman at 42:22-23.

[9] *See* 11/16/01 Letter from the FDA to G.D. Searle & Co. which attaches the FDA-approved label for Bextra, bearing Bates No. Bex NDA 21-341 00025109-127 (attached to ECF No. 383).

92. Bextra's launch also was a success, notwithstanding the limitations on its approved indication. In 2002, the first year of its launch, Bextra generated revenues of $470 million.

F. Pfizer Significantly Increases Its Financial Stake In The COX-2 Market

93. To further capitalize on the launch of Celebrex and Bextra, and concerned about the loss of its patents, Pfizer acquired Pharmacia, its Co-Promoter in the development and commercialization of Celebrex and Bextra, in a $60 billion transaction announced on July 15, 2002, and completed on or about April 16, 2003. Through the merger, pursuant to which Pharmacia became a wholly owned and controlled subsidiary of Pfizer, Pfizer gained all rights to Celebrex and Bextra. As Defendant McKinnell explained to *The New York Times* that day, "[b]y acquiring Pharmacia … Pfizer will be better prepared than any other drug company to thrive at a time when the industry is reeling from what some say is intense financial pressure caused by expiring patents on top-selling products and public anger over rising prices."

94. Analysts applauded the announcement. On August 22, 2002, for example, a team of analysts from Credit Suisse reported, "[w]e believe there is a strong strategic fit in the merger of these two companies, particularly with respect to complementary established and emerging new product development platforms." In discussing specifically the COX-2 product lines, the Credit Suisse analysts cited "integrated coordination in allowing the current franchise to extend it's current lead over Merck within the COX-2 strategy."

95. In announcing the acquisition, Defendants emphasized their own significant role in the initial development and commercialization of Celebrex and Bextra. For example, during a July 15, 2002 investor call, Defendant McKinnell highlighted that "[w]orking together, we have introduced Celebrex and [now] [Bextra]." Defendant Katen echoed that "through ***our partnership***, Pfizer and Pharmacia [have] buil[t] an impressive track record in the [COX-2] area.

First with the most successful launch in the pharmaceutical industry of Celebrex, followed by the recent lauch of [B]extra."

96. In addition, Defendant McKinnell assured investors that "we know Pharmacia well" through their collaboration to develop and commercialize Celebrex and Bextra. Through that collaboration, Pfizer had access to all of Pharmacia's confidential information relating to the safety and efficacy of the two drugs, including all of its clinical data. In addition, Defendants "kn[e]w Pharmacia well" through its due diligence in advance of the merger, which provided the Company with additional access to its Co-Promoter's confidential information.

97. On April 16, 2003, Pfizer and Pharmacia "began operating as a unified company," as stated on Pfizer's website Pfizer's website further quotes Defendant McKinnell, who explained that, beginning April 16, 2003, "we go forward as a single company." Once the merger was completed, Pfizer entirely controlled and owned all of Pharmacia's confidential information relating to the two drugs, including all of its clinical data.

G. Celebrex And Bextra Become Critical To Pfizer's Overall Financial Results

98. After the completion of the merger, Pfizer was entitled to 100% of all revenues from Celebrex and Bextra. Both drugs remained popular with patients and prescribing doctors, and generated extraordinary revenues for the Company. As reflected in the chart below, the combined sales of Celebrex and Bextra were in excess of $3.5 billion in 2002, or ***12.4% of the Company's total pharmaceutical revenues.*** In 2003, the two drugs produced sales of over $2.5 billion and, in 2004, the drugs generated over $4.5 billion, which constituted ***nearly 10% of the Company's overall sales***.

Year	Celebrex Sales (in millions)	Bextra Sales (in millions)	Celebrex and Bextra Sales (in millions)	Celebrex/Bextra Sales as Percent of Revenue from Pharmaceuticals
FY 1999	$1,471	-	$1,471	6.7%
FY 2000	$2,614	-	$2,614	11.0%
FY 2001	$3,114	-	$3,114	12.3%
FY 2002	$3,050	$470	$3,520	12.4%
FY 2003	$1,883	$687	$2,570	6.5%
FY 2004	$3,302	$1,286	$4,588	9.9%
FY 2005	$1,730	$(61)	$1,669	3.8%

Throughout the Relevant Period, Pfizer was dependent on a steady stream of multibillion dollar sales from these drugs to compensate for lost revenues due to the expiration of its critical patents.

VI. DEFENDANTS CONSISTENTLY EMPHASIZE THE CARDIOVASCULAR SAFETY AND COMMERCIAL IMPORTANCE OF CELEBREX AND BEXTRA

99. From the time of Celebrex's launch in 1999 and continuing beyond Merck's withdrawal of Vioxx from the market in September 2004, Pfizer consistently represented Celebrex and Bextra as highly effective and entirely safe drugs from a cardiovascular perspective, completely free of any cardiovascular risk. In press releases, SEC filings, analyst conference calls, advertisements and other public statements, Defendants repeatedly touted internal testing and other safety data which they claimed demonstrated cardiovascular safety and generated no evidence of cardiovascular risk. In addition, they highlighted Celebrex's and Bextra's allegedly superior cardiovascular safety profile as compared to the drugs' primary COX-2 competitor, Merck's Vioxx. Defendants further touted the extraordinary commercial

success and importance of the drugs, including to Pfizer's overall financial results, and represented this performance would continue well into the future.

100. Unbeknownst to Pfizer's investors, however, from at least as early as 1999, and in stark contrast to their public statements, Defendants were in possession of completed drug safety studies, epidemiological data, and other information which documented serious cardiovascular risks of Celebrex and Bextra. These materials, derived from a multitude of clinical studies and other internal tests, flatly contradicted or rendered false or misleading statements made by or on behalf of the Defendants throughout the Relevant Period. Once the truth materialized in a series of events and disclosures, sales of Celebrex fell dramatically and Bextra was removed from the market. As a result, Pfizer's stock price declined substantially.

A. From The Outset Of Launch, Defendants Tout The Cardiovascular Safety And Commercial Importance Of Celebrex And Bextra

101. Almost immediately after it first sought approval of Celebrex in 1998, until late 2004 and 2005, Pfizer and its Co-Promoter publicized the purported cardiovascular safety and commercial importance of Celebrex. Pfizer and its Co-Promoter made similar statements with respect to Bextra from the time of Bextra's approval in 2001 until late 2004 and 2005.

102. For example, on February 1, 1999, Dr. Needleman (head of Research & Development at Searle and, later, Pharmacia) gave an interview to the *Philadelphia Inquirer* in which he boasted that "There has been no evidence of extra heart problems in the approximately 9,000 people who have taken Celebrex in trials." In addition, Dr. Peter Isakson (also a senior Research & Development executive at Searle, and its executive director of COX-2 technology) assured the investing public that Searle and Pfizer would be monitoring the cardiovascular safety of Celebrex. "In fact we'll keep track of all safety around the patients taking the drug," Dr.

Isakson stated. "We'll monitor cardiovascular just like we monitor all the safety around Celebrex," he stated.

103. On the one-year anniversary of Celebrex's launch, Pfizer issued a press release boasting that Celebrex was "***the most successful pharmaceutical launch in U.S. history***." The February 22, 2000 press release, titled "Celebrex Sets Industry Records in First Year Generating 19 Million Prescriptions: An Estimated Seven Million Patients," further declared that "The overwhelming response to Celebrex, including the number of patients who are continuing on the product, is a ***clear signal*** that this is a safe and effective arthritis medication that can be used for the long term."

104. As sales of the drug reached blockbuster status, Pfizer continued to publicize Celebrex as an effective and safe form of pain reliever compared to traditional NSAIDs, with no increase in cardiovascular side effects even at high doses. In an April 17, 2000 press release, for example, Pfizer highlighted the results of a "landmark" study to assess the overall long-term safety of Celebrex (*i.e.*, the CLASS Study), which Pfizer claimed showed that the drug was effective and safe, that arthritis patients taking four times the recommended osteoarthritis dose of Celebrex "experienced fewer symptomatic gastrointestinal (GI) ulcers and ulcer complications than patients taking ibuprofen and diclofenac," and, "[i]mportantly, [that] Celebrex showed ***no increase*** in thromboembolic or other cardiovascular-related events, even among non-aspirin users."

105. Pfizer issued numerous other statements emphasizing the comparative safety of Celebrex over traditional NSAIDs shortly after Celebrex's launch. A Pfizer press release dated May 23, 2000, for example, highlighted Celebrex's comparative cardiovascular safety over ibuprofen and diclofenac during the first few days of treatment. According to the press release,

new data from a Celebrex long-term safety study revealed that "the risk for serious gastrointestinal complications with the NSAID comparators ibuprofen and diclofenac can start within the first few days after treatment begins," however, there was "no such increase" observed with patients taking Celebrex. According to the press release, the benefits continued even at high doses. "The long-term safety study also indicated that four times the recommended OA dose of Celebrex, taken with or without aspirin, posed ***no increased risk*** of heart attacks or strokes compared with ibuprofen and diclofenac," the press release declared.

106. Pfizer was particularly eager to differentiate the cardiovascular safety profile of Celebrex from Vioxx, which was a pillar of the Company's marketing strategy for Celebrex. Thus, for example, in a June 22, 2000 press release, Pfizer declared that "[n]ew data derived from the first-ever head-to-head safety study" comparing Celebrex with Vioxx showed that hypertensive osteoarthritis patients taking Vioxx "experienced statistically significantly more increases in edema and systolic blood pressure compared with those taking Celebrex." The press release further highlighted that "Vioxx-treated patients experienced a ***two-fold increase*** in clinically significant edema compared to the Celebrex-treated patients" and, "[o]f greater importance, results reveal that within two weeks of the start of the study, ***significantly more patients on Vioxx*** had clinically meaningful increases in systolic blood pressure … versus those on Celebrex."

107. In response to early concerns that COX-2 inhibitors as a class may elevate cardiovascular risk, Pfizer and its Co-Promoter reassured the market via press interviews that in their "extensive clinical experience, involving thousands of patients, there was ***no incidence*** of

serious cardiovascular events that could be attributed to Celebrex."[10] Q&A's developed by Pfizer, Searle, and a public relations firm for posting on Monsanto's (Searle's parent company) website, including a "Q&A" and "Message Points" dated March 4, 1999, stressed that in clinical trial data, there was no difference in the incidence of cardiovascular events between patients taking Celebrex and those taking a placebo. The Q&A presented the following series of questions and answers:

> Question: How many people experienced an adverse cardiovascular event in the clinical trials? What types of events were experienced?
>
> Answer: There was ***no difference*** in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo.
>
> Question: Does Celebrex pose cardiovascular risk to patients who already have a prior history of cardiovascular disease or risk factors?
>
> Answer: There was ***no evidence*** of increased risk of cardiovascular events among patients taking Celebrex.[11]

108. Analysts embraced these and other public statements made (and adopted) by Defendants at Celebrex's launch. For example, an April 18, 2000 Deutsche Bank Alex Brown analyst report upgraded Pfizer to a "STRONG BUY," and in its next report on May 2, 2000, predicted that "Celebrex could achieve peak sales of $3 billion." Likewise, a May 16, 2000 JPMorgan research report stated that "Celebrex is expected to be a huge success, with sales projected to increase 60% in 2000 to $2.4 billion and grow to $4.4 billion by 2004 ($5.9 billion including valdecoxib [Bextra] - Searle's next generation COX-2)." JPMorgan further reported that, "The COX-2s (Celebrex and valdecoxib [Bextra]) are together expected to drive roughly 7-8% of overall revenue growth between 2000 and 2003." Analysts supported their reports and

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[10] *See* 1/15/99 Draft "Searle & Pfizer Statement on 'Cox-2 Inhibitors' and Cardiovascular Risk," bearing Bates No. GVL 10000243298-99 (quoted at ECF No. 420 at 26).

[11] *See* Q&A Regarding the University of Pennsylvania Study: Celebrex and Cardiovascular Risk, bearing Bates No. Lefkow-J 10000211705-10 (quoted at ECF No. 420 at 29).

conclusions by referencing Celebrex's purported superior safety profile. "Importantly, Celebrex was not implicated in any thromboembolic or other cardiovascular event, such as edema or increased risk of heart attack," stated a December 5, 2000 CSFB analyst report.

B. Defendants Continue To Tout Celebrex's And Bextra's Cardiovascular Safety And Commercial Importance After Sales Of The Drugs Reached Blockbuster Status

109. As sales of Celebrex and later Bextra reached blockbuster status, Defendants continued to emphasize to investors and the public the purported cardiovascular safety of the two drugs, their comparative cardiovascular safety over traditional NSAIDs and Vioxx, and the drugs' commercial success and importance to the Company's overall financial results.

110. For example, a January 24, 2001 press release announcing Pfizer's fourth quarter 2000 and fiscal year 2000 financial results declared that "Celebrex provides ***unsurpassed efficacy, outstanding tolerability, and a superior safety profile to Vioxx***," and "Celebrex showed ***no increase*** in thromboembolic or other cardiovascular-related events, even among non-aspirin users." The press release underscored that "***Celebrex remains the most successful drug launch in the history of the pharmaceutical industry***, as measured both by its first year on the market and by its continued performance in its second year."

111. In February 2001, the FDA held hearings regarding the cardiovascular safety of Celebrex and Vioxx. Pfizer's Co-Promoter, Searle prepared a submission for the hearings regarding the cardiovascular safety of Celebrex. The 2001 FDA advisory committee hearings resulted in a cardiovascular warning for Vioxx, but not for Celebrex. This difference in cardiovascular safety profiles between Celebrex and Vioxx gave Pfizer and its Co-Promoter a powerful marketing advantage over Vioxx, and Pfizer exploited the differing cardiovascular safety profiles in marketing efforts for years afterward.

112. Indeed, shortly after the FDA advisory committee hearings, on April 18, 2001, Pfizer issued a press release boasting of Celebrex's competitive and safety advantage to Vioxx. The press release, which also announced Pfizer's first quarter financial results, declared that "***Celebrex provides unsurpassed efficacy, outstanding tolerability, and a superior safety profile to Vioxx***." The statement became a Company mantra, as it was repeated verbatim in numerous press releases and other public statements made by Defendants during the Relevant Period.

113. In August 2001, an article was published in the Journal of the American Medical Association ("JAMA") that questioned the cardiovascular safety of COX-2 inhibitors. In response to the JAMA article, Pfizer issued a press release on August 21, 2001 emphasizing that "Celebrex studies have consistently shown ***no increased risk for heart attack or stroke,*** compared to traditional NSAIDs studied." The press release stated that "Pharmacia and Pfizer strongly support the cardiovascular safety profile of Celebrex," and that the JAMA article "is not based upon any new clinical study." Finally, the press release warned that "it is essential to exercise extreme caution in drawing any conclusions from this type of analysis," which is "inconsistent with the clinical experience of CELEBREX."

114. On or about November 16, 2001, the FDA approved Bextra for use in treating osteoarthritis, rheumatoid arthritis, and primary dysmenorrhea. Three days later, Pfizer issued a press releasing announcing the approval of its second-generation COX-2 inhibitor, which emphasized Bextra's cardiovascular safety. The press release declared that "[i]n controlled arthritis trials, the use of BEXTRA at the recommended dose has ***not been associated with any increased risk of cardiovascular or renal complications*** versus NSAIDs studied." Likewise, on December 18, 2001, Pfizer declared over the *PR Newswire* that Bextra "offers improved

gastrointestinal toleration with ***no increase in renal or cardiovascular risk*** versus traditional non-steroidal anti-inflammatory drugs."

115. Analysts reacted positively to these and other public statements made (and adopted) by Defendants in 2001. For example, on October 17, 2001, a Bear Stearns report rated Pfizer shares "Attractive," set a target price of $45-48, and referenced management's statement that it was "confident that the upcoming label changes for Celebrex would be differentiated from Vioxx (Merck), potentially conveying a marketing advantage."

116. Indeed, on June 7, 2002, Pfizer issued a press release publicizing FDA approval of new Celebrex prescribing information. The press release highlighted that, in addition to new gastrointestinal safety data, "the revised label also includes data indicating that there was ***no increased risk for serious CV adverse events*** observed compared to the non-specific NSAID comparators," including "heart attack, stroke and unstable angina." Furthermore, the press release declared that "[t]he revised label ***reaffirms the cardiovascular safety profile of CELEBREX***" and "[a]nalysis of the safety data from CLASS shows there were ***no significant differences*** between treatment groups in the overall incidence of serious CV thromboembolic adverse events, such as heart attack, stroke and unstable angina."

117. On July 16, 2002, the *Wall Street Journal* published an article quoting Defendant McKinnell as saying, "[w]e have to communicate that cardiovascular safety is critical differentiation between Celebrex and Vioxx." McKinnell regarded this purported difference as "the drug's major advantage" over Vioxx since "Celebrex hasn't been linked to a risk of any heart problems, while the Merck pill has." Similarly, on July 29, 2002, Defendant McKinnell stated in an interview with *The Pink Sheets*: "I think the naproxen cardioprotection story is

thoroughly debunked. . . . ***There is no cardiovascular issue with Celebrex, clearly***. . . . I think I'd rather put, as a comparator in this study, Vioxx to show what the difference really is."

118. Analysts reacted positively to these and other statements made (and adopted) by Defendants in 2002. For example, on July 16, 2002, Deutsche Bank-North America issued a report that rated Pfizer shares a "Strong Buy" and stated that the Celebrex/Bextra franchise was "winning" a "fierce" marketing battle with Vioxx due, in part, to "positive" Celebrex label changes that were "more favorable on CV risks" than Vioxx and "nagging concerns around CV safety that focus primarily on Vioxx."

119. After Pfizer had completed its merger with Pharmacia on or about April 16, 2003, and assumed sole responsibility for marketing Celebrex and Bextra (and was to receive all of the revenue generated from sales of the drugs), Pfizer continued to trumpet the purported cardiovascular safety and commercial importance of Celebrex and Bextra, including in press releases, SEC filings, and general advertisements to the public.

120. For example, Pfizer filed multiple reports with the SEC during 2003 repeating the Company's mantra that "***Celebrex provides strong efficacy, excellent tolerability, and a proven safety profile***" and boasting that "***Celebrex is the #1 branded non-steroidal anti-inflammatory drug (NSAID) and the #1 COX-2-specific inhibitor in the world.***" The same or substantially identical statements were included in press releases issued by Pfizer on: (i) April 22, 2003, announcing the Company's first quarter financial results; (ii) on July 25, 2003, announcing the Company's second quarter financial results; and (iii) on October 22, 2003, announcing the Company's third quarter financial results – all of which were publicly filed with the SEC as exhibits to Forms 8-K.

121. Furthermore, beginning with a July 25, 2003 press release, Pfizer began to tout to the marketplace a "meta-analysis" that purported to show no increased cardiovascular risk in Celebrex relative to both placebo and traditional arthritis medicines. "We are continuing to demonstrate Celebrex's safety advantages," the press release stated. "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," the Company declared.

122. Once again, analysts embraced Pfizer's representations about the efficacy and cardiovascular safety of Celebrex and Bextra, including the Company's efforts to cast its Cox-2 franchise as having a comparative safety advantage over Merck's Vioxx. On March 7, 2003, for example, analysts from SG Cowen reported that "Pharmacia/Pfizer has delivered on its goal of adding market share points on a global basis with Bextra without cannibalizing Celebrex. Indeed, Celebrex/Bextra has gained about 11 percentage points of share since January 2002. This share gain is due in part to Bextra's profile, which features powerful efficacy and good safety, and a fierce marketing battle in which Pfizer/Pharmacia have gained the upper hand by portraying Vioxx as capable of inducing cardiovascular risk."

123. By 2004 Celebrex and Bextra had solidified their status as blockbuster drugs, with combined annual revenues of several billion dollars. As revenues from the drugs slipped in 2003 from previous years, in 2004, Defendants renewed their publicity campaign regarding cardiovascular safety. For example, Pfizer's January 22, 2004 press release announcing fourth quarter and fiscal year 2003 financial results repeated that "***Celebrex is the number 1 COX-2-specific inhibitor in the world, having the broadest range of approved indications.***" Likewise, the press release stated that "[i]n controlled comparative arthritis trials of up to 26 weeks, Bextra

in daily doses of 10 mg or 20 mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs."

124. Similar statements were also included in Pfizer's Form 10-Q for the first quarter of 2004, which added that: "***Since its launch in 1999, Celebrex has accumulated more than 10 million patient years of use and more than 149 million prescriptions worldwide, demonstrating efficacy and tolerability among a patient population whose need for long-term, effective relief of pain and inflammation is great and growing***." The Company's Form 10-Q for the second quarter of 2004 also contained substantially similar representations about Celebrex's and Bextra's purported safety and commercial importance, and added that European regulators had recently "completed a safety review and reaffirmed the use of COX-2-specific inhibitors such as Celebrex in a broad range of patients."

C. Defendants Reassure Investors Of The Cardiovascular Safety Of Celebrex And Bextra Even As Vioxx Is Withdrawn From The Market

125. On September 30, 2004, Merck announced that it was withdrawing its COX-2 inhibitor Vioxx from the market due to cardiovascular risks associated with the drug. The withdrawal of Vioxx followed a major safety study by the FDA which found that patients taking Vioxx at the highest recommended daily dosage had a threefold higher risk of heart attack and sudden cardiac death than those who had been taking a placebo.

126. Pfizer viewed the withdrawal of Vioxx as a major strategic opportunity to market its own COX-2 franchise virtually free of competition. Defendant McKinnell, Pfizer's then-CEO, immediately issued a directive to senior Pfizer management to seize upon Vioxx's withdrawal as a marketing opportunity for Pfizer's COX-2 inhibitors. Specifically, on September 30, 2004, at 8:47 a.m., McKinnell emailed Defendants Katen, LaMattina and Feczko and other senior officers of the Company regarding "VIOXX Withdrawal" and wrote:

> ***We need to move immediately to avoid collateral damage and to exploit what could be a major opportunity***. I see the priorities as the following: 1. Avoid this becoming a class effect. We need a press release out the door before 9 am making it clear that our clinical studies in tens of thousands of patients show no signal of cardiovascular complications. To the contrary we have seen strong signals of beneficial effects in cancer, etc. ***How to handle Bextra is an interesting problem. I suggest we focus on Celebrex***....[12]

127. Thus, on September 30, 2004, at 9:31 a.m., the same day that Merck announced the withdrawal of Vioxx and within forty-five minutes of McKinnell's "exploit what could be a major opportunity" email directive, Pfizer released a statement affirming the "well-established" "long-term cardiovascular safety" of Celebrex and Bextra. The September 30, 2004 press release declared that none of the Company's Celebrex studies had ever shown any increased cardiovascular risk, reasserted the cardiovascular safety of Bextra, and, once again, denied the existence of a class-wide COX-2 cardiovascular effect. Furthermore, Pfizer issued another press release the next day reiterating that: "***The 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, the world's most prescribed arthritis and pain relief brand***."

128. With senior management's approval and oversight, Defendant Cawkwell proceeded to broadcast this message in a spree of interviews with the press. For example, an October 1, 2004 article in *The Boston Globe* reported: "A Pfizer official, Dr. Gail Cawkwell, said the company knows of ***no study*** that shows an increased risk with Celebrex, which holds the largest share of the Cox-2 market." Likewise, on October 6, 2004, the *Associated Press Online* reported that Defendant Cawkwell called Dr. Fitzgerald's hypothesis regarding a class effect of

[12] *See* 9/30/04 Email from McKinnell to Katen, LaMattina, Feczko and other senior officers of the Company, bearing Bates No. Litwac-A 10000729025 (quoted at ECF No. 420 at 146).

COX-2 inhibitors "an interesting theory," but asserted that "'there is ***no evidence***' of increased risk of heart problems among the ***75 million*** Americans who have taken Celebrex."

129. Pfizer also ran media advertisements touting the supposedly "strong cardiovascular safety" of Celebrex. For example, a Pfizer advertisement in *The New York Times* on October 7, 2004, touted that (underlining in original):

(a) "Important patient studies with Celebrex show strong cardiovascular safety";

(b) "numerous studies of Celebrex show no increased risk of heart attacks or strokes"; and

(c) "Patients treated in clinical studies of <u>up to 4 years</u> show no increased cardiovascular safety concerns."

130. Pfizer further exploited the withdrawal of Vioxx by posting the following statements on the website, www.celebrex.com:

> For years, CELEBREX has been helping people with pain and arthritis feel better. Now we'd like to put your mind at ease, too. As you've probably heard, VIOXX®, a COX-2 drug for arthritis and pain, has been withdrawn from the market because it increased the risk of heart attacks and strokes. But, the information below should make you feel good about CELEBREX, which is also a COX-2 drug.
>
> * * *
>
> Does CELEBREX increase the risk of stroke, heart attack, or death by effects on the heart or blood vessels?
>
> ***In numerous studies, CELEBREX did not increase the risk of heart attack, stroke, or death caused by heart attack or stroke compared to patients taking traditional arthritis medications or a sugar pill.***

131. Analysts reacted positively to Defendants' strategy to capitalize on Vioxx's withdrawal. For example, on October 7, 2004, analysts from Smith Barney Citigroup stated that "we continue to believe the Vioxx withdrawal remains an incremental positive for PFE. Based on our analysis of available information, Celebrex cardiac safety profile appears much better than that of Vioxx . . . . We forecast 2005 WW Celebrex sales of $3.2 bill (6% of sales) & $1.3

bill (2% of sales) for Bextra, w/ total COX-2 EPS contrib of approx $0.42. If PFE gains 20-60% of Vioxx sales, we expect 2005 EPS to increase $0.05-0.15." The same day, analysts from SunTrust Robinson Humphrey reported that "with the market removal of Vioxx, we believe Celebrex (celecoxib) and Bextra (valdecoxib) are in prime position to gain the Vioxx market share. On October 4, we therefore boosted our Celebrex estimates by $195 million in 2004 (due to the 4Q), by $1.1 billion in 2005, by $1.325 billion in 2006, and by $1.425 billion in 2007 (see our note from last week). We stand by our recent Celebrex and Bextra revenue estimate increases. We reiterate our Buy rating on shares of PFE."

D. The Truth Begins To Emerge And Pfizer's Stock Price Declines, But Defendants Distort The Market With Further Misrepresentations

132. Approximately one week after Vioxx was withdrawn from the market, an editorial was published in *The New England Journal of Medicine* late Wednesday October 6, 2004, that questioned the safety of all COX-2 arthritis drugs, including Vioxx, Celebrex and Bextra. Whereas the market had consistently ignored such general comparisons in the past, this practice ceased once Vioxx's cardiovascular dangers were established and Vioxx was pulled from the market. The following day, on October 7, 2004, Pfizer's stock price fell stock fell 6% in response to the *The New England Journal of Medicine* editorial, as reported that day by the *Dow Jones News Service*.

133. As pressure continued to mount from the announcement of Vioxx's withdrawal, Pfizer could no longer deny that Bextra studies had shown increased cardiovascular risk (*i.e.*, the "interesting problem" referred to by McKinnell in his September 30 email directive). On October 15, 2004, Pfizer finally revealed the cardiovascular safety results of the CABG-2 Study in a so-called "Dear Healthcare Professional Letter" sent to physicians, which was discussed in

an accompanying press release.[13] Pfizer continued to claim, however, in the accompanying press release that CABG-2 "was just recently completed." The October 15, 2004 partial disclosure "knocked 4% off [Pfizer's] shares today," as reported by analysts at CIBC World Markets.

134. Although the market had learned some of the truth relating to Bextra, it credited Pfizer's continued denial that there was any study that showed Celebrex had increased cardiovascular risk. As noted in an October 15, 2004 UBS report: "Although we view the known risk/benefit profile of Bextra as acceptable, PFE is clearly positioning Celebrex as the lead COX-2. Despite exhaustive analysis and the most robust clinical database of all COX-2s, to date, Celebrex enjoys the complete absence of any CV red flag."

135. On November 4, 2004, *The National Post* of Canada reported that Celebrex "is itself suspected of contributing to at least 14 deaths and numerous heart and brain-related side effects," causing Pfizer's stock to slide by as much as 6.2%, as reported that day by *Reuters News.* However, in a story carried in *Dow Jones* the same day, Dr. Patrice Roy, Pfizer Canada's director of scientific affairs, represented that "[y]ou have to look at the data accumulated over time . . . . 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." As reported by *Dow Jones*, Roy went so far as to claim that Pfizer has recently announced a major program to investigate the ***cardio-protective potential*** of the drug.

136. The notion that Celebrex might actually ***prevent*** heart attacks and decrease the risk of other adverse cardiovascular events was conceived and publicized by Pfizer in an effort to divert attention from the recent disclosures about Bextra's increased risk of heart attack and stroke in certain patients. The notion was publicly repeated on multiple occasions, both before

[13] *See* 10/15/04 Dear Healthcare Professional Letter, bearing Bates No. East-P 10000567341-7347 (quoted at ECF No. 420 at 154).

and after *The National Post* article, by several other Pfizer executives, including Defendants McKinnell and Feczko.

137. For example, during an October 20, 2004 conference call with securities analysts to discuss the Company's third quarter 2004 financial results, Defendant Feczko represented that "a lot of the epidemiological studies" in the Company's possession "actually showed a trend toward some kind of ***beneficial effects*** seen on vasculature. So as part of what we're doing here – this isn't strictly a safety study, we're looking at improvement in inflammatory markers for cardiovascular disease and another aspect that improve its function."

138. Similarly, on the November 10, 2004 episode of the *Nightly Business Report*, Defendant McKinnell categorically denied any "cloud of uncertainty" about the safety and effectiveness of Celebrex and Bextra, and claimed that Pfizer's "current information" actually showed that Celebrex might be "***protective of the heart***."

139. The marketplace continued to credit Pfizer's denials of the existence of any study that showed Celebrex's increased cardiovascular risk, including placebo-controlled studies, as well as management's "cardio-protective" claim. For example, on November 4, 2004, Merrill Lynch reaffirmed its "buy" rating on Pfizer shares. In discussing why Pfizer is still rated a "buy," the Merrill Lynch "FlashNote" emphasized: "It is important to note than none of Pfizer's active control Celebrex studies have shown any difference from placebo. In addition, PFE has stated publicly that there has been no increased CV risk seen in its placebo controlled studies for Alzheimer's and FAP (prevention of colon ademonas) . . ." Similarly, an earlier October 21, 2004 A.G. Edwards & Sons, Inc. report on Pfizer, stated: "PFE recently reviewed the cardiovascular profile of Bextra with healthcare professionals, reiterating that there is no increased risk of cardiovascular thromboembolic events in people treated for osteoarthritis (OA)

and rheumatoid arthritis (RA). . . . PFE had also announced results from studies with Bextra in surgical settings (for which the product is not approved). . . . In general surgery Bextra in combination with parecoxib (IV formulation) showed no increase in cardiovascular thromboembolic events."

140. On November 10, 2004, *The New York Times* published an article linking Bextra to Vioxx based upon a presentation of results at an American Heart Association conference held the preceding day. The article explained that a professor from the University of Pennsylvania presented a study that suggested that Bextra usage was even more harmful to cardiovascular health, and referred to his findings as "***a time bomb waiting to go off***." Pfizer was able to blunt some of the impact of this news report by suggesting that the professor's findings were unreliable because the professor's study focused on the high risk setting of heart surgery. Pfizer pointed to other studies of Bextra involving 8,000 patients with arthritis, who were followed for 6 to 52 weeks, which found no heart problems.

141. In December 2004, Pfizer began to lose control over clinical study data it had concealed from the market relating to Celebrex's increased cardiovascular risks and could no longer contain the truth about Celebrex's safety profile. On December 17, 2004, the National Cancer Institute announced the premature cessation of a long-term, placebo-controlled trial of Celebrex in non-arthritis patients (known as the "APC Study") because of a dramatic increase in cardiovascular death and stroke among the trial participants. On this news, Pfizer's stock price dropped by 12%, as reported that day by *Reuters News*.

142. Once again, rather than admit that it had been concealing evidence of increased cardiovascular risk, Pfizer continued to mislead the market by maintaining publicly that the increased cardiovascular risk seen in the APC Study was an outlier and that no prior

cardiovascular risk signals had been seen in its studies. For example, in a December 20, 2004 broadcast of CNBC's *Kudlow & Cramer,* Defendant McKinnell stated, "we had lots of data, 10 years of data and over 40,000 patients from controlled clinical studies that showed ***no evidence of cardiovascular risk***. There's also been five very large published reports of our database and other people's databases since the drug was introduced. ***Five out of five show cardiovascular risk less than any other treatment option*** . . . . That [the APC Study] was the first time we had that kind of information." Likewise, the *Wall Street Journal* reported the same day that McKinnell stated: "Vioxx made us alert to this risk. We had early signals of cardiovascular risk with Vioxx. ***We saw none of that in our data for Celebrex.***"

E. Pfizer Secretly Changes The Alzheimer's 001 Study Conclusions

143. In late 2004 and early 2005, in response to increasing pressure from the FDA and European regulators, Pfizer secretly worked to change the conclusion that had been reported to the FDA in 2001 regarding the Alzheimer's 001 Study. Pfizer continued, however, to represent publicly that ***no evidence*** of cardiovascular risk had been seen in the clinical trial data for Celebrex. For example, in an interview published in *USA Today* on January 4, 2005, when asked why Celebrex should still be on the market given Vioxx's cardiac risks, Defendant McKinnell answered:

> There are two major differences. One is they are different chemical families. They both target the COX-2 enzyme, but they're different molecules. They affect the body differently. ***Secondly, all of our own clinical data, which include 40,000 patients, show no evidence of cardiovascular risk.*** In these large patient-test studies, they show consistently that ***Celebrex actually has less cardiovascular risk than people receiving no treatment at all.***

144. On January 24, 2005, however, with no surrounding publicity, Pfizer quietly posted the five-year-old, never-before-published cardiovascular results of the Alzheimer's 001 Study in a study "synopsis" on an industry-specific web site. Pfizer's surreptitious posting of the

Alzheimer's 001 Study synopsis on the Internet did not work, as the "synopsis" was soon discovered by a health advocacy group and brought to light in *The New York Times* February 1, 2005 exposé detailing how Pfizer had concealed the results since 1999. The article explained that Sidney M. Wolfe, a director of Public Citizen, a consumer advocacy group, found the synopsis at the end of January 2005 "on a new Web site where Pfizer and other drug companies have begun to post some clinical trial results" and that "the results had not been on the site a few weeks earlier." Dr. Wolfe, who was present for and spoke at the February 7, 2001 Advisory Committee hearings (discussed above) where neither the Alzheimer's 001 Study or the SUCCESS Study results were disclosed, was quoted in *The New York Times* exposé as stating, ***"'It's a clear signal that I would have loved to have known about four years ago.'"*** *The New York Times* further reported that Dr. Kenneth Brandt, a professor of medicine at Indiana University School of Medicine, who was part of a panel that reviewed Celebrex safety in 2001, "said that if the safety panel had known about the study, it might have recommended that ***both Vioxx and Celebrex be taken with greater caution***."

145. Defendants continued to misrepresent the cardiovascular safety profile of Celebrex and Bextra through the end of the Relevant Period, claiming that all studies showing increased cardiovascular risk for Celebrex were isolated or aberrations. Misleading patients, doctors and investors, Pfizer also spun the less damning story that COX-2's "needed more study." For example, an April 5, 2005 press release issued by Pfizer stated:

> For the Cox-2 portfolio, Pfizer looks forward to finalizing changes to its U.S. labeling with the U.S. Food and Drug Administration (FDA) as well as moving ahead with plans for clinical studies to further explore the benefits as well as the risks of the Cox-2 specific medicines compared to older, non-selective medicines. In the interim, Pfizer remains focused on the importance of these products for millions of patients around the world. "We believe that, with continued clinical work and appropriate labeling, these medicines will remain

important treatment options for patients and doctors for many years to come," Katen said.

F. The FDA Requires A "Black Box" Warning Label On Celebrex And Directs Pfizer To Pull Bextra From the Market

146. The FDA ultimately requested that Pfizer change the label for Celebrex after considering the presentations, discussions and recommendations from a joint meeting of the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees held on February 16, 17 and 18, 2005. The Committees informed the FDA that "for at least the three approved COX-2 products [Vioxx, Celebrex and Bextra], a class effect appears to be present." The Committees also reported that "the GI benefits of the COX-2s appear to be less than first reported . . . [with] no clear data that show GI benefit[s] for Celebrex and Bextra."[14]

147. On April 7, 2005, upon urging from the FDA, Pfizer agreed to insert a black box warning in Celebrex's label. A black box warning is the most serious of three levels (contraindications, cautionary statements, black box warnings) of product label warnings required by the FDA for human prescription drugs. Black box warnings are reserved for special problems, particularly those that may lead to death or serious injury. Black box warnings must be prominently displayed in the labeling of the prescription medicine in an area determined by the FDA. Other than pulling the drug from the market, the black box label is the most potent FDA warning, and often has a significant negative impact on a drug's sales. Physicians tend not to prescribe drugs with a black box warning because they fear liability if an adverse event occurs and the label clearly states why the drug should not be prescribed.

[14] *See* Feb. 16-19, 2005 Minutes of Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee (attached to ECF No. 60-7).

148. Celebrex's black box warning highlights the potential for increased risk of cardiovascular events and gastrointestinal bleeding associated with Celebrex use. Specifically, Celebrex's black box warning stated:

CELEBREX®
celecoxib capsules

Cardiovascular Risk

- **CELEBREX may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (see WARNINGS and CLINICAL TRIALS).**
- **CELEBREX is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS).**

Gastrointestinal Risk

- **NSAIDs, including CELEBREX, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (see WARNINGS).**

149. Today, Pfizer's Celebrex website states: "Important Safety Information" Celebrex ***"may . . . increase the chance of a heart attack or stroke that can lead to death."***

150. In the same press release in which it announced the "black box" label for Celebrex, Pfizer also announced that it had been told by the FDA to remove Bextra from the market. Pfizer's press release stated that "the company has agreed to suspend sales of the medicine pending further discussions with the FDA" and that "[f]or now, patients should stop taking Bextra and contact their physicians about appropriate treatment options."

G. Pfizer Discloses The Financial Impact Of Its Prior False Statements

151. On April 19, 2005, Pfizer issued a press release announcing Pfizer's financial results for the first quarter of 2005. The press release disclosed the financial impact of Pfizer's April 7, 2005 decision to suspend Bextra sales – a $1.213 billion charge-off in the first quarter of 2005 –underscoring Pfizer's reason for concealing Bextra's cardiovascular risks in the first place.

152. Finally, on October 20, 2005, before the market opened, Pfizer announced the impact of the revelations about the cardiovascular risks of Celebrex and Bextra on the Company's overall financial results. In announcing the Company's third quarter 2005 financial results, Pfizer stated that certain regulatory actions relating to Celebrex and the suspension of sales of Bextra contributed to an additional decline in Celebrex and Bextra revenues of $754 million (a 67% drop) and a year-to-date decline of over $2.0 billion (down 62%) compared to the prior year. Discussing the Company's disclosures the following day, *The New York Times* reported that Pfizer, "[f]acing increasing . . . concerns about the heart risks of Celebrex, its once-popular painkiller . . . Pfizer said yesterday that sales in the third quarter fell 5 percent compared with the period in 2004," which "led Pfizer's battered shares to plunge $2.07 to $21.90," or 8.6%.

153. The stock market responded to the negative disclosures about Celebrex and Bextra with a massive sell-off of Pfizer stock. From October 31, 2000, through and including October 19, 2005, Pfizer's stock rose to a high of $47.44 per share before falling to $21.90 upon Pfizer's October 20, 2005 disclosure of Celebrex's disappointing sales. From the time the partial disclosures commenced in October of 2004, Pfizer's stock fell from $31.18 per share to $21.90, a drop of over ***$74 billion*** in market capitalization, as reflected in the chart below.

VII. DEFENDANTS KNEW AND CONCEALED THE SERIOUS CARDIOVASCULAR SIDE EFFECTS OF CELEBREX AND BEXTRA

A. Defendants Knew Of The "Fitzgerald Hypothesis" And The Scientific Concern That All COX-2 Inhibitors Cause Cardiovascular Harm

154. As discussed above, the scientific rationale and justification for COX-2 inhibitors was safety, not efficacy. COX-2 inhibitors were believed to be safer than traditional NSAIDs, with fewer GI and renal side effects. However, well before the launch of Celebrex and Bextra, Dr. Garrett A. Fitzgerald ("Dr. Fitzgerald") and his team of scientists at the University of Pennsylvania expressed concern that COX-2 inhibitors, such as Celebrex and Bextra, were not safer than traditional NSAIDs. Just the opposite, these scientists hypothesized that COX-2 inhibitors were far more dangerous than traditional NSAIDs. In particular, COX-2 inhibitors, unlike traditional NSAIDS, were believed to cause cardiovascular harm, including heart attacks and strokes.

155. Beginning in 1984, Dr. Fitzgerald and his team published a series of studies concerning the impacts of thromboxane and prostacyclin on the cardiovascular system. These studies suggested the importance to cardiovascular health of maintaining a balance of thromboxane and prostacyclin. According to Dr. Fitzgerald's studies, inhibiting the production of prostacyclin, while leaving levels of thromboxane unchanged, had a negative impact on the body's cardiovascular system.

156. Dr. Fitzgerald's studies additionally suggested that COX-2 inhibitors, such as Celebrex and Bextra, create an unhealthy imbalance in the body. In particular, COX-2 inhibitors block the biosynthesis of prostacyclin, but do not interfere with the biosynthesis of thromboxane. As a result, Dr. Fitzgerald and his team hypothesized that these drugs create a chemical "imbalance" in the body that has negative cardiovascular side effects.

157. According to the expert report of Professor Joel Bennett, M.D. ("Professor Bennett"), who was approved by Judge Swain to testify at trial in the Pfizer Securities Class Action, "what Dr. Fitzgerald described in 1998, was that, from a biological mechanism standpoint, use of celecoxib (Celebrex) could lead to increased risks of cardiovascular harm for persons at risk for cardiovascular disease. This is the 'Fitzgerald/imbalance' hypothesis."[15] As Judge Swain held, in denying Defendants' motion to preclude Professor Bennet from testifying at trial, Dr. Fitzgerald's "hypothesis has been deemed plausible and credible in the relevant medical literature."

158. Throughout the Relevant Period, Defendants were aware of the Fitzgerald hypothesis, and his conclusion that COX-2 inhibitors have significant cardiovascular side effects. Based on his review of Pfizer's internal documents produced in the Pfizer Securities Class

[15] *See* Expert Report of Professor Joel S. Bennett, M.D., dated 3/6/09, at 8 (attached to ECF No. 205-15).

Action, Professor Bennett opined that "[i]t is clear . . . that Pfizer had access to information about the FitzGerald hypothesis well before 2004, even while stating publicly that there were no cardiovascular issues associated with the use of Celebrex or Bextra." For example, in an outline of a "COX-2 Cardiovascular Special Initiative," prepared in January 2002, Pfizer specifically acknowledged as a "Problem" that "[t]here is a credible scientific hypothesis (Fitzgerald) that suggests COX-2 inhibitors may have a prothrombotic effect."[16]

159. Notwithstanding their internal recognition of the validity of the Fitzgerald hypothesis, Pfizer and its Co-Promoter publicly denounced his hypothesis. For example, a January 19, 1999 article in the *Globe and Mail* quoted a spokesman for Pfizer's Co-Promoter, who assured that Dr. Fitzgerald's "concerns should not be overblown. 'This is only a hypothesis based on tests that were done invitro, done only in the lab, but we've done clinical trials with more than 13,000 people…. The trials showed no elevated heart problems,'" the spokesman explained.

B. Defendants Knew Of Numerous Clinical Trials And Internal Studies Demonstrating That Celebrex Causes Cardiovascular Harm

160. Throughout the Relevant Period, Defendants had access to undisclosed internal clinical trial results and studies confirming the Fitzgerald hypothesis and documenting the cardiovascular side effects associated with Celebrex. These clinical trials and studies demonstrated that Celebrex use may result in cardiovascular harm. Defendants knew about these studies and appreciated their significance, but nevertheless concealed them from patients and investors.

[16] *See* January 2002 outline of a "COX-2 Cardiovascular Special Initiative, bearing Bates No. Kitsis-E 10000008521 (attached to ECF No. 205-52).

161. The pre-clinical and clinical trial results for a drug are critical to its commercial success. As an initial matter, a drug may only be sold in the United States if the FDA determines that the drug is safe and effective for its intended use. The FDA, however, relies upon drug companies seeking to gain the FDA's approval to perform the appropriate preclinical and clinical trials to demonstrate the drug's safety and efficacy. The FDA does not independently conduct tests on drugs to verify data submitted by new drug applicants. In addition, before the passage of the FDA Amendments Act in 2007, the FDA lacked the authority to require drug companies to conduct certain post-marketing safety studies or make post-marketing changes to their drug labels.

162. The FDA, which is responsible for over 10,000 approved drugs, expects and requires applicants seeking approval for a new drug to provide it with all clinical data so that it may assess the drug's efficacy and safety. As Defendant McKinnell acknowledged in a June 24, 2005 interview with Charlie Rose, "[i]t's our responsibility to make all the information that we generate on our medicines available to the FDA. Every adverse event, every study we do is available to the FDA."

163. Patients and prescribing physicians consider and compare the published results of drugs' clinical trials in selecting between competitor drugs. If a drug's clinical trial results show that a drug is safer or more effective than its competitor drugs, patients will be more inclined to purchase that drug. On the other hand, if a drug's clinical trial results show that the drug is less safe or effective than its competitor drugs, patients will be less inclined to purchase that drug.

164. Drug companies are expected to publish all of the results from their clinical trials, both positive and negative. This obligation to publish all study results is set forth, among elsewhere, in Section B.27 of the internationally recognized Declaration of Helsinki, which

provides that "[n]egative as well as positive results should be published…."[17] This expectation is further embodied in the PhRMA Principles of Clinical Trials and Communications of Clinical Trial Results (the "PhRMA Principles"), which Pfizer has publicly endorsed. The PhRMA Principles, which were adopted in October 2002, state that "PhRMA members commit to communicate the results of all hypothesis-testing clinical trials they conduct, regardless of outcome, for marketed products or investigational products that are approved for marketing."[18]

165. The need to publish clinical trial results is particularly heightened when those results suggest that a drug may be associated with adverse side effects. Trial results may show a statistically significant association between the drug and an adverse side effect. Trial results may also show an adverse trend in the data, referred to as a "safety signal," which does not necessarily rise to the level of statistical significance due to the size of the sample tested. Pfizer's website has explained, on a page titled "What is a Safety Signal?," that "a safety signal [is] reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. When a safety signal is identified, further investigation is generally warranted to determine whether an actual connection exists."

166. Drug companies confronted with a "safety signal" or statically significant evidence of an undisclosed adverse side effect relating to one its drugs are expected to promptly publish underlying clinical data and disclose the safety risk. As Defendant LaMattina specifically acknowledged in his book titled *Drug Truths: Dispelling the Myths About Pharma*

[17] *See* Expert Report of Professor Curt D. Furberg, M.D., Ph.D., dated 5/6/09, at 13 (attached to ECF No. 205-21).
[18] *See* Expert Report of John Abramson, M.D., dated 6/1/11, at 14 (attached to ECF No. 328-28 in the Pharmacia Securities Class Action).

R&D, "[i]t is important that, when safety signals are seen with new drugs, these get properly communicated broadly to patients and physicians."[19]

1. June 1998: Internal ISS Report Shows That Celebrex Leads To A Statistically Significant Increase Of Heart Attacks

167. Celebrex's cardiovascular side effects were internally known and documented well before the FDA's approval of the drug. Professor Curt D. Furberg, M.D., Ph.D. ("Professor Furberg"), an industry expert approved by Judge Swain to testify in the Pfizer Securities Class Action, has reviewed the clinical trial data available to Defendants prior to the FDA's approval and has opined that "[a] statistically significant risk of adverse cardiovascular events induced by the use of Celebrex was documented prior to the FDA approval in December, 1999."[20]

168. Indeed, on June 5, 1998, Pfizer's Co-Promoter submitted to the FDA a report titled "Celecoxib Integrated Summary of Safety Information" in support of its new drug application ("NDA") for Celebrex (the "ISS Report"). The ISS Report summarized and analyzed the safety data from certain early osteoarthritis and rheumatoid arthritis clinical studies of the drug. The ISS Report was available to Pfizer at all relevant times, and Pfizer has admitted in its Answer to the Amended Class Action Complaint in the Pfizer Securities Class Action (the "Answer") that it was provided a copy of the ISS Report and reviewed the underlying clinical data.

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[19] *See* John D. LaMattina, *Drug Truths: Dispelling the Myths About Pharma R&D* at p. 80 (John Wiley & Sons, Inc. Publication 2009).

[20] As noted in Judge Swain's March 29, 2010 Order denying Defendants' motion to exclude Professor Furberg's expert testimony [ECF No. 193], "[t]he breadth of knowledge, experience, and expertise Dr. Furberg brings to proceedings in this case is considerable. Dr. Furberg has wide-ranging training and practice in both clinical and research settings. His opinions are based on individual study data available to Pfizer and, to arrive at them, he employed the methods and analysis he has applied in his lengthy and distinguished career as an expert in the fields of drug safety and clinical trial design."

169. The ISS Report included an analysis of the cardiovascular side effects of Celebrex on elderly patients. Even before Celebrex's launch, Defendants knew that elderly patients would be one of the largest groups to use Celebrex. As noted in the ISS Report, the "[c]haracterization of the safety profile of celecoxib in the elderly (≥ 65 years) is important since the elderly arthritis population is one of the larger patient subgroups who will use the drug."[21] Defendants also knew that elderly patients were generally at greater risk for suffering cardiovascular events.

170. The ISS Report acknowledged the Fitzgerald hypothesis. As explained in the ISS Report, "[t]he association of COX inhibitors with cardiovascular disease is based on their effects upon prostaglandins, primarily in the kidney, but also to a lesser extent, in platelets in the vascular endothelium."[22]

171. Consistent with the Fitzgerald hypothesis, the ISS Report found ***"an apparent excess of myocardial infarction [i.e., heart attacks] in [celecoxib-treated] elderly [patients]."*** "Myocardial infarction was noted to occur at a higher rate in celecoxib than placebo patients." In particular, the data showed "seven events (0.5%) in the elderly celecoxib patients compared to one event (0.1%) in the elderly placebo group and two events (0.3%) in the active control patients" – a difference that the ISS Report recognized ***"was statistically significant."***

172. Defendants, however, never publicly disclosed the ISS Report during the Relevant Period.

2. June 1999: Pfizer's "Alzheimer's 001 Study" Shows That Celebrex Use Increases The Risk Of An Adverse Cardiovascular Event By 337%

173. On June 24, 1999, after Pfizer and Searle entered into the Co-Promotion Agreement, the two companies completed a clinical study to assess the effects of Celebrex on the

[21] *See* 6/5/98 Celecoxib Integrated Summary of Safety Information, bearing Bates No. Cele NDA 20-998 00348285 (attached to ECF No. 383-9).
[22] *See id.* at Cele NDA 20-998 00348312.

progression of Alzheimer's disease. This study, referred to as the Alzheimer's 001 Study, was a randomized, double-blind study conducted on patients with mild-to-moderate symptoms of the disease. Patients were provided with either a placebo or Celebrex, and their health was then closely monitored.

174. The study was of particular importance to Defendants because it was the longest controlled clinical study for Celebrex, with patients receiving the drug for 52 weeks. In addition, the Alzheimer's 001 Study was particularly critical to assess the drug's safety because it was placebo-controlled. As Defendant McKinnell admitted at his deposition in the Pfizer Securities Class Action, "[i]n order to make a claim of no increased risk, an absolute claim of no increased risk, you have to be using a placebo as a comparator."[23]

175. The results of the Alzheimer's 001 Study showed that the incidence of serious adverse cardiovascular events in the Celebrex treatment group, including stroke and heart failure, was ***337%*** higher than in the placebo group. The rate of cardiovascular deaths was ***more than twice*** as high in the Celebrex group compared to the placebo group.

176. The Alzheimer's 001 Study was of special interest to the joint Executive Management Committee ("EMC"), which included Defendants McKinnell and Katen. A slide presentation for a July 16, 1999 EMC meeting stated that the EMC would determine whether to seek FDA approval for an Alzheimer's indication for Celebrex based on the results of the Alzheimer's 001 Study. It further stated that "[a] preliminary estimate of peak revenue resulting from an indication for Treatment of Alzheimer's Disease is $465 million," while noting that

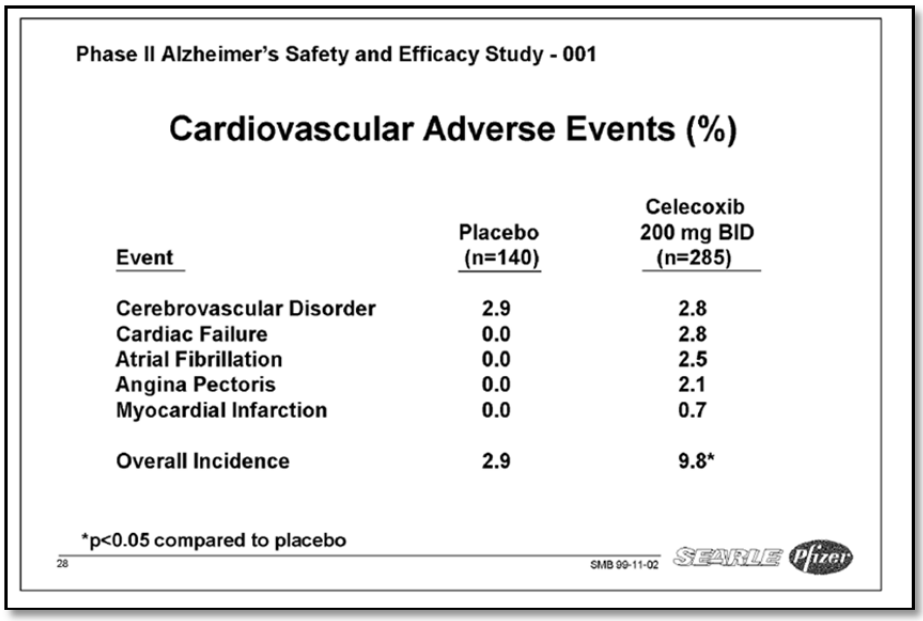
[23] *See* Excerpts of the 11/9/2011 Deposition Tr. of H. McKinnell, at 132:4-10 (quoted at ECF No. 420 at 149).

Pfizer's pharmaceutical rival, Merck, would be seeking FDA approval for an Alzheimer's indication for Vioxx. [24]

177. On November 2, 1999, Pfizer and Searle employees presented the results of the Alzheimer's 001 Study to the Senior Management Board of the joint Searle/Pfizer collaboration. The slide presentation, which bears both companies' logos, stated that the core objective of the Alzheimer's 001 Study was to "evaluate the safety and efficacy of celecoxib in treating the progression of Alzheimer's disease."[25]

178. As set forth in the below slide, which was included in the November 2, 1999 joint Pfizer/Searle presentation to the Senior Management Board, the percentage of patients experiencing serious adverse events was meaningfully higher in the Celebrex treatment group for nearly ***all*** types of adverse cardiovascular events. In addition, the overall rate of reported cardiovascular adverse events was ***337%*** higher in the group of patients that received Celebrex than in the patients who received placebo, with ***9.8%*** of the Celebrex group suffering an adverse cardiovascular event during the course of the 52-week treatment – a difference that the presentation acknowledged was statistically significant (*i.e.*, with "$p<0.05$ compared to placebo").[26]

[24] *See* 7/16/99 Presentation to EMC, bearing Bates No. Phelan-K 10000193846 (quoted at ECF No. 420 at 38-39).
[25] *See* 11/2/99 Presentation entitled, "Celebrex (Celecoxib) Alzheimer's Disease, Senior Management Board", bearing Bates No. Coughl-O 10000078784-8871 (attached to ECF No. 351-23).
[26] *See id.*



179. An internal January 12, 2005 email from Dr. Claire Wohlhuter, Pfizer's Pain and Arthritis Medical Group Leader, to her supervisor, Vice President and Global Medical Affairs, Antonia Kolokathis, confirmed that ***"[w]ith regard to Alzheimer 001, Patients treated with 200 mg BID were at greater risk of serious CV thromboembolic adverse events vs. placebo."***[27]

180. Pfizer closely analyzed the results of the Alzheimer's 001 Study. According to an internal January 18, 2000 Pfizer Quarterly Development Summary for the First Quarter of 2000, which was sent to Pfizer's Dr. Mona Wahba (a Pfizer Clinical Research Associate II) and others, "Pfizer received the phase II study 001 Alzheimer's trial data on August 20" and the "joint Searle/Pfizer Alzheimer's team . . . conducted extensive analyses of [the] data."[28] In addition, the results of the Alzheimer's 001 Study were discussed at a May 17, 2000 Development Planning Committee meeting attended by Defendants McKinnell Katen, LaMattina and Feczko. The minutes from that meeting state that a senior marketing executive "reviewed the key changes

[27] *See* 1/12/05 Email re: TN4Q04 Update Slides.ppt, bearing Bates No. Wohlhu-C 10000376917-75 (quoted at ECF No. 420 at 52).
[28] *See* 1/18/00 Email from L. Shafner to M. Wahba, et al., bearing Bates No. Wahba-M 10002799104-11 (attached to ECF No. 351-24).

in the Celebrex development program including dropping Alzheimer's Disease" from the new drug application for Celebrex.[29]

181. The cardiovascular safety results of the Alzheimer's 001 Study were not publicly disclosed at any time before January 2005. Nor were the results disclosed in Pfizer and its Co-Promoter's submission to the FDA seeking approval for Celebrex. Rather than disclose the true results of this pivotal study, Pfizer falsely represented in its April 2000 abstract for the Alzheimer's 001 Study that "Celecoxib 200 mg BID was ***safe*** and well tolerated in this elderly population" and "***[t]he safety profile was similar*** in the two treatment groups." In addition, Defendants purposefully excluded the results from the Alzheimer's 001 Study from their 2003 "meta-analysis" of Celebrex's cardiovascular safety.

182. Pfizer employees internally questioned the propriety of concealing the cardiovascular safety results of the Alzheimer's 001 Study, including the decision to exclude them from their 2003 meta-analysis. For example, in an April 7, 2003 email bearing the subject line "CV Questions," Dr. Gandelman, a senior physician in Pfizer's medical group, questioned Dr. William White, who was involved in the preparation of the meta-analysis, as follows: "In your Celebrex CV meta-analysis did you ever look at the data from high risk CV patients and compare to NSAIDs or placebo?" In response, Dr. White replied: "***I will talk to you about this issue on the phone - it is not very promising - I can tell you that.***"[30]

183. Outsiders also questioned Pfizer's decision to withhold the results of the Alzheimer's 001 Study. For example, on June 10, 2004, Dr. Larry Hirsch, a vice-president at Pfizer's competitor, Merck, sent an email to a Pfizer employee that specifically questioned why Pfizer failed to publish the results of its Alzheimer's 001 Study. Dr. Hirsch wrote:

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[29] *See* 5/17/00 Meeting Minutes, bearing Bates No. Wahba-M 000020055 (quoted at ECF No. 420 at 44-45).
[30] *See* 4/7/03 Email from Dr. Gandelman to the W. White, bearing Bates No. Gandle-M 10001567631 (quoted at ECF No. 420 at 49).

> I've been meaning to ask you (again) - what about the celecoxib Alzheimer's Disease treatment study? In fact [sic], there may have been two - one treatment, one prevention/early intervention. ***Principles text language and public assertions aside, we are judged by our actions.***[31]

The Pfizer employee responded to Dr. Hirsch's email, copying Defendant Cawkwell and Michael Parini, an in-house Pfizer lawyer, stating as follows:

> Michael [Parini], Can fill us in [sic] (Larry Hirsch is a VP at Merck) on if the trial below is published or is being published or if it has been presented? Larry's point is that ***Pfizer subscribes to the PhRMA Clinical Trial Code and pursuant to that document and our SOPs, we are committed to publishing/communicating all (non-exploratory) clinical trial results for marketed products.***[32]

184. In violation of the PhRMA Clinical Trial Code, Pfizer only disclosed the results of the Alzheimer's 001 Study prior to 2005 to the Data Safety Monitoring Committee, an independent agency that reviews clinical trial data ("DSMC"). In 1999, when the results were provided to the doctors on the DSMC, they "urged the drug maker to get the results [of the Alzheimer's 001 Study] into print so they could be factored into the medical assessment of the painkiller," according to a February 2, 2005 *Wall Street Journal* report. Pfizer and its Co-Promoter, however, simply "ignored the advice."

185. On December 23, 2004, three members of the DSMC contacted Defendant Cawkwell and another Pfizer employee regarding the undisclosed results of the Alzheimer's 001 Study. Shortly thereafter, Defendant Cawkwell sent an email to nine of her colleagues, including Pfizer's in-house counsel, Michael Parini, memorializing the conversation. Defendant Cawkwell's email states that the DSMC called to "express some potential safety concern[s] that can be seen in the [Alzheimer's 001] study itself…. Specifically, they noted that there were numeric imbalance[s] in CV events including CV SAEs [*i.e.*, Cardiovascular Serious Adverse Events] previously noted, including between 6-10 CV events in drug group vs. almost none in

[31] *See* 6/10/04 Email from L. Hirsch, bearing Bates No. Cawkwe-G 10000387705 (quoted at ECF No. 420 at 50).
[32] *See Id*. at Cawkwe-G 10000387704.

placebo group." In response, Defendant Cawkwell admitted to the DSMC that ***"Pfizer [was] aware of the study," "ha[d] reviewed the data,"*** and – contrary to its prior representations to the DSMC and the public – ***"recognize[d] that this is a study that had shown unfavorable imbalances of specific CV events."***[33]

186. The next day, on December 24, 2004, Dr. Lon S. Schneider of the DSMC followed upon on his call to Defendant Cawkwell with a formal letter concerning Celebrex's cardiovascular safety and the Alzheimer's 001 Study. The letter stated that DSMC's "review of final data in August 1999 and later showed that ***there was an indication of excess cardiovascular-related and other risk***." The letter, which was sent to Defendant Cawkwell and forwarded to Defendant Feczko and other Pfizer employees, cautioned that "nominal risk rates [in the study] for cardiovascular events are potentially ***very high***, approaching 5 or so and the absolute risk differences also approach about 3%, so that the number needed to harm is in the range of 30 to 50, ***a fairly concerning number, much higher than that that can be estimated from press reports of the prevention trials.***"[34]

187. In addition, the DSMC expressed concern that Defendants never published the results of the Alzheimer's 001 Study in any scientific manuscript. As Dr. Schneider explained, "we note that this trial was never published, just orally presented in 2002 at an AD [Alzheimer's Disease] meeting in Stockholm. ***It should have been fully published in 2000, and perhaps if it had been some attention might have been drawn to potential safety issues."***[35]

188. The DSMC's December 24, 2004 letter further stated that, "[a]s the only independent body with this information and having had past responsibility for the safety of the

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[33] *See* 12/23/04 Email from G. Cawkwell to Michael Parini, et al., bearing Bates No. Cawkwe-G 10002020455 (attached to ECF No. 205-61).
[34] *See* 12/24/04 Letter from L. Schneider to G. Cawkwell, bearing Bates No. Cawkwe-G 100003198906-908 (attached to ECF No. 205-60).
[35] *Id.*

subjects in the trial, [the DSMC members] have an obligation to ensure the visibility of this trial." In this regard, the DSMC insisted that Defendants provide "assurance that [they] have included this data in [their] safety analyses and communicated with FDA on this individual trial, identifying for the agency these and other potentially important observations."[36]

189. Following the DSMC's letter, Pfizer was forced to change course and submit a "supplement" to its original Alzheimer's 001 Study report to the FDA, which it did on January 5, 2005 (over four years after the completion of the study). In its "supplement," Pfizer admitted that "there were ***statistically significant differences observed*** between treatment groups for certain cardiovascular-related WHOART Body Systems (Cardiovascular Disorders, General; Heart Rate and Rhythm Disorders; Myo, Endo, Pericardial & Valve Disorders)."[37]

190. In addition, in its "supplement," Pfizer changed the conclusion of its prior study report submitted to the FDA years earlier. No longer did Pfizer claim that the "the results of this study demonstrate[d]" that "[o]ral doses of celecoxib 200 mg BID ***were generally safe and well tolerated*** in this elderly, debilitated population." Instead, Pfizer falsely asserted in the January 2005 "supplement" that "the safety and tolerability of celecoxib 200 mg BID, compared to placebo, in this elderly, debilitated population ***cannot be decisively concluded*** from this study."[38]

191. Pfizer did not disclose to investors this "supplement" to the Alzheimer's 001 Study report. Nor were any modifications made to the publicly available abstract for the Alzheimer's 001 Study, which continued to falsely assure patients and investors that "Celecoxib 200 mg BID was ***safe and well tolerated*** in this elderly population." Indeed, Pfizer did not

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[36] *Id.*
[37] *See* 1/5/05 IND application to the FDA for Celebrex, bearing Bates No. Cele IND 48395 00001134-1135 (quoted at ECF No. 420 at 173).
[38] *Id.*

publish the cardiovascular safety results of the Alzheimer's 001 Study any time before January 2005.

192. Rather, Pfizer posted online a "Clinical Study Synopsis" of the Alzheimer's 001 Study on a new, relatively obscure industry-specific website with no surrounding publicity. Contrary to its previously published "abstract" for the Alzheimer's 001 Study, but continuing to mislead the public, the synopsis stated that (i) "a statistically significant difference favoring placebos in AEs [*i.e.*, adverse events] was observed [in the Alzheimer's 001 Study] for certain CV-related body systems"; and (ii) the safety and tolerability of Celebrex in Alzheimer's patients "cannot be decisively concluded."[39]

193. The "Clinical Study Synopsis" for the Alzheimer's 001 Study was soon discovered and publicized in a February 1, 2005 exposé in *The New York Times*. The exposé stated that the "Clinical Study Synopsis" was located at the end of January 2005 by Dr. Sidney Wolfe, a director of the consumer advocacy group Public Citizen who participated in the February 7, 2001 FDA hearings. The article explained that "Dr. Wolfe publicized [the Alzheimer's 001 Study] yesterday, after finding it last week on a new Web site where Pfizer and other drug companies have begun to post some clinical trial results. Dr. Wolfe said the results had not been on the site a few weeks earlier." The article quoted Dr. Wolfe, who stated that ***"[i]t's a clear signal that I would have loved to have known about four years ago."***

194. According to the same article, Dr. Kenneth Brandt, a professor at Indiana University School of Medicine, who was part of a reviewing panel in 2001 for Celebrex, stated that ***"if the safety panel had known about the study, it might have recommended that both Vioxx and Celebrex be taken with greater caution."***

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[39] *See* Clinical Study Synopsis, bearing Bates No. Cawkwe-G 10000515670-5677 (quoted at ECF No. 420 at 176-177).

3. July 1999: "Cardiovascular Safety Summary" Highlights Celebrex's Serious Cardiovascular Risks

195. Defendants concealed from the public another significant safety analysis of Celebrex clinical data. On July 14, 1999, Dr. Kenneth Verburg circulated a memorandum titled the "Cardiovascular Safety Summary" to Searle executives and Pfizer scientists, including Pfizer biostatistician Rebecca Adler (the "Safety Summary").[40] The Safety Summary collected the combined results of 15 prior studies, which were conducted on over 9,000 uniquely treated patients. As explained in the "Methodology" Section of the Safety Summary, the purpose of the summary was to "provide a synthesis of the ISS tables associated with the Phase II and Phase III trials and the long-term open label study of celecoxib."[41]

196. The memorandum attaching the Safety Summary was authored by Dr. Verburg, then a physician in Searle's research and development department. Dr. Verburg, who worked on the New Drug Application for Celebrex, became an employee of Pharmacia after it acquired Searle in early 2000, and then became an employee of Pfizer when it acquired Pharmacia in April 2003. Dr. Verburg remained an employee of Pfizer during the remainder of the Relevant Period.

197. The Safety Summary begins by acknowledging the Fitzgerald Hypothesis, and Dr. Fitzgerald's scientific concerns about the cardiovascular safety risks of COX-2 inhibitors. In particular, the Safety Summary states that "COX-2 inhibitors may cause cardiovascular disease by suppressing the synthesis of prostaglandins, which regulate blood pressure, blood clotting, and blood vessel dilation in addition to inflammatory action." The Safety Summary explained that Dr. Fitzgerald and his team have raised concerns that COX-2 inhibitors "increase the

[40] *See* 7/14/99 Memo from V. Verburg to Searle executives and Pfizer scientists, bearing Bates No. Verbur-K 10004432329-356 (attached to ECF No. 351-26).
[41] *See Id.* at Verbur-K 10004432332.

incidence of thrombosis [i.e., a blood clot]" and that "larger trials are necessary to establish the cardiovascular consequences of inhibiting prostacyclin biosynthesis."[42]

198. The Safety Summary analyzed multiple clinical trials and compared the number of adverse cardiovascular events experienced by patients given Celebrex versus those given a placebo or an active control. The Safety Summary states that:

> This report reproduces only those results which are related to cardiovascular disorders and which occur with an incidence of ≥0.1% within the study population. Four general categories of adverse events (as designated in the ISS) were examined for incidence of cardiovascular disorders: General Cardiovascular Disorders, Heart Rate and Rhythm Disorders, Myo/Endo/Pericardial and Valve Disorders, and Vascular (Extracardiac) Disorders.[43]

199. As reflected in the below chart, the Safety Summary found that North American patients given Celebrex at 100 and 200 mg doses were more than three-times more likely to experience cardiovascular events than patients given a placebo, and that this difference was statistically significant:

Type of Adverse Event	Celebrex	Placebo	Statistically Significant Difference In Risk?
Total Cardiovascular Events	178 AEs	55 AEs	**YES**
Heart Rate and Rhythm Disorders	24 AEs	5 AEs	**YES**

200. The Safety Summary also found that North American patients given Celebrex at 100 and 200 mg doses were far more likely to experience certain cardiovascular events than patients given an active control (*i.e.*, a traditional NSAID), and that this difference was also statistically significant:

Type of Adverse Event	Celebrex	Active Control	Statistically Significant Difference In Risk?
Myo Endo Percardial and Valve Disorders	22 AEs	7 AEs	**YES**
Tachycardia	8 AEs	1 AE	**YES**

[42] *See Id.* at Verbur-K 10004432331.
[43] *Id.*

201. The Safety Summary further found that North American patients given Celebrex at 400 mg doses had an elevated risk of certain adverse cardiovascular events, with nine patients in the Celebrex group suffering Heart Rate and Rhythm Disorders versus zero in the placebo group, and four patients in the Celebrex group suffering MyoEndoPericardial and Valve Disorders versus zero in the active control group.

202. The Safety Summary next contained "Subgroup Evaluations," which focused on patients suffering from osteoarthritis and rheumatoid arthritis. For the osteoarthritis patients, the Safety Summary found that Celebrex usage increased the likelihood that these patients would suffer tachycardia – an abnormal increase in heart rate – by a statistically significant amount. Five patients in the Celebrex group suffered tachycardia during the treatment period versus zero in the active control group. The Safety Summary also found that Celebrex usage increased the likelihood that rheumatoid arthritis patients would suffer adverse cardiovascular events, including Heart Rate and Rhythm Disorders and MyoEndoPericardial and Valve Disorders. Nine patients in the Celebrex group suffered Heart Rate and Rhythm Disorders versus zero in the placebo group, and six patients in the Celebrex group suffered MyoEndoPericardial and Valve Disorders versus zero in the active control group – both of which were statistically significant differences.

203. The Safety Summary also considered the risks of adverse cardiovascular events in its "International Arthritis Trials" for the drug. For those trials, the Safety Summary showed, among other things, that ten patients in the Celebrex group suffered Heart Rate and Rhythm Disorders versus just two patients in the active control group – another statistically significant difference.

204. Finally, the Safety Summary included an analysis of the data from both domestic and international arthritis clinical trials. For these trials, the Safety Summary similarly showed that patients treated with Celebrex suffered an elevated risk of Heart Rate and Rhythm Disorders, with twenty-four patients in the Celebrex group experiencing an adverse cardiovascular event versus five in the placebo group. It also showed that twenty-four patients in the Celebrex treatment group suffered MyoEndoPericardial and Valve Disorders versus only nine in the control group – also a statistically significant difference.

205. Furthermore, the Safety Summary would have shown an even greater risk of adverse cardiovascular events associated with Celebrex if Defendants had included the results of the Alzheimer's 001 Study in their analysis, which was completed weeks earlier. The Safety Summary, however, did not include the results of the Alzheimer's 001 Study.

206. Notwithstanding the significance of these findings, the Safety Summary was never publicly disclosed nor provided to the FDA or any other regulatory body.

4. April 2000: Undisclosed SUCCESS Study Shows That Celebrex Patients Are Five Times More Likely To Suffer A Heart Attack

207. Defendants also concealed the adverse cardiovascular safety results from the poorly named "SUCCESS Study." The SUCCESS Study was a double-blind, randomized trial involving 13,274 osteoarthritis patients. The SUCCESS Study compared the safety of Celebrex to two traditional, non-selective NSAIDs – diclofenac and naproxen. One group of patients was provided with Celebrex, and the other group was provided either diclofenac or naproxen. The study was completed on April 18, 2000.

208. The results of the SUCCESS Study further demonstrated that Celebrex use increases the risk of heart attack. In particular, the rate of heart attacks in the Celebrex treatment group was ***five times*** higher than compared to the NSAID groups, with ten heart attacks reported

in the Celebrex group (0.55 per person/year) and only one heart attack in the combined naproxen/diclofenac group (0.11 per person/year).

209. Professor Richard A. Kronmal, a biostatistician and expert approved by Judge Swain to testify in the Pfizer Securities Class Action, explained in his May 19, 2009 expert report that the SUCCESS Study "showed an increased risk of MI [i.e., heart attack] events when the celecoxib treatment arm is compared … to the combined naproxen and diclofenac groups." Dr. Kronmal further opined that, contrary to Defendants' public representations, "[i]t is quite clear that the results of these trials do ***not*** support the contention that celecoxib was safer than either these NSAID comparators or Vioxx."[44] Indeed, on January 26, 2001, the medical monitor for the SUCCESS Study emailed his colleagues at Pharmacia concerning the SUCCESS Study results and concluded that "***[t]he rates of myocardial infarction are worrisome."***[45]

210. Based on the results of the SUCCESS Study, as well as prior Celebrex safety studies, Pfizer internally knew (and sought to conceal) that Celebrex had the same or similar cardiovascular side effects as those observed with Vioxx. Indeed, in a February 19, 2001 internal Pfizer email, Dr. Weiner updated the prior year's Pfizer "Question and Answer" section of Pfizer's 2001 shareholder book to avoid any disclosure of Celebrex's cardiovascular risks. In response to the question, "Do you have cardiovascular problems like Vioxx?," Dr. Weiner instructed that Pfizer representatives ***"do not disclose"*** the true answer to inquiring shareholders.[46]

211. Less than a month later, Pfizer and its Co-Promoter again internally acknowledged that the SUCCESS Study demonstrated Celebrex's cardiovascular risks and also

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[44] *See* Expert Report of Professor Richard A. Kronmal, dated 5/19/09, at p. 24 (attached to ECF No. 205-26).
[45] *See* 1/26/01 Email from J. Fort to C. Wallenmark re: Table 35.3, bearing Bates No. Fort-J 10000138443 (quoted at ECF No. 420 at 53).
[46] *See* 2/19/01 Email from E. Weiner attaching Shareholders Q and A for COX-2 with edits, bearing Bates No. Wahba-M 1000122195 (quoted at ECF No. 420 at 105).

highlighted the potential negative impact of the findings if disclosed to government regulators. Dr. Geis emailed Dr. Verburg and other senior Pharmacia executives, attaching a document that explained that "[i]n terms of cardiovascular safety, the data shows an excess of myocardial infarctions comparing celecoxib to NSAIDs (10 vs. 1)" and noted that the "trend contrasts with the NDA [new drug application] and CLASS databases." Dr. Geis further explained that "a possible trend towards an increase in myocardial infarctions ***may raise additional regulatory concerns***" and cautioned that the ***"potential negative impact of this aspect of the data may outweigh any potential advantages when put forth in a regulatory context."***[47]

212. Nevertheless, no disclosure was made of the results of the SUCCESS Study results. Pfizer internally recognized that their failure to disclose the results of the SUCCESS Study conflicted with basic disclosure principles. According to the Action Minutes from an April 15, 2003 meeting of Pfizer's Global Development Review Committee (the "GDRC"), which was attended by Defendant Feczko (the chair of the committee), Defendant LaMattina, and Ian Read (Pfizer's current CEO), the GDRC acknowledged that "[t]he question of the safety of COX-2s in [coronary artery disorder] patients has ***remained an issue***," which has interfered with Pfizer's "ability to differentiate Celebrex and Bextra from other COX-2s" – a "key to expanding their market share." The "medical community and health authority[']s questions on the GI ***and CV*** profiles of [the COX-2s]" has put the COX-2 ***"portfolio's future growth … at risk."*** The "team briefly reminded GDRC of the results of the SUCCESS trial and ***the concern that publication has taken longer than Pfizer believes is optimal,"*** and the GDRC acknowledged that there was ***"an obligation to make the results of the study available in a timely manner."***[48]

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[47] *See* 3/17/01 Email from G. Geis re: SUCCESS –GI Event, bearing Bates No. Geis-S 10000195941 (quoted at ECF No. 420 at 54).
[48] *See* 4/15/03 GDRC Meeting Minutes, bearing Bates No. Silber-S 10000004027-36 (attached to ECF No. 351-34).

213. The Minutes from GDRC's April 15, 2003 meeting also list as a future "action" item to "offline, provide more details on … the SUCCESS safety data and review the proposed CV efficacy trial and objectives with [Defendant] Feczko and other GDRC members as appropriate to inform next steps." Notwithstanding these "offline" discussions, no disclosure of the SUCCESS Study results was made after the meeting.

214. Defendants knew that disclosure of the results of the SUCCESS Study would negatively impact sales of Celebrex. Pfizer's June 5, 2003 "Cox-2 Strategic Operation Plan," which was sent to Defendant Cawkwell and other Pfizer officers, expressly cautioned that the "***SUCCESS I Publication May Raise Questions,"*** and would interfere with Defendants' goal of "[d]ifferentiat[ing] [Celebrex's] CV Benefits" from Vioxx. The results of the SUCCESS Study would "raise questions" because they showed that patients provided Celebrex had a ***"5 X Increase in MIs [myocardial infarctions]."***[49]

215. Ultimately, Defendants attempted to publish the results of the SUCCESS Study but conceal evidence of the adverse cardiovascular events. On July 9, 2003, Pfizer submitted to the *New England Journal of Medicine* ("NEJM") a draft manuscript titled "Efficacy and Upper Gastrointestinal Safety of Celecoxib Compared to Naproxen and Diclofenac in Patients with Osteoarthritis: Results from a Large, International, Randomized, Double-Blind, Controlled Clinical Trial." Pursuant to the terms of the Co-Promotion Agreement, both Pharmacia and Pfizer were provided with an "advanced copy" of this article "prior to [its] submission for publication."[50] The proposed manuscript discussed the SUCCESS Study but nowhere mentioned that patients in the Celebrex group were five-times more likely to suffer a heart attack. Rather,

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[49] *See* 6/5/03 "Cox-2 Strategic Operation Plan," bearing Bates No. Cawkwe-G 10003103755-3769 (attached to ECF No. 351-33).

[50] *See* 2/18/98 Global Agreement, bearing Bates No. DEFS 00508894-9080 (attached to ECF No. 328-4 in the Pharmacia Securities Class Action).

the draft manuscript, under the heading "Cardiovascular Safety," stated that "[t]he risk of acute myocardial infarction was low, and statistically similar among the different groups."

216. The NEJM rejected Pfizer's proposed manuscript. In its September 4, 2003 rejection letter, which was faxed to Defendant Cawkwell, the Deputy Editor of the NEJM, Elizabeth Philmister, Ph.D., specifically took issue with Defendants' assertion in the draft manuscript that "[t]he risk of acute myocardial infarction was low, and statistically similar among the different groups." Dr. Philmister wrote as follows:

> ***It is unacceptable to state that the MI [myocardial infarction] rates were statistically similar [for Celebrex and traditional NSAIDs]*** - given the lack of definition of what would be accepted as similar, the small numbers, the brief duration of follow-up, and large confidence intervals. This is especially unacceptable because Table 5 shows that 10 celecoxib patients had MI's vs. 1 NSAID patient. Therefore, the RR [i.e., Relative Risk] is 5.0 (95% CI 0.6-39.0; p=0.11). ***This is anything but statistically similar.***[51]

217. The NEJM's rejection letter additionally stated that "the authors cannot use this study to indicate that celecoxib does not have any CV risk." As the NEJM warned, "[t]he fact that there was a 5-fold increase in MI's with celecoxib … must be commented on and prevents the authors from concluding there is no potential CV issue with coxibs or celecoxib."[52]

218. The NEJM concluded that the unpublished results of the SUCCESS Study raise ***"a potential 'signal'"*** that Celebrex causes heart attacks, and requiring disclosure:

> As the authors state, there is much interest in CV events with Coxibs. Given a short duration study that is markedly underpowered to show a CV difference, and given the fact that the CV difference in VIGOR was due to a difference in MI's, the authors need to specifically comment on the fact that ***they also had a potential 'signal' that raises the issue of coxib-induced MI's.***[53]

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[51] *See* 09/4/03 Rejection Letter fax to G. Cawkwell from the New England Journal of Medicine, bearing Bates No. Cawkwe-G 10000338418-423 (attached to ECF No. 345-14).
[52] *Id.*
[53] *Id.*

219. The editors of the NEJM further expressed concern that Pfizer had attempted to present the cardiovascular safety results of the SUCCESS Study in a misleading manner aimed at hiding Celebrex's true cardiovascular side effects. While Defendants emphasized in the draft manuscript that their analyses were "performed on ***combined groups***," the data concerning the cardiovascular risks was "broken out in ***separate analyses***." As explained in the NEJM's rejection letter, "it looks like such data [showing the number of heart attacks in the Celebrex treatment group] ***are being hidden.***"[54]

220. Internally, Pfizer's employees expressed similar concerns about the Company's failure to disclose the cardiovascular safety results of the SUCCESS Study. For example, in an e-mail dated April 22, 2003, Pfizer physician Dr. Elizabeth Kitsis urged the Company to publish the SUCCESS Study results "in a timely manner because they could be useful to the medical community."[55] In addition, a Pfizer employee wrote Defendant Cawkwell on February 6, 2004, specifically questioning her as follows:

> ONE QUESTION. Why don't they publish SUCCESS I? We have been awaiting the article. ***It is rumored, although a very tiny rumor, that SUCCESS I may contain serious (!?) CV risks of celecoxib. Is it true or just libel?***[56]

221. Despite these expressed internal and external concerns, the results from the SUCCESS Study were not published in a scientific manuscript prior to 2005. In addition, Defendants concealed the results of the SUCCESS Study from the FDA during the February 2001 Advisory Committee hearings.

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[54] *See id.* at Cawkwe-G 10000338423.
[55] *See* 4/22/03 Email from E. Kitsis to A. Kolkathis, bearing Bates No. Gandle M 10000527775 (quoted at ECF No. 420 at 58).
[56] *See* 2/6/04 Email from H. Akama to G. Cawkell re: Question, bearing Bates No. Cawkwe-G 10000871207 (quoted at ECF No. 420 at 58).

5. April 2000: Defendants "Cherry Pick" And "Massage" The Data From The CLASS Study To Conceal Celebrex's Cardiovascular Risks

222. Defendants also misrepresented the results of another pivotal study designed to evaluate Celebrex's safety in treating osteoarthritis and rheumatoid arthritis, known as the Celecoxib Long-Term Arthritis Safety Study or the "CLASS Study." The CLASS Study was actually a combination of two separate studies: (i) the CLASS 1 Study, which compared Celebrex to diclofenac; and (ii) the CLASS 2 Study, which compared Celebrex to ibuprofen. The CLASS Study was one of the largest clinical trials for Celebrex, involving 8,059 patients and conducted over a 12 to 16 month period.

223. The CLASS Study showed that Celebrex patients were more likely to suffer rheumatoid arthritis compared to participants in the diclofenac group. Nine participants suffered myocardial infarctions in the Celebrex group versus zero in the diclofenac group, a statistically significant difference. A February 19, 2001 email from Dr. Steven Geis to Drs. James Lefkowitz and Kenneth Verburg states, "I think that showing CV events adjusted for time of exposure – from the NDA and then from 024 and CLASS serves to reinforce the story that ***we are seeing a signal."***[57]

224. Pfizer had access to, and reviewed, the results of the CLASS Study. According to an internal slide presentation, Pfizer received the results of the CLASS Study on or about April 3, 2000.[58] Minutes from an April 6, 2000 Joint Operations Committee meeting attended by Defendant LaMattina, among others, reflect that Dr. Geis presented at the meeting a "summary

[57] *See* 2/19/01 Email from S. Geis to J. Lefkowith, bearing Bates No. Verbur-K 100004372926-27 (quoted at ECF No. 420 at 61).
[58] *See* Internal Slide Presentation re CLASS Study, bearing Bates No. DEFS 0104864-971 (attached to ECF No. 328-11).

analysis" of the CLASS Study data.[59] In addition, on April 16, 2000, Dr. Leland Loose (Pfizer's Global Candidate Team Leader from 1998 to 2001) forwarded to Defendant LaMattina and his fellow Pfizer colleagues a presentation made concerning the CLASS Study, titled "Anti-Inflammatory Drugs for Arthritis: Focus on COX-2 inhibitors." Finally, according to the sworn testimony of Dr. Loose, Pfizer's Operations Committee, including himself and Feczko, and the Executive Management Committee, including Defendants Katen and McKinnell, received the full results of CLASS Study shortly after they were unblinded.

225. On April 17, 2000, Pharmacia and Pfizer issued a joint press release announcing the supposed results of the CLASS Study, titled "New Findings Presented on Celebrex(R) Safety and Tolerability from Long-Term Outcomes Study of 8,000 Arthritis Patients." The press release stated that the CLASS Study was "a landmark study," "groundbreaking," and a "rigorous outcomes trial [that] set the bar higher than any previous study of its kind." Significantly, in describing the results of the CLASS Study, Defendants emphasized that it was an "approximately 13-month," "long-term" safety study:

> The Celecoxib ***Long-term*** Arthritis Safety Study, ***an approximately 13-month,*** multi-center, randomized, double-blind outcomes trial of about 8,000 arthritis patients – 5,800 with OA and 2,200 with rheumatoid arthritis (RA) – was designed to mirror everyday clinical practice by enrolling a broad spectrum of patients, including adult patients of all ages and disease severity, and patients taking low-dose aspirin for cardioprotection.

226. Unknown to investors, but known to Defendants, Pfizer based its public statements about Celebrex's "safety" on less than ***half*** of the actual data it gathered as part of the CLASS Study. In publicly discussing the safety and efficacy of the drug, Pfizer mentioned only the first ***six months*** of the approximately 13-months of data, concealing approximately ***seven***

[59] *See id.* 4/6/00 Videoconference Minutes from Searle Pfizer Operations Committee, bearing Bates No. DEFS 00170973-976 (attached to ECF No. 328-30)

months of the data from the study. Significantly, when the entire data set was considered, the benefits that Defendants reported based upon six months of data did not hold true but, instead, showed that Celebrex caused cardiovascular harm.

227. On April 28, 2000, Pfizer's Co-Promoter issued another press release, which was reviewed by Defendants, entitled "New Study Validates Safety of Pharmacia Corporation's Celebrex on Stroke, Heart Attack Issues." The press release again purported to discuss the results of the CLASS Study, and touted the drug's purported cardiovascular safety:

> Recent news reports have associated Vioxx (rofecoxib), a treatment for osteoarthritis and pain, with stroke and heart attacks. It has been suggested that this may be an effect common to COX-2 inhibitor compounds. However, new data reaffirm that this is not the case for Pharmacia Corporation's innovative COX-2 specific inhibitor, Celebrex® (celecoxib capsules). A landmark study just released continues to demonstrate ***a strong safety profile for Celebrex***, which is not only indicated for osteoarthritis but also rheumatoid arthritis….
>
> ***The long-term, 13-month outcomes*** study compared 4,000 patients taking very high doses of Celebrex (four times the usual osteoarthritis dose) with 2,000 patients taking prescription daily doses of ibuprofen, and 2,000 patients taking prescription daily doses of diclofenac…..
>
> ***Even at these very high doses, Celebrex showed no increases in stroke or heart attack with or without aspirin. The Celebrex data thus indicate that there is no class-related issue on this important safety parameter, suggesting that any potential risk associated with Vioxx may be specific to that compound.***

228. In addition, on September 13, 2000, the *Journal of the American Medical Associatio*n ("JAMA") published an article written by Pfizer's Co-Promoter and paid consultants about the CLASS Study (the "JAMA Article"). The JAMA Article similarly disclosed only the CLASS Study data from the initial ***six*** months of the trial, nowhere mentioning the unfavorable results of the second half of the study. Based on the incomplete six-month data set, the authors concluded that Celebrex was safer than traditional NSAIDs.

229. Pharmacia provided Pfizer with an "advanced copy" of the JAMA Article "prior to [its] submission for publication" for review and approval, as required by the Co-Promotion

Agreement. On July 11, 2000, Pfizer's Dr. Wahba sent to Pharmacia an email stating that "[t]hese are Pfizer comments on the CLASS MS [i.e., manuscript]."[60] In its comments, Pfizer approved the article's use of the truncated, six-month data set, as well as the other false and misleading statements in the JAMA Article.

230. The same publication of JAMA included an editorial written by Dr. Michael Wolfe, a gastroenterologist at Boston University, about the CLASS Study. Much like investors, Dr. Wolfe believed Defendants had data for only six months of the study, which he described in his editorial as "a 6-month randomized, double-blind, controlled trial." Based on the purported results of the CLASS Study, Dr. Wolfe praised Celebrex's safety and efficacy.

231. On September 13, 2000, Defendants issued a press release titled "JAMA Study Shows Arthritis Medication Causes Fewer Gastrointestinal Problems than Traditional Drugs." The press release directed readers to the JAMA article, Dr. Wolf's editorial, and the purported results of the CLASS Study reprinted in the publication.

232. Unlike investors, Defendants knew about the full data set for the CLASS Study, including the exclusion of the unfavorable results from the second half of the study. In an April 9, 2000 email, Emilio Arbe (a Pharmacia associate medical director) identified "several flaws in the way [Pfizer/Pharmacia] present[ed] the data" in the CLASS Study. As he explained, "[w]ith ***a bit of data massage***, what Steven Geis and his team have done is to ***focus on the 6 month data, for no other reason that [sic] it happens to look better.***"[61] He continued: "The point I am trying to make though is that I don't see what is so great about CLASS. Personally I find it bizarre that we would want to roll out the data to opinion leaders who aren't necessarily ***dupe[d] and I***

[60] *See* 7/11/00 Email from M. Wahba to J. Lefkowith, bearing Bates No. DEFS 00546367-69 (attached to ECF No. 328-26).
[61] *See* 4/9/00 Email from E. Arbe, bearing Bates No. DEFS 00118475-78 (attached to ECF No. 328-3).

wouldn't feel too comfortable presenting a fudged version of the facts."[62] A widely-circulated July 11, 2000 email sent by Dr. Mona Wahba (a Pfizer clinical researcher who worked on Celebrex) also criticized the study for "***cherry picking the data (using 6 m[onths] as study duration).***"[63] Dr. Wahba again criticized Defendants' selective public disclosure of information concerning the CLASS Study in a January 22, 2001 email, in which she wrote to Dr. Weiner, Pfizer's Vice President and Worldwide Therapeutic Head of Inflammation, and others at Pfizer that the "[r]ationale for [six-month] analysis is ***not convincing."***

233. On May 23, 2000, Pfizer's Dr. Mona Wahba forwarded to her colleagues a news report discussing the cardiovascular safety results of the CLASS Study, with the subject line of the email "Good News on Celebrex."[64] The news report, written without the full data set from the CLASS Study, concluded that Celebrex "posed no increased risk of heart attacks or strokes" compared with traditional NSAIDs, as set forth below:

> The long-term safety study also indicated that four times the recommended OA dose of Celebrex, taken with or without aspirin, posed no increased risk of heart attacks or strokes compared with ibuprofen and diclofenac. Approximately 70 percent of the aspirin group and 50 percent

Pfizer's Dr. Samuel Zwillich, who – unlike investors – knew the full data results from the Class Study, including the number of reported adverse cardiovascular events, responded to Dr. Wahba with the following email message commenting on the news report, ***"[t]hey swallowed our story, hook, line and sinker …."***[65]

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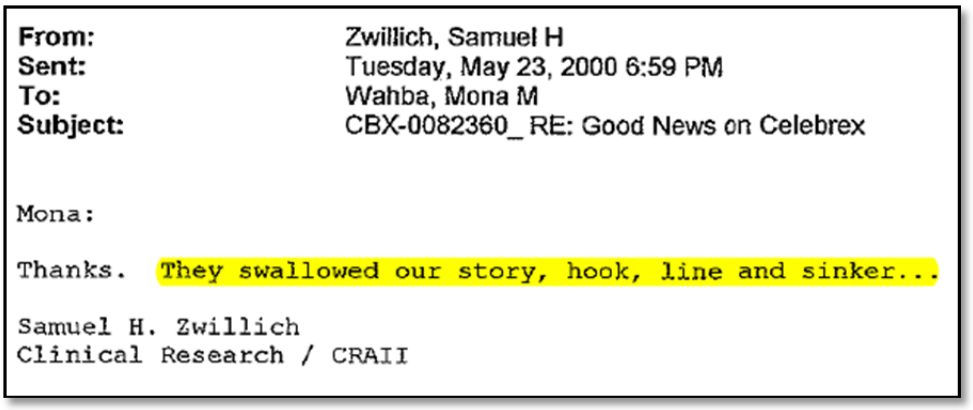
[62] *Id.*
[63] 7/11/00 Email from M. Wahba to J. Lefkowith, bearing Bates No. DEFS 00546367-69 (attached to ECF No. 328-26).
[64] *Id.*
[65] *Id.*



From: Zwillich, Samuel H
Sent: Tuesday, May 23, 2000 6:59 PM
To: Wahba, Mona M
Subject: CBX-0082360_ RE: Good News on Celebrex

Mona:

Thanks. They swallowed our story, hook, line and sinker...

Samuel H. Zwillich
Clinical Research / CRAII

234. Pfizer eventually provided on a confidential, non-public basis the full data set from the CLASS Study to the Arthritis Advisory Committee of the FDA in February 2001. Examining the full data set, the Committee concluded that Celebrex provided ***no*** safety advantage to traditional NSAIDs. Indeed, the FDA prepared an analysis of the CLASS Study, which was sent to Pfizer's Dr. Weiner, among others. The FDA found that Defendants' "rationale for six-month[s] as [a] meaningful endpoint [for the Study was] ***not convincing."*** In addition, the FDA concluded that, when the full data set was considered, "***for global safety, there does not appear to be any meaningful advantage for Celebrex***."

235. On August 5, 2005, the *Washington Post* published an article that revealed that, at the same time that Defendants touted Celebrex's safety and the results of the CLASS Study, they had the full data set for the study. Dr. Wolfe, the same scientist who praised the results of the CLASS Study in the September 2000 JAMA publication, stated that he was ***"flabbergasted"*** when he learned that the true duration of the study was 12 to 16 months. The 2005 *Washington Post* investigative report explained:

> The [CLASS] study – already completed at the time [Dr. Wolf] wrote the editorial – had lasted a year, not six months as he had thought, Wolfe learned. Almost all of the ulcer complications that occurred during the second half of the study were in Celebrex users. When all of the data were considered, most of Celebrex's apparent safety advantage disappeared.

The article further quoted Dr. Wolfe as stating: ***"'I am furious. . . . I wrote the editorial. I looked like a fool . . . . [But, a]ll I had available to me was the data presented in the article.'"***

236. JAMA also never learned about the full data set for the CLASS Study until years after the publication of the September 2000 JAMA Article. According to the same *Washington Post* investigative report, "JAMA's editor, Catherine D. DeAngelis, said the journal's editors were not informed about the missing data. ***"'I am disheartened to hear that they had those data at the time that they submitted [the manuscript] to us,' she said. 'We are functioning on a level of trust that was, perhaps, broken.'"***

237. Dr. Alastair J. J. Wood, who was chairman of the FDA advisory panel that examined Celebrex, similarly stated that "[i]t clearly would have been nice to have had this information [about the CLASS Study] long ago," according to a June 24, 2012 article in the *The New York Times*.

6. May 2005: Undisclosed Pooled Analysis Shows That Celebrex Patients Are Seven-Times More Likely To Suffer A Cardiovascular Event

238. As discussed above, on April 7, 2005, at the insistence of the FDA, Pfizer agreed to insert a black box warning in Celebrex's label advising patients of the drug's cardiovascular risks. Approximately one month later, Pfizer confidentially sent to the FDA a previously undisclosed "Celecoxib Cardiovascular Safety: Meta Analysis of 41 Randomized, Controlled Clinical Trials." The cover memorandum to Pfizer's May 13 letter to the FDA states that:

> Pfizer has completed a CV safety meta-analysis of 41 completed randomized, controlled clinical trials (up to 52 weeks duration) with celecoxib. The objective of the meta-analysis was to assess the risk of serious cardiovascular thromboembolic adverse events and cardiorenal adverse events in patients treated with celecoxib, placebo, and non-selective NSAIDs, using adverse events data

from Pfizer-sponsored clinical trials that studied celecoxib in chronic indications.[66]

239. The results of this pooled meta-analysis showed that, when all of Pfizer's trials for Celebrex were considered collectively, patients treated with Celebrex showed a ***seven times, statistically significant*** increase in "myocardial thromboembolic" events for Celebrex 400 mg compared to placebo.[67]

240. Pfizer never disclosed the results of its May 2005 pooled analysis to investors. Indeed, the May 13 Letter to the FDA attaching the meta-analysis expressly prohibited the FDA from "disclos[ing] or us[ing], in whole or in part, [the meta-analysis] for any other purpose without the prior written consent of Pfizer Inc."

C. Defendants Knew Of Numerous Clinical Trials And Internal Studies Demonstrating That Bextra Causes Cardiovascular Harm

241. Throughout the Relevant Period, Defendants knew that their other blockbuster COX-2 inhibitor, Bextra, also caused serious cardiovascular harm. As detailed below, Defendants conducted a series of clinical studies both before and after the FDA's approval of Bextra, which identified significant cardiovascular risks associated with the drug. To avoid public disclosure of these risks, Defendants concealed from investors and patients the true results from these studies. As Professor Furberg explained in his March 6, 2009 expert report, a "statistically significant risk of adverse cardiovascular events induced by the use of Bextra was documented prior to the FDA approval in 2001. Additional studies post-approval further confirmed the harmful cardiovascular effects of Bextra."[68]

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[66] *See* 5/13/05 Letter from Pfizer to B. Rappaport, M.D., bearing Bates No. Cele NDA 48395 00007946-48; 8085 (attached to ECF No. 351-39).
[67] *See id.* at Cele NDA 48395 00008085.
[68] *See* Expert Report of Professor Furberg, dated 3/6/09, at 10.

1. June 1998: Study 016 Raises "Major Concerns" That Bextra Causes Heart Attacks, But Is Left Undisclosed For Nearly Seven Years

242. Prior to the FDA's approval of Bextra, Defendants completed a six-week, Phase 2 clinical trial on patients suffering rheumatoid arthritis, referred to as the Study 016. The 678 participants in the trial were divided into three groups. One group was treated with Bextra, one group received naproxen, and the final group received a placebo. Patients treated with Bextra received the drug at various dose-levels, including at doses below the recommended-use level (referred to as "subtherapeutic levels").

243. The clinical data from the Study 016 showed that Bextra (like Celebrex) caused cardiovascular harm. Even within the study's small sample, two of the patients treated with Bextra suffered heart attacks and died. In addition, of the twelve patients who experienced adverse events in the Bextra group, six of them were heart attacks, compared to no heart attacks in patients given a placebo or the active control, naproxen. Finally, multiple patients that received subtherapeutic doses of the drug experienced adverse cardiovascular events and were forced to withdraw from the study. In contrast, no patients in the placebo group withdrew from the study based on cardiovascular events. Based on his expert review of the clinical data, Professor Furberg concluded that the "results of this study demonstrated that ***Bextra was associated with adverse cardiovascular events even at subtherapeutic doses***."

244. On June 12, 2000, Dr. Zwillich, a Pfizer Clinical Researcher, sent Dr. Mona Wahba, a Pfizer Clinical Research Associate II, an email with the subject line "016 Study Report." Dr. Zwillich's email, which was marked "Importance: High," begins: ***"Mona: Not very pleasant reading this weekend!"*** Dr. Zwillich explained that he was ***"worried about the safety data,"*** including the number of reported cardiovascular events. As noted by Dr. Zwillich, the study showed that there were ***"6 MIs [i.e., myocardial infractions (commonly known as "heart***

attacks")] on valde [i.e., Bextra] vs. 0 on placebo or naproxen."[69] Further concerning, as noted by Dr. Zwillich, four of the patients in the Bextra treatment group experienced heart attacks within only fourteen days of their first dose of Bextra.

245. Two days after receiving Dr. Zwillich's email, Dr. Wahba sent an email of her own to a number of Pfizer employees titled ***"016 major concerns."***[70] The email begins: "Dear all, i'll address only major concerns about 016 in this message, the rest of the comments will be faxed to Greer." Under the heading "Safety," Dr. Wahba highlighted for her colleagues the cardiovascular safety data identified by Dr. Zwillich in his email sent to her two days earlier:

> CVS: 6 MI's [i.e., myocardial infarctions] on Valde [i.e., Bextra], none on [placebo] or Naproxen. 4 MI's took place within 10 days of first dose of medication…. More heart rate disorders on Valde, a case of retinal artery thrombosis on 10 mg QD and case of vasculitiis on 0.5 mg dose. slight increase in SBP [i.e., systolic blood pressure] on the high valde dose!

Based on her review of the study results, Dr. Wahba concluded that she was ***"not sure if we can exclude [Bextra] as a contributing factor in the causality of these [adverse cardiovascular] events."***

246. In response to Dr. Wahba's email listing her "major concerns," Dr. Leland Loose directed that she not use the phrase "major concerns" in her written communications concerning the 016 Study because ***"it sound[ed] ominous."***[71] In response, Dr. Wahba wrote, "Dear Boss,…. i'll consider your recommendations next time . . . ."

247. Defendants failed to disclose these "major concerns" or publish any stand-alone analysis of the results of the Study 016.

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[69] *See* 6/12/00 email from Dr. Samuel Zwillich to Dr. Mona Wahba, bearing Bates No. Wahba-M 10000584069 (attached to ECF No. 345-22).
[70] *See* 6/14/00 email from Dr. Mona Wahba to Dr. Leland Loose, bearing Bates No. Wahba-M 10000200605-06 (attached to ECF No. 345-21).
[71] *Id*.

2. May-July 2000: Pfizer's 060 And 061 Studies Show "Clearly An Increased Incidence" Of Heart Attacks In Rheumatoid Arthritis Patients

248. Pfizer conducted two additional, larger-scale Bextra clinical studies on rheumatoid arthritis patients, which were referred to as the "060 and 061 Studies." The two studies were completed on, respectively, May 31, 2000, and July 4, 2000. The results of both studies further demonstrated Bextra's cardiovascular side effects.

249. The 060 Study was a 12-week study conducted between September 18, 1999, and May 31, 2000 that compared the efficacy and safety of Bextra with naproxen and placebo in 1,089 patients. On August 15, 2000, Pfizer's Head of European Union Development and Development Operations in the European Union and Asia, Dr. Eliot Forster wrote an email to Defendant LaMattina, Ethan Weiner and other Pfizer employees summarizing the results of the 060 Study, with the subject "emerging data from valdecoxib phase III."[72] Dr. Forster concluded that the 060 Study showed that Bextra usage leads to an increased risk of heart attack. In particular, he wrote:

> Of note, there were two MIs in the valdecoxib groups and an increased incidence of edema, hypertension and rash. ***[T]here is clearly an increased incidence of MI with valdecoxib compared to placebo and NSAIDs at this point in the data-base.***

Dr. Ryder sent a response email to Dr. Forster, noting that ***"the mi issue needs surveillance. If real, it would position the drug like Vioxx."***

250. Recognizing that the public would eventually learn about Bextra's undisclosed cardiovascular side effects, and litigation was bound to follow, Dr. Saxton (via an email sent by his assistant) instructed Dr. Forster to "discuss this further by telephone" (emphasis in original),

[72] *See* 8/15/00 email from E. Forster to LaMattina, bearing Bates No. PFE SECURITIES HC 000232235-5 (quoted at ECF No. 420 at 80).

i.e., not through written communications that would later be subject to discovery.[73] Dr. Leland Loose, Executive Director in Pfizer's global research and development unit and a member of Pfizer's COX-2 team, wrote Dr. Forster two days later to underscore the need to avoid any potential disclosure of the study's cardiovascular risks. In his email, Dr. Loose cautioned: "I spoke with [Dr. Forster] after he had spoken to [Dr. Saxton]. ***In essence [Dr. Saxton] wants the visibility decreased as you can understand."***[74]

251. The related 061 Study also demonstrated Bextra's cardiovascular side effects. The 061 Study was a 12-week study conducted between September 3, 1999, and July 4, 2000. Participants in the 061 Study were given Bextra, naproxen, or a placebo. Approximately 77% of the total patients that experienced serious cardio-renal events, such as hypertension or congestive heart failure, were in the Bextra treatment group. As Dr. Furberg explained in his expert report, "[m]edically-speaking, renal and cardiovascular events tend to go together . . . . The significance of Study 061 is that it is a ***further replication of harmful serious cardiovascular complications following Bextra exposure***."[75]

252. Pfizer and Pharmacia employees also concluded that the 061 Study demonstrated Bextra's adverse cardiovascular side effects. For example, on August 15, 2000, Dr. Forster forwarded an email from Dr. Verburg of Pharmacia to Defendant LaMattina and others, stating:[76]

> We unblinded the second valdecoxib Phase III RA study [061] on Friday night. . . . note that peripheral edema and to a certain extent, hypertension were higher in the valdecoxib treatment groups than placebo and naproxen. The incidence of these adverse events appeared to be dose-related. We saw a similar pattern in the 060 trial.

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[73] *See* 8/20/00 email from E. Weiner to L. Loose, bearing Bates No. 10000190367-68 (quoted at ECF No. 420 at 81).
[74] *Id.*
[75] *See* Expert Report of Professor Furberg, dated 3/6/09, at 32.
[76] *See* 8/15/00 email from Dr. Forster to LaMattina and others, bearing Bates No. PFE SECURITIES HC 000232266-73 (quoted at ECF No. 420 at 84).

In Dr. Forster's email forwarding the above message to Defendant LaMattina and others, he cautioned: ***"I think the data speak for themselves… Note the peripheral edema and hypertension at 20mg and 40mg."*** [77]

253. Two weeks later, on August 28, 2000, Dr. Verburg sent an email to Drs. Needlemen and Geis titled "Valdecoxib 061 Results." In his email, Dr. Verburg also "note[d] that peripheral edema and to a certain extent, hypertension were higher in the valdecoxib treatment groups than placebo and naproxen." Dr. Needleman, Head of Research and Development, agreed with Dr. Verburg's assessment, stating in his response email that "***[i]t does look like we're seeing a [sic] dose dependent cardiovascular effects.***"[78]

254. Notwithstanding the above facts, Defendants did not publish a manuscript containing the results of the 061 Study in any medical or scientific journal during the Relevant Period.

3. June 2000: Pfizer's Undisclosed CABG-1 Study Shows That Patients Receiving Bextra Are Three Times More Likely To Suffer A Serious Cardiovascular Event

255. On June 16, 2000, Pfizer completed its first study on coronary artery bypass graft (CABG) patients for both Bextra and parecoxib, the intravenous form of Bextra. This "CABG-1 Study" included a total of 462 patients from Canada, the United States, Germany, and the United Kingdom. Patients received either a placebo or parecoxib, followed by valdecoxib (the oral form of Bextra). The results of the CABG-1 Study further demonstrated the adverse cardiovascular side effects of Bextra.

256. The CABG-1 Study found that over ***20%*** of the patients in the Bextra treatment group reported a serious adverse event, or approximately ***twice*** the percentage of patients in the

[77] *Id.*
[78] *See* 8/28/00 email from Dr. Needleman re: "Valdecoxib 061 Results," bearing Bates No. Verbur-K10000826457 (quoted at ECF No. 420 at 84).

placebo group. In addition, all four of the deaths were in the Bextra treatment group. Finally, patients treated with Bextra, as opposed to a placebo, were ***three times*** more likely to report a serious cardiovascular event.

257. As Professor Furberg explained in his expert report:

> The significance of the [CABG-1 Study] is obvious. First, it confirmed the safety signal seen in Study 016 . . . . Second, the findings for any serious adverse events, serious cardiovascular events[,] . . . and sternal wound infections were ***all statistically significant***. Third, all patients in the trial had coronary heart disease and, thus, were at an ***increased risk of a coronary event***.[79]

258. On July 18, 2000, Dr. Ethan Weiner sent an email to Drs. Steve Ryder and Leland Loose, and Jeff Finman, Ph.D., and Eliot Forster, Ph.D., stating:

> Steve Geis called me late yesterday regarding a parecoxib-valdecoxib switch study Pharmacia had conducted. Since they considered this a parecoxib study we were not consulted on the design nor on the execution; however, after consultation with Phil Needleman, Steve felt these results needed to be shared with us. . . . By the protocol defined criteria, [clinically relevant AEs, including MI and stroke] occurred in 23% of the pare/valde group and 15% of the PBO group, ***a difference that was statistically significant.***[80]

259. Pfizer received the data results of the CABG study. In an email dated July 26, 2000, Dr. Leland Loose wrote to Dr. Ethan Weiner concerning the CABG study that, "I am anxious to see the real data," to which Dr. Weiner responded that "[y]ou should have it – it came last Friday."[81]

260. On November 27, 2000, Phyllis Christensen forwarded to Defendant Feckzo and others an email from Laraine Meyers, which stated that Dr. Feniechel, Pfizer's outside

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[79] *See* Expert Report of Professor Furberg, dated 3/6/09, at 31.
[80] *See* 7/26/00 email from E. Weiner to D. Ryder et al., bearing Bates No. PFE SECURITIES 001825783-84 (quoted at ECF No. 420 at 88-89).
[81] *Id.*

consultant, raised a "primary concern . . . around CABG study findings, *i.e.*, pro-thrombotic events. His concern was high enough for him to question it as an [FDA] approvability issue."[82]

261. In March 2001, nearly seven months after the completion of the CABG-1 Study, Pfizer and its Co-Promoter prepared a draft manuscript concerning the Study's results. The draft manuscript attempted to conceal the Study's true results, and JAMA refused to publish it.

262. Indeed, on March 26, 2001, Pfizer Dr. Mark Fletcher emailed Dr. Ethan Weiner and others commenting on the draft manuscript, stating:

> Given that this study was predominantly a safety trial and has safety mentioned in the title, it really begs the issue that nothing about safety is summarized in the conclusions (for obvious reasons to us, but ***the whole presentation seems somewhat unbalanced*** and one picks up right away about a potential safety issue that is really being obfuscated. While it is probably marginally OK to due [sic] this in the abstract itself, ***when it comes time to give the talk/poster I am assuming that the real data will have to be shown.***[83]

263. The FDA also voiced concerns about the results of the CABG-1 Study. Internal "Minutes of a meeting with FDA" on August 3, 2001, attended by Drs. Needlemen, Geis, and Verburg, reflect that the "FDA firmly believe[d] that the CABG study, though inconclusive, revealed ***'signals' of serious adverse events*** for which the general surgery safety database is too small to rule out their potential occurrence in a non-CABG surgical population."[84] As further noted in the minutes, the "FDA was insistent that ***the safety signal could not be ignored*** and that ***it was not possible to 'label around it'*** with a contraindication or warning (even a 'black box' may not be effective) regarding use in these patients." Based on these safety concerns, the FDA rejected the new drug application ("NDA") for parecoxib, the intravenous form of Bextra.

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[82] *See* 11/27/00 email from Eric Sirota to Pat Kelly and Teri Natalicchio re: "Celebrex NDA and Valde NDA," bearing Bates No. Natali-T 10000119299-300 (quoted at ECF No. 420 at 92).
[83] *See* 3/26/01 email from M. Fletcher to E. Foster, E. Weiner and N. Hounslow, bearing Bates No. PFE SECURITIES 002259467 (quoted at ECF No. 420 at 106).
[84] *See* 8/20/01 Minutes of a Meeting with FDA (August 3, 2001) re parecoxib sodium, NDA 21-294, bearing Bates No. Phelan-K 100000343727-3 (attached to ECF No. 387-8).

264. Tellingly, upon learning of the FDA's rejection of the NDA for parecoxib, Pfizer employees immediately concluded that the FDA's rejection related to the same cardiovascular safety side effects observed for Bextra. For example, in one July 15, 2001 email, Dr. Ryder wrote Dr. Weiner and his other Pfizer colleagues, ***"Ominous. Do you think it is the cardiovascular safety issue?"*** Dr. Weiner also suspected that the FDA's rejection related to the drugs' cardiovascular risks, responding to Dr. Ryder as follow:

> ***I suspect (based on no evidence yet) that the safety issue [identified by the FDA] is cardiovascular*** and the efficacy issue is problems with the post-surgical pain models. ***In that case, the valdecoxib [i.e., oral Bextra] dossier is in big trouble as well.***[85]

Dr. Weiner appreciated that the oral form of Bextra presented the same cardiovascular "safety issue" as the intravenous form of the drug and, as a result, the Bextra ***"dossier [wa]s in big trouble as well."***[86]

265. Pfizer senior management, including Defendants Katen and LaMattina, were told about the FDA's rationale for rejecting the parecoxib NDA, and were advised that these same cardiovascular side effects were identified in other Bextra studies. Internal Pfizer emails sent in mid-July 2001 discussed the need "to put together a concise update for [Defendant] Karen Katen regarding the pare [i.e., parecoxib] situation" and stated that Defendant "John Lamattina ha[s] demanded the same."

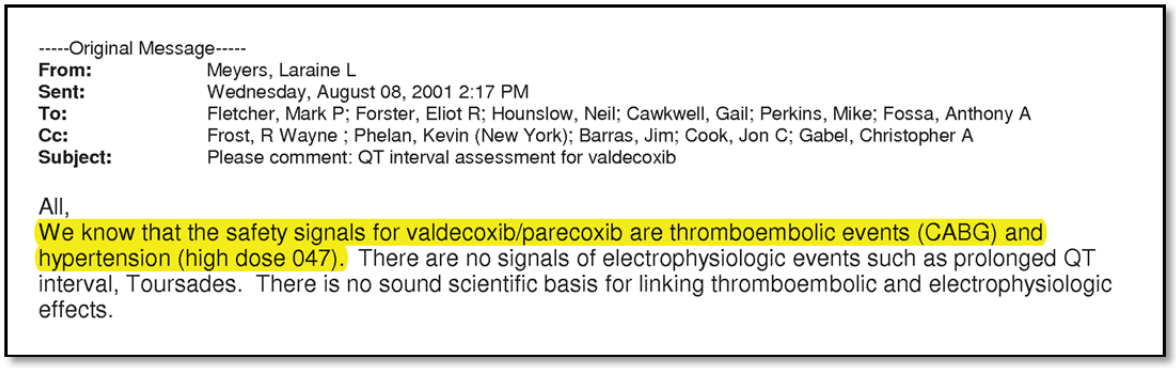
266. Pursuant to these instructions, on July 16, 2001, a Pfizer employee sent an email to Defendant LaMattina and others, which contained a "high level summary of what we know re: the parecoxib action letter that [Pharmacia] received from FDA on Friday, July 13, 2001 (and which we first heard about [from Pharmacia] later that evening)." The email attachment, titled "non approval impact.doc," discussed the impact of the FDA's non-approval of parecoxib on the

[85] *See* 7/15/01 email from Ethan Weiner to Steven Ryder re: Parecoxib, bearing Bates No. Weiner-E 10000495056-58 (quoted at ECF No. 420 at 95).
[86] *Id.*

FDA's forthcoming NDA approval decision for Bextra, as well as the FDA's concerns with the CABG-1 Study. The full safety results of the CABG-1 Study were described as follows:

> ***Safety in CABG trial unacceptable due to thromboembolic events, GI events, renal dysfunction.*** Safety data from long term exposure to oral valdecoxib in an outpatient setting is not adequate to characterize the safety profile of a parenteral agent in a different intended population. ***Not enough non-CABG surgical data to give FDA comfort that this problem limited to this study or to CABG, therefore this applies to all acute and peri-operative settings.***[87]

267. Pfizer internally understood that the results from the CABG study showed that ***both*** parecoxib (the intravenous form of Bextra) and valdecoxib (the oral form of Bextra) posed serious cardiovascular risks. For example, on August 8, 2001, Dr. Laraine Meyers, who worked in Pfizer's Regulatory department, sent an email to eleven Pfizer employees, including Defendant Cawkwell, an excerpt of which is below:[88]



-----Original Message-----
From: Meyers, Laraine L
Sent: Wednesday, August 08, 2001 2:17 PM
To: Fletcher, Mark P; Forster, Eliot R; Hounslow, Neil; Cawkwell, Gail; Perkins, Mike; Fossa, Anthony A
Cc: Frost, R Wayne ; Phelan, Kevin (New York); Barras, Jim; Cook, Jon C; Gabel, Christopher A
Subject: Please comment: QT interval assessment for valdecoxib

All,
We know that the safety signals for valdecoxib/parecoxib are thromboembolic events (CABG) and hypertension (high dose 047). There are no signals of electrophysiologic events such as prolonged QT interval, Toursades. There is no sound scientific basis for linking thromboembolic and electrophysiologic effects.

As reflected in Ms. Meyer's email, based on the results of the CABG study, Pfizer ***"kn[e]w that the safety signals" for Bextra "are thromboembolic events"*** – *i.e.*, blood clots causing, among other things, strokes and pulmonary embolisms – as early as August 2001.

268. In fact, based on the adverse cardiovascular findings identified in the CABG study, Defendants attempted to negotiate down the amount of "milestone payments" due to its

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[87] *See* 7/16/01 email from M. Fletcher to S. Ryder, et al., bearing Bates No. Fletch-M 10000692570-72 (quoted at ECF No. 420 at 96).
[88] *See* 8/13/01 email from G. Cawkwell to M. Wahba re: "Please comment: QT interval assessment of valdecoxib," bearing Bates No. Cawkwe-G 10000889321 (attached to ECF No. 345-23).

Co-Promoter. On August 9, 2001, Pfizer employees prepared "talking points" for Defendant McKinnell to use in connection with negotiating the milestone payments due under the Co-Promotion Agreement. Defendant McKinnell's talking points concluded that "the milestone [payment for Bextra] is inflated" because the "Commercial Estimate of Valdecoxib's value" had declined.[89]

269. The "talking points" also summarized the "[r]ationale for the need to revise downward the Commercial Estimate of Valdecoxib's value, based on information related to FDA's review of the parecoxib NDA and their not approvable action letter." In short, the commercial value of Bextra had declined because the CABG-1 Study and other clinical studies showed that Bextra was unsafe. On this subject, the talking points for Defendant McKinnell specifically noted that one factor "most material to revising the commercial estimate of valdecoxib's value center[ed] around … the adequacy of data to support the safety of valdecoxib in the perioperative period for the treatment of acute pain, ***in lieu [sic] of the excess in serious cardiovascular adverse events with parecoxib/valdecoxib-treated patients in the Coronary Artery Bypass -Graft (CABG) surgery study (N93-035).***"[90]

270. The talking points, including the comments of Drs. Ethan Weiner and Mark Fletcher, further stated that:

- "[T]he FDA has indicated that the CABG study data 'raise the possibility that parecoxib is associated with ***serious, life-threatening adverse events*** … (and by implication also valdecoxib which was also employed in this study coxib)."
- "[t]he AP [i.e., acute pain] dose [for Bextra], when given over time, is one at which the ***cardio-renal side effects become an issue***"; and

[89] *See* 8/13/01 email from M. Fletcher to R. Loewi, bearing Bates Number Fletch-M 10001052146 (quoted at ECF No. 420 at 99-102).
[90] *See* 8/12/01 email from E. Weiner to R. Loewi, bearing Bates No. Weiner-E 10000472867-71 (quoted at ECF No. 420 at 100).

- "An extrapolation of data from the NDA database, comparing the cardio-renal safety profile of valdecoxib to both Celebrex and Vioxx via normalization to Naprosynnaproxen, shows ***a rate of clinically significant hypertension amongst valdecoxib users.***"

271. The talking points concluded that Pfizer's Co-Promoter "ha[d] not properly accounted for the cardio-renal or AP label impact in the projections of valdecoxib sales. Therefore, the milestone [wa]s inflated."[91]

272. On September 14, 2001, Defendant Katen sent a letter to Carrie Cox, Executive Vice President and President, Global Prescription Business, which also argued for a reduction in the amount of "milestone payments" due to Pharmacia based on Bextra's undisclosed safety risks, as demonstrated by the CABG Study.[92] Defendant Katen explained:

> Pfizer believes the milestone evaluation must account adequately for the potential impact of two other important factors which would be material to the sales forecasts of valdecoxib. The first relates to the possibility that ***FDA may view valdecoxib as more like Vioxx than Celebrex with respect to hypertension and peripheral edema side effects;*** the second concerns FDA's ultimate view of the the [sic] scope of the acute pain indication for valdecoxib. ***The companies have clearly assigned different probabilities to these two factors.***

273. On or about October 31, 2001, the results of the CABG-1 Study were reviewed at an internal Pfizer Development Planning Committee meeting. Defendants McKinnell, Feczko, LaMattina, Katen participated in the meeting. The results of the CABG study were extensively discussed, and a slide presentation summarized the study's results. One of the slides, under the heading "CABG Surgery (High Risk) Patients," specifically noted that "[t]he incidence of thrombo-embolic events with 2x the recommended daily dose of parecoxib/valdecoxib for acute

[91] *Id.*
[92] *See* 9/14/01 letter from K. Katen to C. Cox, bearing Bates No. PFE SECURITIES HC 00295420 (quoted at ECF No. 420 at 102).

pain ***was higher than placebo***."[93] As noted in one of the slides presented at the meeting, the ***"[Valdecoxib] CABG data adds credence to Cox-2 CV class effect."*** [94]

274. Defendants also discussed at the October 31, 2001 meeting how the CABG-1 Study results, if publicly disclosed, could impact future Bextra sales. On this subject, a presentation slide discussing the "Market Impact" of the study noted that ***"Valdecoxib label with CABG warning [would cause a] loss 25%"*** in Bextra sales.[95]

275. Defendant McKinnell was particularly troubled by the results of the CABG-1 study, and critical of Pharmacia for having originally suggested that they perform the study. As Dr. Weiner recounted in an email sent the day after the meeting, "[m]uch criticism of Pharmacia for doing the CABG trial in the first place – Hank [McKinnell] wanted to see the [CABG] data again."[96]

276. Less than a week later, on November 5, 2001, the Valdecoxib Joint Product Team, which included Defendant Cawkwell, also held a meeting to discuss the results of the CABG-1 study. The Joint Product Team shared the Development Planning Committee's concern that there would be a significant decline in Bextra sales if the results of the CABG-1 study were publicly disclosed. The Valdecoxib Joint Product Team meeting minutes acknowledge that the "CABG data will affect managed care perceptions of the portfolio, ***possibly raising safety concerns about Celebrex***" and "***Merck might use CABG as ammo***."

277. In addition, Dr. Weiner and others at Pfizer internally recognized that the results of the CABG-1 study contradicted Defendants' public representations about the drug's

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[93] *See* 10/31/01 DPC Slide Presentation, bearing Bates No. Phelan-K 10000214351-71 (quoted at ECF No. 420 at 91).
[94] *Id.*
[95] *Id.*
[96] *See* 11/1/01 email from E. Weiner to E. Forster, bearing Bates No. Weiner-E 10000073334 (quoted at ECF No. 420 at 90-91).

cardiovascular safety. On November 20, 2001, within weeks of the Valdecoxib Joint Product Team meeting, Dr. Weiner sent to Dr. Ryder and other Pfizer colleagues an email commenting on the bolded language in the following excerpt of a November 19, 2001 *Wall Street Journal* news article (emphasis in original):

> Pharmacia anticipates no such problems for Bextra. **"We do not see any evidence of increased risk for any kind of serious cardiovascular problems," said Steve Geis,** group vice president for clinical research at Pharmacia.

Commenting on the bolded text, Dr. Weiner wrote Dr. Ryder and his other fellow Pfizer colleagues: "Please see the highlighted text. ***After all the trouble with JAMA, they just don't learn."*** [97]

278. Based in large measure on the undisclosed clinical trial results of the CABG-1 Study, the FDA rejected Pfizer's application for an acute pain indication for Bextra. The FDA's November 16, 2001 rejection letter specifically identified "Safety" as the first "deficienc[y]" preventing approval, and further stated that "safety of valdecoxib for the management of acute pain in the peri-operative setting ***has not been established based on the findings of study 035 (CABG)***."[98] To avoid disclosure of this deficiency, Pfizer and its Co-Promoter successfully urged the FDA to redact its rationale for denying an acute pain indication from the publicly-available version of the FDA's November 16, 2001 letter.

279. To assuage any potential public concern about the FDA's denial of an acute pain indication for Bextra, Defendants attempted again to have JAMA publish a scientific journal article that skewed the results of its clinical studies. This time, however, JAMA identified the deficiencies in Pfizer and its Co-Promoter's manuscript before accepting the article. According

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[97] *See* 11/20/01 email from E. Weiner to S. Ryder, bearing Bates No. Weiner-F 10000254259-60 (quoted at ECF No. 420 at 112-113).

[98] *See* 11/27/01 Letter from the FDA to G.D. Searle & Co., bearing Bates No. Bex NDA 21-341 00025109-127 (attached to ECF No. 202-15).

to a March 12, 2002 email from Dr. George Sands to Defendant Cawkwell and others, ***"JAMA rejected the CABG paper; they said 'it was not good science.'"***[99] In her response to Dr. Sands, Defendant Cawkwell agreed with JAMA, and sarcastically asked "Science victorious over politics?"[100] Later that night, Defendant Cawkwell breathlessly wrote Dr. Sands regarding the CABG manuscript, exclaiming ***"I mean it isn't good science!!!!"***[101]

280. Defendants failed to publish a manuscript containing any results from the CABG-1 Study until June 2003. Defendants understood that the publication of the CABG-1 results would cause a public backlash. As Dr. Gandelman explained to Defendant Cawkwell, "[t]he CABG paper will likely hit the street in June, we need to present to management a plan of how we will address the negative CV perception on Bextra, Celebrex, and the Cox-2s. We need strategy and tactics."[102]

281. As part of their "strategy and tactics," Defendants misrepresented the results of the CABG-1 study in their published manuscript. As Professor Furberg explained in his March 6, 2009 expert report:

> [The 2003 manuscript] ***failed to include complete data*** that were relevant to an assessment of the protocol-specified cardiovascular thromboembolic risk with Bextra. Specifically, they failed to include in the statistical analysis two cases of pulmonary embolism in the Bextra treatment group. The authors also excluded in Table 5 of the CABG-1 publication serious adverse events that occurred in 2 or fewer patients . . . . ***If the two cases of pulmonary embolism had not been excluded from the analysis, a statistically significant increased incidence of pre-specified serious cardiovascular thromboembolic events with Bextra would have been found . . . .***[103]

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[99] *See* 3/12/02 email from G. Cawkwell to G. Sands, bearing Bates No. Cawkwe-G 10000261656 (quoted at ECF No. 420 at 117).
[100] *Id.*
[101] *Id.*
[102] *See* 5/5/03 email from M. Gandelman, bearing Bates No. Cawkwe-G 10001171330 (quoted at ECF No. 420 at 118-119).
[103] *See* Expert Report of Professor Furberg, dated 3/6/09, at p.39.

282. It was not until Pfizer published an amended prescribing label for Bextra in November 2004 that the Company first disclosed the complete, statistically significant results of the CABG-1 study.

4. August 2000: Pfizer "Embargoes" The Results Of The 047 Study Showing An "Annoying" Bextra Cardiovascular Safety Signal

283. Bextra's cardiovascular side effects were also confirmed by the results of the "047 Study," a six-month long double-blind study completed in August 2000 that compared the safety of Bextra to naproxen on 900 patients. As Professor Furberg explained in his March 6, 2009 expert report, the results from the 047 Study "were troubling and reflected, compared to naproxen, a ***doubling and in some cases a tripling in the incidence of such adverse events*** as reduced renal perfusion/filtration, renal tubular dysfunction (including proteinuria, edema and hyponatremia), and interference with blood pressure."[104]

284. Defendant Cawkwell and other Pfizer scientists internally appreciated that the 047 Study raised a safety "signal" for hypertension adverse events. On August 8, 2001, Laraine Meyers, Associate Director of Regulatory Affairs, wrote to Defendant Cawkwell, among others, stating that "[w]e know that the safety signals for valdecoxib/parecoxib are thromboembolic events (CABG) and hypertension (high dose 047)." On October 17, 2000, Dr. Needleman, a senior scientist at Searle, emailed Dr. Verburg and Dr. Geis about the cardiovascular safety data for the 047 Study, similarly concluding that "***[t]o me it looks like a small but annoying signal is present*** . . . . Obviously ***great pains*** will be required in the write-up, submission and global regulatory debates."[105]

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[104] *See id*. at 33.

[105] *See* 10/17/00 email from P. Needlemen to K. Verburg re: "Valdecoxib -038 Rapid Results," bearing Bates No. Cawkwe-G 10000889321 (attached to ECF No. 205-7).

285. On October 3, 2000, Dr. Ethan Weiner emailed his boss, Dr. Steven Ryder, to advise him of the results of the 047 Study, which he described as "the big 6 month safety study of high dose valdecoxib." [106] Dr. Weiner concluded, based on his review of the 047 Study results, that "***the safety profile looks very Vioxx-like in my opinion.***" As Dr. Weiner was aware at the time, scientific studies had demonstrated that Vioxx caused cardiovascular harm.

286. Again, on October 21, 2000, Dr. Weiner emailed Dr. Ryder slides of the results of the 047 Study from the Joint Pfizer/Pharmacia Development Committee meeting, with the note: "FYI ***please don't circulate too widely yet***… these are the results of the 6 month safety study of 20 mg valde bid vs. 40mg valde bid vs. naproxen 500 bid. Renal effects, even of 20 mg bid are ***Vioxx like***, although Pharmacia makes the conclusion 'not significantly different from naproxen.'"[107]

287. Defendants intentionally suppressed the safety results of the 047 Study, fearful that their disclosure would raise concerns about the cardiovascular safety of the drug. The Bextra Publications Working Group, a joint Pfizer/Pharmacia group that included Defendant Cawkwell and other Pfizer employees, specifically discussed the potential disclosure of the results of the 047 Study at a February 5, 2002 meeting. They concluded that the results should be ***"embargoed"*** and not released to the public because publication of the data would be ***"damaging to the product."*** The minutes from the Publications Working Group Meeting, which were sent to Defendant Cawkwell, memorialized the discussion as follows:

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[106] *See* 10/3/00 email from E. Weiner to S. Ryder re: "FW: 047," bearing Bates No. Weiner-E 10000245778-816) (attached to ECF No. 205-8).

[107] *See* 10/21/00 email from E. Weiner to S. Ryder, bearing Bates No. PFE SECURITIES 001593534-3556 (quoted at ECF No. 420 at 73-74).

	047 manuscript *Post-meeting note:* The decision to go ahead with this publication, made at the face-to-face meeting, was over turned at a subsequent telecon (March 5, 2002). Originally the group had decided that these data should be published as an issue of crediability as the data are published in the label. However, the group subsequently decided that publication of these data would be damaging to the product and that the publication should be embargoed.	

288. To avoid any "damag[e] to the product," Defendants never published any manuscript that included the results of the 047 Study, notwithstanding Pfizer's stated policy of publishing all safety data "regardless of outcome."

5. January 2002: Pfizer's 040 Cancer Study Confirms Bextra's Serious Safety Risks And The Study Is "Embargoed"

289. On January 25, 2002, Defendants completed another major Bextra clinical study, the "040 Cancer Study." The 040 Cancer Study was a 12-week, randomized study designed to evaluate Bextra's efficacy as an add-on therapy to opiods in cancer patients suffering chronic pain.

290. The results of the 040 Cancer Study further demonstrated Bextra's significant cardiovascular side effects. The 040 Cancer Study showed that a statistically significant higher number of cancer patients treated with Bextra suffered peripheral edema. In addition, over 22% of the 119 patients in the Bextra group died during the treatment, as compared with only 10% in the placebo group. This 22% mortality rate in the Bextra group was particularly concerning because the study was limited to patients that were pre-screened to ensure that they had life expectancies longer than the study period.

291. The results of the 040 Cancer Study were provided to Pfizer. On March 1, 2002, Jeff Kent, Medical Director for Celebrex and Bextra, sent Dr. Mark Fletcher, the Clinical Research Appointed Global Clinical Leader for Pfizer's COX-2 Alliance, an email with the subject, "Valde 040 Cancer Pain," and stated:

> Data hot off the presses. Ken [Verburg] asked me to send this to you. We closed the database for the Valdecoxib 040 cancer pain study. A summary of the results is provided below and a slide deck for each study is attached. . . . Significantly more patients treated with valdecoxib experienced peripheral edema (22.0% vs. 10.0%) . . . . [108]

Dr. Fletcher forwarded Jeff Kent's email to Defendant Cawkwell among others on March 3, 2002.[109]

292. Defendants made a concerted effort to conceal the results of the 040 Cancer Study. On April 23, 2003, Dr. Gandelman, a senior doctor in Pfizer's medical group, emailed Defendant Cawkwell and others, to advise that Pfizer had created a "special committee to focus on upcoming publication issues," including the "cancer pain trials with valde." In response, Defendant Cawkwell urged concealment of the 040 Cancer Study's results, explaining that Pfizer already has ***"embargoed a number of celebrex and bextra studies."***[110]

293. Defendants adhered to Cawkwell's instruction. On the following day, an internal Pfizer email was sent to Defendant Cawkwell that listed the 040 Cancer Study as a study "for which we [Pfizer] currently have no pub[lication] plans." To this day, Pfizer has never published the results of the 040 Cancer Study in any scientific or medical journal.

6. January 2004: Pfizer's Second CABG Study Again Shows A "Significantly Higher Incidence Of CV" Events For Bextra Patients

294. In light of the troubling results of the CABG-1 study, the FDA urged Pfizer to conduct a second Bextra safety study on coronary artery bypass graft patients, *i.e.*, the "CABG-2

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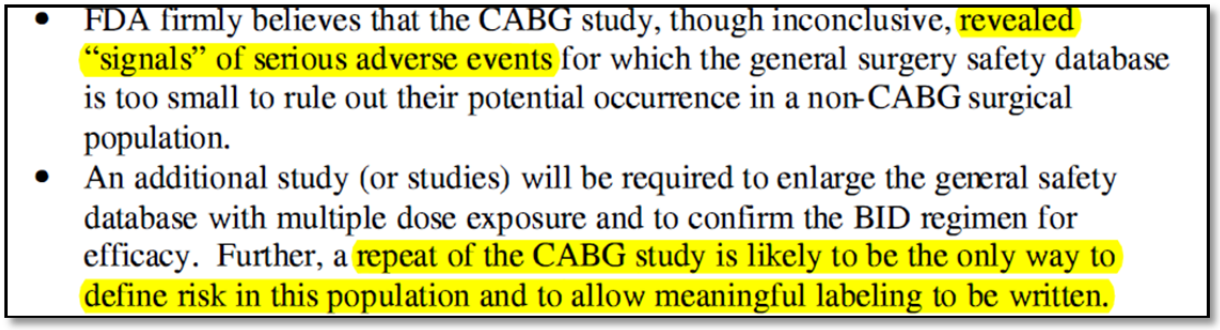
[108] *See* 4/5/02 email from Kevin Phelan to Stephen Cristo, bearing Bates No. Phelan-K 10000093533-3535 (quoted at ECF No. 420 at 131).
[109] *Id.*
[110] *See* 4/24/03 email from G. Cawkwell to M. Gandelman re: "Publication Committees," bearing Bates No. Gandle-M 10000046442-43 (attached to ECF No. 351-42).

Study." Minutes from an August 3, 2001 meeting with the FDA documented the FDA's reasons for an additional CABG study:[111]



- FDA firmly believes that the CABG study, though inconclusive, revealed "signals" of serious adverse events for which the general surgery safety database is too small to rule out their potential occurrence in a non-CABG surgical population.
- An additional study (or studies) will be required to enlarge the general safety database with multiple dose exposure and to confirm the BID regimen for efficacy. Further, a repeat of the CABG study is likely to be the only way to define risk in this population and to allow meaningful labeling to be written.

295. Defendants, however, anticipated the likely cardiovascular safety results and ramifications of a second CABG study and, thus, were reluctant to follow the FDA's instruction. As Dr. Weiner explained to Defendant Cawkwell in a November 2, 2001 email concerning a possible design for a second CABG study:

> ***All of these designs are predicated, as well, on the absolute certainty that there will be no repeat of the signal.*** While that would clearly be a desired outcome, we should not pursue a strategy where we put all our money on that being the case, and ***if the signal is confirmed we are DOA [i.e., dead on arrival].***[112]

296. Approximately fifteen months later, Pfizer belatedly began the CABG-2 Study. The CABG-2 Study, which ended on January 23, 2004, was designed to evaluate the safety of Bextra and parecoxib, the intravenous form of Bextra. The 1,636 patients enrolled in the study were given (i) intravenous parecoxib and oral Bextra; (ii) intravenous placebo and oral Bextra; or (iii) intravenous placebo and oral placebo. The results of the study showed that patients who took Bextra had a statistically significant increased risk of suffering a major cardiovascular event.

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[111] *See* 8/20/01 Minutes of a Meeting with FDA (August 3, 2001) re parecoxib sodium, NDA 21-294, bearing Bates No. Phelan-K 100000343727-3 (attached to ECF No. 387-8).

[112] *See* 11/2/01 email from E. Weiner to D. Fisher, bearing Bates No. Weiner-E 10000340216 (quoted at ECF No. 420 at 136).

297. On March 2, 2004, Pfizer's "Parecoxib/Valdecoxib Full Development Team" distributed a memorandum summarizing the "Top-line results" of the CABG-2 Study (the "Top-Line Memorandum"). The Top-Line Memorandum, which was sent to over 30 Pfizer employees, including Defendants Cawkwell and Feczko, contained an "Executive Summary" detailing the ***"significantly higher incidence"*** of cardiovascular Clinically Relevant Adverse Events observed across all categories studied, as set forth in the excerpt below: [113]

> A blinded review committee comprised of external experts reviewed and adjudicated Clinically Relevant Adverse Events (CRAEs) according to pre-specified definitions. CRAEs were defined for (1) cardiovascular (CV) thromboembolic events (2) renal dysfunction/failure (3) upper gastrointestinal GI ulcer complications and (4) wound-healing events. In addition, adverse events and serious adverse events were reported in the usual manner.
>
> The primary analysis for this study (all CRAEs combined from the 4 categories described above) showed a statistically significant increase in the incidence of confirmed CRAEs for each active treatment arm when compared to placebo treatment (see table below). Across the 4 CRAE categories, a significantly higher incidence of CV thromboembolic CRAEs was observed in the parecoxib/valdecoxib treatment group compared to the placebo-treated patients. No treatment-related differences were observed in the overall incidence of adverse events or serious adverse events
>
> The results indicate that there may be safety signal that needs to be evaluated especially in light of the results from the earlier CABG surgery study (Study -035) which was conducted at higher doses. Further review and additional exploratory analysis are needed to fully understand and assess the clinical significance of these data.

298. On March 7, 2004, Dr. Verburg wrote an email to Dr. Steve Ryder concerning the CABG-2 study, which stated: "***Need your help. Cardiovascular signal was still evident in the second parecoxib/valdecoxib CABG surgery study.***"[114]

299. As Professor Bennet, who has been approved to testify at trial in the Pfizer Securities Class Action, explained in his March 6, 2009 expert report:

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[113] *See* 3/5/04 email from J. Feczko to E. Harrigan and D. Doogan re: "Important: top-line results for parecoxib/valdecoxib CABG study," bearing Bates No. Harrig-E 10000010075-96 (attached to ECF No. 345-24).
[114] *See* 3/8/04 email from E. Weiner to S. Ryder, bearing Bates No. PFE SECURITIES 0001821072 (quoted at ECF No. 420 at 142).

> Even though CABG-2 was designed to minimize the safety risk, ***Bextra users experienced a significantly greater frequency of cardiovascular/thromboembolic events***, including myocardial infarction, ischemia, cerebrovascular accident, deep vein thrombosis, and pulmonary embolism. Specifically, 2% of patients on Bextra experienced adverse CV events compared to 0.5% of patients taking placebo.

300. Defendants understood the significance of the CABG-2 Study. On July 23, 2004, a Pfizer regulatory employee sent an email to Ed Harrigan, the global head of Pfizer's regulatory group who reported directly to Defendant Feczko concerning the CABG-2 Study. [115] The email listed "possible outcomes," including that Pfizer would need to include "Stronger Wording" for the Bextra label "[e]ither around CABG OR even perhaps broader risk (CV - general or High Risk patients)." Harrigan forwarded this same email to Defendants Feczko and LaMattina, cautioning that this ***"could be the next thing to hit the fan."***[116]

301. Four days later, Defendants McKinnell, Katen, LaMattina and other senior Pfizer executives received a draft Pfizer Form 10-Q, which failed to mention the results of the CABG-2 Study and, instead, stated:

> In May 2004, Bextra achieved a 10.2% share of new prescriptions in the U.S. NSAID market and European regulators completed a safety review and reaffirmed the use of COX 2-specific inhibitors such as Bextra in a broad range of patients. Additional Bextra studies in acute pain for a U.S. supplemental filing were completed in 2004.

302. Notwithstanding the true facts concerning the CABG-2 study, Defendants McKinnell, Katen and LaMattina approved the above language for Pfizer's Form 10-Q, which was filed with the SEC for the quarter ending June 27, 2004.

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[115] *See* 7/23/04 email from E. Harrigan email to J. Feczko and J. LaMattina, bearing Bates No. Harrig-E 1000012493-2494 (quoted at ECF No. 420 at 146).
[116] *Id.*

D. Defendants Knew Of Numerous Regulatory Analyses And Investigations Concerning The Side Effects Of Celebrex And Bextra

303. Defendants also knew about Celebrex's and Bextra's undisclosed cardiovascular risks through their interactions with foreign and domestic regulators. As discussed below, Defendants received a stream of requests for information, analyses, warnings and reprimands from regulatory agencies that identified Celebrex's and Bextra's cardiovascular side effects and urged public disclosure.

1. The World Health Organization Warns Defendants Of A Cardiovascular "Safety Signal"

304. The World Health Organization collects reports of suspected adverse drug reactions in a database maintained by the Uppsala Monitoring Centre (the "UMC"). The UMC patrols the database and identifies "safety signals" for follow-up and investigation. The World Health Organization has defined a safety signal as "[r]eported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously." As noted above, Defendant LaMattina, in his book titled *Drug Truths: Dispelling the Myths About Pharma R&D*, specifically acknowledged that ***"[i]t is important that, when safety signals are seen with new drugs, these get properly communicated broadly to patients and physicians."***

305. On September 20, 2001, Mats Persson of the UMC sent an email to Pfizer's Co-Promoter reporting a Celebrex "safety signal" for myocardial infarctions (heart attacks). The "Safety Signal Report" was widely circulated to employees at both Pharmacia and Pfizer, and marked as "Importance: High."

306. The Safety Signal Report identified "48 cases where celecoxib [is] listed as the only drug suspected of association with MI [myocardial infarction]."[117] The Safety Signal Report concluded that: "In summary, in most cases where information is available, the time of onset of MI following or during celecoxib administration is ***consistent with causality***" and "In view of[, among other things,] the evidence of possible causality proved by the reviewed case reports . . . , ***myocardial infarction observed with celecoxib should be regarded as a serious signal.***"

307. In response to the Safety Signal Report, John G. Fort of Pharmacia wrote to Mats Persson of the UMC warning that "this 'signal' announcement … has ***significant potential downside***." Nevertheless, Defendants never publicly disclosed the UMC's finding of a cardiovascular "safety signal" for Celebrex.

2. A German Regulator Warns Of A "Clear Signal" That Celebrex Causes Heart Attacks

308. In Germany, adverse drug event reports are collected and evaluated by the Federal Institute for Drugs and Medical Devices ("BfArM"), an independent federal agency operating within Germany's Ministry of Health that is tasked with protecting people from unsafe pharmaceuticals.

309. On January 22, 2003, a Pharmacia employee sent an email to Dr. Verburg, among others, cautioning that: "As a heads up, at [a] meeting today a comment was made by Dr. Koch from Germany (statistician) [and a representative of BfArM] that they have done their own meta-analysis across the arthritis studies and have determined a Relative Risk of 2.3 for cele[brex] v.

[117] *See* 9/20/01 email from J. Lefkowith to K. Verburg re: "Signal draft on Celecoxib & Mycocardial infarcation," bearing Bates No. Verbur-K 10004372926-936 (attached to ECF No. 351-28).

diclofenac for thromboembolic events."[118] According to BfARrM, Celebrex patients were 2.3 times more likely to experience thromboembolic events than patients treated with diclofenac, a traditional NSAID.

310. On February 17, 2003, the BfArM sent Pfizer a Preliminary Assessment Report documenting their findings (the "Rapporteur's Report").[119] The Rapporteur's Report was prepared by Professor Dr. Rolf Bass (the "Rapporteur") and six specialists from various fields. Dr. Bass is a highly distinguished professor of Pharmacology and Toxicology at the Charité in Berlin, and has served as the Head of Preclinical Department of the German Authority's Drug Institute.

311. The Rapporteur's Report, which was broadly circulated internally at Pfizer, contains a section titled "Biostatistical Comments for cardiovascular safety *(Koch).*" There, the BfArM hotly disputed Pfizer assertion "that 'the incidence of serious CV thrombotic events in patients treated with celecoxib is similar to that seen with non-selective NSAIDs.'" These claims of cardiovascular safety, the Rapporteur's Report concluded, are ***"not supported."*** The Rapporteur Report concluded that:

- "[T]here is still a ***clear signal for an increased risk of myocardial infarctions*** with celecoxib [i.e., Celebrex] in comparison to (some) non-selective NSAIDs";
- "[T]he submitted data of the … Controlled Arthritis Trials, the CLASS- and the SUCCESS-studies show that ***celecoxib was associated with [a] dose-dependent increased frequency of myocardial infarction*** in the celecoxib groups compared to conventional NSAIDs"; and
- "The analysis of the available findings from CLASS and SUCCESS shows that ***in both studies a clear trend towards an increased risk for MI is seen***, which is significant in a respective meta-analysis."

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[118] *See* 10/9/01 email from S. Cristo to M. Gandelman re: "Signal draft on Celecoxib & Mycocardial infarcation, bearing Bates No. Cristo-S 1000001101-7 (attached to ECF No. 351-29).

[119] *See* 2/18/03 email from M. Wahba to M. Gandelamn and others re: "Cox-2 referral – parecoxib, valdecoxib, and celecoxib individual assessment reports," bearing Bates No. Wahba-M 100003823050-3218 (attached to ECF No. 351-30).

312. The Rapporteur's Report also included a meta-analysis of available clinical data for Celebrex, which further supported the BfArM's conclusion that Celebrex causes cardiovascular harm. As explained in the Rapporteur's Report, "[a] meta-analysis for the endpoint MI including also the … controlled arthritis trials (CAT) and comparing celecoxib-results to un-specified NSAIDs likewise ***shows an increased risk for celecoxib with respect to the endpoint MI.***"

313. Notwithstanding the Rapporteur's finding of a "clear signal" and "clear trend" for an increased risk of heart attacks with Celebrex, Defendants never publicly disclosed the Rapporteur's Report.

3. A Swedish Regulator Requires A Long-Term Celebrex Cardiovascular Safety Study

314. The Swedish Medical Products Agency (the "Swedish MPA"), the governmental authority in Sweden responsible for regulation and surveillance of the development, manufacturing and marketing of drugs and other medicinal products, also expressed concern about Celebrex's cardiovascular risks.

315. On September 30, 2004, the Swedish MPA sent Pfizer a form "Health Authority Contact" that directed Pfizer to submit "long-term cardiovascular (CV) safety data for Celebrex." In response, Pfizer submitted in October 2004 a Celecoxib Cardiovascular Safety Summary (the "Celebrex Safety Summary"), which represented that "there is no evidence for concerns regarding an increased risk of CV adverse events with celecoxib."[120] Pfizer further assured the Swedish regulator that, with regard to the Alzheimer's 001 Study, the "data do[es] not suggest any cardiovascular risks in an Alzheimer's population."

[120] *See* 10/6/04 Health Authority Contact Form re: MAA Celebrex, bearing Bates No. Gandle-M 100001224793-4806 (quoted at ECF No. 420 at 149-150).

316. In the Celebrex Safety Summary provided to the Swedish MPA, Defendants intentionally concealed data concerning the cardiovascular risks of Celebrex. As explained in a December 7, 2004 email from a Pfizer employee to Defendant Cawkwell, Defendants made a "strategic" decision to "defer any inclusion of CV data" in the October 2004 Celebrex Safety Summary. The email memorialized Pfizer's strategy as follows:

> A Celebrex CV safety summary (at the time) was presented to the MPA (immediately post Vioxx withdrawal) which included reference to Alzheimer's trials - 30 Sept 2004. ***The strategic position of the team & the Cox-2 rapid response team (RRT) was to defer any inclusion of CV data*** to the EU referral response currently ongoing (which we are trying to synchronize in EU with the US AC [*i.e.*, FDA Advisory Committee].[121]

317. Consistent with its "strategic position," Defendants sent to the MPA a report on January 8, 2005, (months after their initial submission) that finally included the cardiovascular safety data that they deferred from inclusion in the original report.[122] In their delayed submission, Defendants admitted that, in the Alzheimer's 001 Study, "patients treated with celecoxib 200 mg BID ***had greater incidence of serious cardiovascular thromboembolic adverse events compared to patients treated with placebo."*** In addition, the January 8, 2005 submission included a table entitled "Serious Cardiovascular Thromboembolic Adverse Events," which showed the following:

[121] *See* 12/9/04 email from J. Gooch to M. Gandelman and G. Cawkwell, bearing Bates No. Gandle-M 10001649269-9271 (quoted at ECF No. 420 at 175).
[122] *See* 1/8/05 European Union Referral Response to EMEA, bearing Bates No. PFE SECURITIES 002264409-4522 (quoted at ECF No. 420 at 174).

Adverse Cardiovascular Event	# of Patients in the Celebrex Treatment Group	# of Patients in the Placebo Group
Cardiac Arrest	1	0
Myocardial Infarction	2	0
Tachycardia Ventricular	1	0
Cerebral Hemorrhage	1	0
Cerebrovascular Disorder	6	3
Pulmonary Embolism	1	0
Total	**12**	**3**

318. As acknowledged by Defendants in their January 8, 2005 submission to the MPA, the Alzheimer's 001 Study demonstrated Celebrex's cardiovascular side effects.

4. Aetna Provides Pfizer With A Two-Year Retrospective Claim Analysis Linking Celebrex To Heart Attacks

319. Aetna Inc. ("Aetna") is a leading national provider of healthcare, dental, pharmacy, group life, and disability insurance, with over eighteen million medical members and over one million healthcare professionals in its insurance network.

320. In November 2004, Aetna sent to Pfizer a retrospective epidemiological study of its claims data for the period beginning January 2002 and ending May 2004 (the "Aetna Claims Analysis"). The Aetna Claims Analysis, which was circulated to Defendant Cawkwell and other Pfizer officers, showed that a statistically significant amount of Celebrex users suffered acute myocardial infarctions compared with those given no treatment, and also that certain subgroups treated with Celebrex suffered a larger number of acute myocardial infarctions compared with those treated with other NSAIDs.[123]

[123] *See* 11/24/04 email from G. Cawkwell to R. Miceli, re: Aetna COX-2 Analysis: A Legible Copy, attaching Cox-2 Claims analysis from Aetna, bearing Bates No. Cawkwe-G 10000709716-9717 (cited in ECF No. 420 at 168).

321. The Aetna Claims Analysis was the subject of considerable internal discussion at Pfizer, including at a November 22, 2004 COX-2 Advisory Committee Steering group meeting attended by Defendant Cawkwell, Dr. Gandelman, Dr.Verburg, and others.[124]

322. Defendants purposefully concealed the results of the Aetna Claims Analysis, recognizing that its public disclosure could impact Celebrex sales and Pfizer's stock price. For example, on January 8, 2005, Ed Harrigan sent an email to Defendant Feczko, Dr. Weiner, and others, concerning the Aetna Claims Analysis, with the note ***"Ethan [Weiner]– do we have any idea if FDA or anyone else will be making Aetna public?"***[125]

323. Although ***Pfizer*** did not promptly disclose the Aetna Claims Analysis, ***Merck*** included a reference to Aetna's study in its briefing materials sent to the FDA in advance of the February 2005 FDA Advisory Committee hearings. Buried in Merck's 176-page briefing book, Merck acknowledged that "rofecoxib ***and celecoxib were associated with a significantly higher risk of MI than non-use of NSAIDs. This [Aetna] study has not been publicly presented in a scientific forum."*** On February 10, 2005, a Pfizer employee sent an email to Defendant Cawkwell and Dr. Gandelman, among others, identifying the above excerpt from Merck's briefing book.[126]

324. Although Defendants internally recognized the significance of the Aetna Claims Analysis, they nevertheless kept its results hidden for months. During this time period, they continued to publicly assert that ***"there have not been any epidemiological studies pointing to***

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[124] *See* 11/22/04 COX-2 Advisory Committee Steering Group Meeting Minutes, bearing Bate No. Cawkwe-G 10001351935-1939 (cited in ECF No. 420 at 168-169).

[125] *See* 1/9/05 email from J. to E. Harrigan re: FOR REVIEW AND COMMENT: Draft FDA Advisory Committee Briefing Document for Celecoxib and Valdecoxib, bearing Bates No. Harrig-E 10000017794 (quoted in ECF No. 420 at 169).

[126] *See* 2/10/05 email from S. Perez to G. Cawkwell., re: COX-2 Additional Epidemiology in Merck Briefing Book, bearing Bates No. Verbur-K 10003604780 (quoted at ECF No. 420 at 170).

increased risk with Celebrex" – an assertion that research analysts adopted and reprinted in their reports, such as a Morgan Stanley December 17, 2004 analyst report.

5. The FDA Repeatedly Admonishes Defendants For Their Misleading Promotional Materials

325. The FDA also expressed concerns about Defendants' public representations concerning the safety of Celebrex and Bextra. Among other things, the FDA sent Defendants and Pharmacia, Pfizer's Co-Promoter, a series of warning letters advising that the promotional materials for Celebrex and Bextra concealed and misrepresented the drugs' true safety risks and, as a result, violated federal drug safety laws.

326. For example, on October 6, 1999, the FDA sent a letter to the President and CEO of Pharmacia warning that Celebrex promotional materials "present[ed] several unsubstantiated comparative claims to Vioxx," including the "superior safety of Celebrex." The FDA ordered the immediate cessation of "all promotional activities and materials for Celebrex that contain violations like those outlined in this letter."

327. Again, on April 6, 2000, the FDA sent a letter to Pharmacia concerning undisclosed safety risks in Celebrex promotional materials. The FDA found that the Co-Promoter's "sales aid present[ed] claims that misrepresent the safety profile for Celebrex," and that their promotional materials "present[ed] several unsubstantiated comparative claims concerning Celebrex to Vioxx." The FDA further concluded that ***"your representatives continue to engage in violative promotional practices"*** and expressed "concern[] that the activities described [in the letter] demonstrate ***a continuing pattern and practice of violative behaviors that evidence widespread corporate involvement and acquiescence with your employee's activities.***"

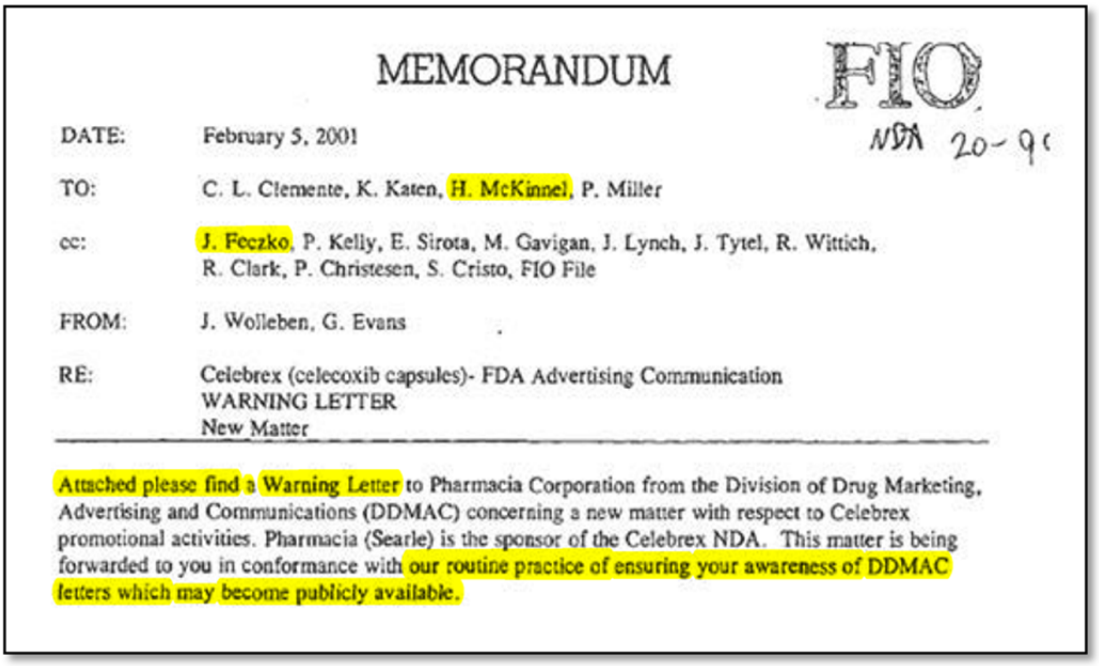
328. On February 1, 2001, after these warnings were left unheeded, the FDA sent an official Warning Letter to Pharmacia's CEO, Fred Hassan. In the Warning Letter, the FDA identified additional misrepresentations in promotional materials for Celebrex which "raise significant health and safety concerns in that they minimize crucial risk information and promote Celebrex for unapproved new uses." The FDA Warning Letter further stated:

> In two previous untitled letters dated October 6, 1999, and April 6, 2000, we objected to your dissemination of promotional materials for Celebrex that misrepresented Celebrex's safety profile by minimizing the updated Celebrex/warfarin risk information, contained unsubstantiated comparative claims, and lacked fair balance. Based upon your written assurance that this violative promotion of Celebrex had been stopped, we considered the matter closed. ***Despite our prior written notification, and notwithstanding your assurances, Pharmacia has continued to engage in false or misleading promotion of Celebrex.***

329. The FDA identified, as one of the "Unsubstantiated Comparative Claims," the "suggestion that Celebrex is safer, or has fewer side effects than Vioxx." As discussed above, the "suggestion" that Celebrex was comparatively safer and had less side effects than Vioxx was, in fact, an affirmative misrepresentation that Defendants consistently repeated throughout the Relevant Period. In the FDA's view, the comparative claim was "false or misleading because such conclusions have not been demonstrated by substantial evidence." Indeed, "Celebrex has not been compared to Vioxx in trials prospectively designed to assess these endpoints," the February 1, 2001 Warning Letter stated. The FDA's official Warning Letter again ordered the immediate cessation of "all promotional activities and materials for Celebrex that contain violations like those outlined in this letter."

330. Pfizer's senior officials, including the Individual Defendants, were advised of the FDA's multiple warning letters. For example, on February 5, 2001, just one day prior to the FDA's advisory committee hearings to consider (among other things) the cardiovascular safety of Celebrex, Jay Wolleben of the Division of Drug Marketing, Advertising and Communication

("DDMAC") sent a memorandum directly to Defendants McKinnell and Feczko, among others, concerning (and attaching) the February 1, 2001 FDA Warning Letter sent to Pharmacia's CEO, Fred Hassan.[127] As noted in the memorandum, an excerpt of which is below, it was "routine practice" for Pfizer to circulate warning letters received from DDMAC to Pfizer senior executives, including the Individual Defendants, to "ensure [their] awareness" of the FDA's findings:



MEMORANDUM

FIO

NDA 20-9

DATE: February 5, 2001

TO: C. L. Clemente, K. Katen, H. McKinnel, P. Miller

cc: J. Feczko, P. Kelly, E. Sirota, M. Gavigan, J. Lynch, J. Tytel, R. Wittich, R. Clark, P. Christesen, S. Cristo, FIO File

FROM: J. Wolleben, G. Evans

RE: Celebrex (celecoxib capsules)- FDA Advertising Communication
WARNING LETTER
New Matter

Attached please find a Warning Letter to Pharmacia Corporation from the Division of Drug Marketing, Advertising and Communications (DDMAC) concerning a new matter with respect to Celebrex promotional activities. Pharmacia (Searle) is the sponsor of the Celebrex NDA. This matter is being forwarded to you in conformance with our routine practice of ensuring your awareness of DDMAC letters which may become publicly available.

331. The above memorandum attaching the FDA's Warning Letter further explained that the FDA found that Celebrex promotional materials violated federal law by "minimizing important safety information" and containing "unsubstantiated comparative claims vs. NSAIDs and Vioxx." The memorandum stated that "Pfizer will work with Pharmacia to prepare [a] response" to the FDA's Warning Letter.[128]

[127] *See* 2/5/01 Memorandum from J. Wolleben to Defendants McKinnell, Katen among others re: FDA WARNING LETTER, bearing Bates No. Cele NDA 20-998 00065450-57 (attached to ECF No. 351-27).
[128] *Id.*

332. Notwithstanding the FDA's numerous warnings, Pfizer and its Co-Promoter continued to misrepresent Celebrex's safety in their promotional materials. Thus, on January 10, 2005, the FDA sent a letter directly to Pfizer warning that promotional materials for Celebrex and Bextra "omit[ted] material facts, including the indication and risk information; fail[ed] to make adequate provision for the dissemination of the FDA-approved product labeling; and ma[d]e misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims."

333. In its January 2005 Warning Letter, the FDA reminded Pfizer that, contrary to the representations made in Pfizer's promotional materials, Celebrex and Bextra are "associated with a number of serious risks." Pfizer omitted these safety risks from its promotional materials, despite highlighting the efficacy of both drugs. The FDA determined that Pfizer's promotional material:

> makes numerous effectiveness claims for Celebrex and Bextra, but fails to include any risk information, thus ***omitting the major side effects and contraindications (including warnings and precautions) of Celebrex and Bextra as required by 21 CR 202.1(e)(1). Omission of this information implies that there are no risks to patients who take these drugs.*** This complete omission of risk information is especially concerning in light of the dramatic portrayals of patients who have been completely restored to health by taking these drugs.

The FDA concluded that ***"[y]ou [Pfizer] should be aware . . . of the serious nature of the violations described above and act to avoid disseminating similarly misleading promotion materials for your products in the future."***

334. The FDA's repeated warnings and reprimands concerning Pfizer and its Co-Promoter's promotional materials for Celebrex and Bextra served to further alert Defendants to the fact that they were materially misrepresenting the safety of these drugs. Rather than take remedial measures concerning the dissemination of false and misleading promotional materials for Celebrex, Defendants encouraged it. Indeed, Pfizer's misconduct was so pervasive that, as

discussed below (*see* ¶ 390-405), it ultimately resulted in a felony guilty plea and the largest criminal fine in history.

E. Defendants Knew And Had Access To Information Concerning Celebrex And Bextra's Cardiovascular Risks Through Their Participation On Key COX-2 Committees And Their High-Level Positions At The Company

335. As discussed above, the undisclosed results of Defendants' clinical trials demonstrated that both Celebrex and Bextra had serious cardiovascular side effects. The Individual Defendants were provided with, and had access to, the results of these trials through, among other things, their top positions at the Company and their membership on key Pfizer committees and joint committees with their Co-Promoter.

1. The Individual Defendants Were Members Of Committees Tasked With Reviewing COX-2 Study Results And Making Disclosure Decisions

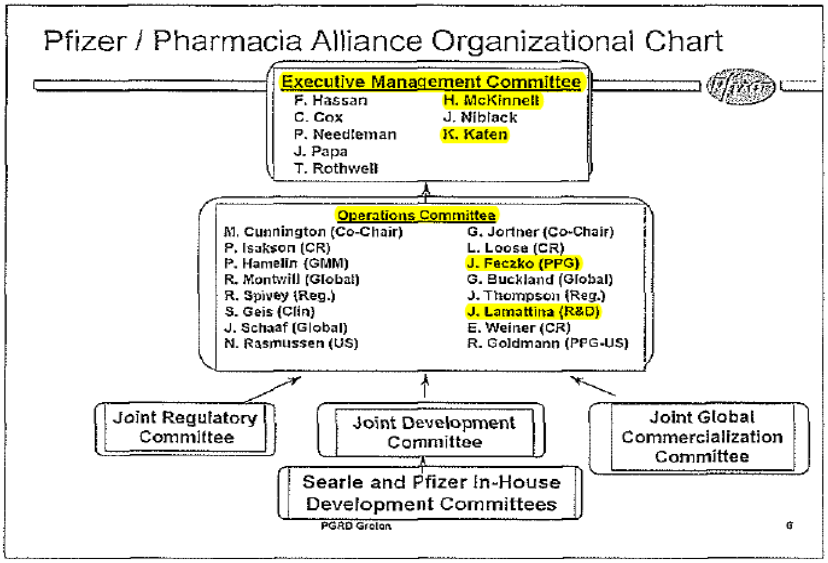
336. During the Relevant Period, each of the Individual Defendants served on committees specifically tasked with overseeing the development and commercialization of Celebrex and Bextra, and formulating disclosure decisions relating to the drugs, as indicated on the table below. Through their participation on these committees, Defendants reviewed, discussed, and had access to the undisclosed clinical trial results for Celebrex and Bextra, including epidemiological evidence of the drugs' cardiovascular risks.

	McKinnell	**LaMattina**	**Katen**	**Feczko**	**Cawkwell**
Joint Executive Management Committee	X		X		
Joint Operations Management Committee		X		X	
Joint Valdecoxib Product Team					X
Joint Bextra Publications Working Group					X

	McKinnell	LaMattina	Katen	Feczko	Cawkwell
Pfizer Leadership Team	X	X	X		
Pfizer Executive Committee	X		X		
Pfizer Development Planning Committee	X	X	X	X	
Pfizer Global Development Review Committee		X		X	

(a) The Joint Executive Management Committee

337. The Co-Promotion Agreement specifically provided for the creation of a joint committee composed of eight senior executives from each company, referred to as the "Executive Management Committee" or "EMC." As reflected in the below slide from an internal Pfizer presentation, the EMC was the highest-ranking committee in the "Cox-2 Alliance," with all of the other committees reporting to it.



338. The EMC had control over all aspects of the COX-2 Alliance, including issues of disclosure. As stated in the Co-Promotion Agreement:

> The EMC shall have ***the final decision making authority with respect to all matters within the jurisdiction of any of the Committees*** established pursuant to

> this Article 3 or pursuant to one of the other Agreements which are referred to the EMC for determination or remain unresolved in the . . . other Committee. The EMC shall exercise this authority in good faith all decisions shall have reasonable basis and ***any such decision shall be binding on the parties.***[129]

339. The EMC considered matters relating to the development and commercialization of Celebrex and Bextra. The Co-Promotion Agreement provided that the EMC is responsible for "oversee[ing] the Co-Promotion" of the COX-2s and "implement[ing] the Development Plan," including "facilitat[ing] the exchange of all development information and data" between the Co-Promoter and Pfizer.

340. The EMC received the clinical trial results for Celebrex and Bextra. Dr. Leland Loose testified at his August 18, 2010 deposition in the Pfizer Securities Class Action, for example, that the EMC would have received the results of the CLASS Study.[130] In addition, a slide presentation for a July 16, 1999 EMC meeting shows that the EMC reviewed the results of the Alzheimer's 001 Study before determining not to seek the FDA's approval for an Alzheimer's Disease indication for Celebrex. Finally, a December 6, 2001 draft presentation to the EMC, titled "Final EMC Rehearsal," shows that the EMC discussed the CABG-1 Study results in preparation for a forthcoming investor conference call.

341. During the Relevant Period, senior Pfizer executives, including Defendants McKinnell and Katen, served on the EMC.

(b) <u>The Joint Operations Management Committee</u>

342. Pfizer and its Co-Promoter also established a joint Operations Management Committee that reported directly to the EMC and was the second highest-ranking committee in the Pfizer/Co-Promoter COX-2 Alliance. The Operations Management Committee also

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[129] *See* COX-2 Alliance Presentation, bearing Bates No. DEFS 00508894-9080 (attached at ECF No. 328-12 in Pharmacia Securities Class Action).
[130] *See* 8/10/10 Deposition Tr. of Dr. Leland Loose at 24:22-25:11.

considered matters relating to the development and commercialization of Celebrex and Bextra, including issues of disclosure. As reflected in the above slide (*see* ¶337), the Operations Management Committee was a cross-functional group, consisting of senior Pfizer and Co-Promoter leaders from various groups within both companies, including their clinical, regulatory, and research departments.

343. As set forth in the Co-Promotion Agreement, the Operations Management Committee's responsibilities included "review[ing] and recommend[ing] for adoption the Global Marketing Plans, Global Development Budgets, Development Plans, Development Budgets, regulatory plans and regulatory budgets."[131] In addition, the Operations Management Committee was specifically tasked with, among other things, "recommend[ing] filing of the NDAs and all supplements or amendments thereto and all equivalent filings outside the United States," "resolv[ing] disputes referred by or remaining unresolved in [other committees]," "review[ing] and approv[ing] any material change in a Co-Promotion Plan or Development Plan," and "recommend[ing] [to the EMC] whether to abandon for any reason development of [Celebrex or Bextra]."

344. During his September 22, 2010 deposition in the Pharmacia Securities Class Action, Dr. Weiner testified that "[t]he purpose of the operations committee was to coordinate business decisions and medical decisions between the two companies. . . . It was sort of an intermediate committee where most of the decisions were made," he explained.[132] Dr. Loose similarly testified at his August 18, 2010 deposition in the Pfizer Securities Class Action that,

[131] *See* 2/18/98 Global Agreement among Pfizer, Monsanto, and G.D. Searle & Co., bearing Bates No. DEFS 00508894-9080 (attached to ECF No. 328-4 in the Pharmacia Securities Class Action).
[132] *See* 9/22/10 Deposition Tr. of Dr. Weiner at 10:18-20; 34:4-7.

"the Operations Committee [would] be kept up -- or kept abreast on ***any*** important developments with respect to Celebrex."[133]

345. The Operations Committee received the undisclosed clinical trial results for Celebrex and Bextra. For example, Dr. Weiner specifically testified at his deposition in the Pfizer Securities Class Action that the full, undisclosed results from the CLASS Study were provided to the Operations Management Committee. The minutes from an April 6, 2000 Operations Management Committee meeting, attended by Defendant LaMattina (among other members of senior Pfizer management), also reflect that the committee reviewed the results of the CLASS study.

346. During the Relevant Period, Defendants Feczko and LaMattina, as well as Dr. Weiner, served on the Operations Management Committee for Pfizer.

(c) <u>The Valdecoxib Joint Product Team</u>

347. Pfizer and its Co-Promoter also created a team specifically devoted to issues concerning Bextra, which was called the "Valdecoxib Joint Product Team." During their regular meetings, the Team would review and discuss Bextra clinical data, as well as development and commercialization plans for the drug. For example, as detailed above, the Team discussed at a November 5, 2001 meeting the results of the CABG-1 study. The Valdecoxib Joint Product Team decided not to publicly disclose the results of the study because such disclosure would negatively impact Bextra sales. As reflected in the Team's November 5, 2001 meeting minutes, the Team concluded that, if disclosed,"Merck might use CABG as ammo" and "disclosure of the "CABG data w[ould] affect managed care perceptions of the portfolio, possibly raising safety concerns about Celebrex."

[133] *See* 8/10/10 Deposition Tr. of Dr. Leland Loose at 24:4-14.

348. During the Relevant Period, Defendant Cawkwell was a member of the Valdecoxib Joint Product Team, along with other Pfizer and Pharmacia officers and executives.

(d) The Bextra Publications Working Group

349. Pfizer and its Co-Promoter also established a joint committee specifically charged with reviewing Bextra clinical trial results and making publication decisions, known as the "Bextra Publications Working Group." As Defendants admitted in their Answer in the Pfizer Securities Class Action, the "'Bextra Publications Working Group' made recommendations and decisions relating to the publication of Bextra studies." For example, as detailed above (*see* ¶287-288), the Bextra Publications Working Group analyzed the results of the 047 Study at a February 5, 2002 team meeting and concluded that the results should be "embargoed" and never released to the public because publication of the data would be "damaging" to Bextra sales.[134] Defendant Cawkwell, who was a member of the Bextra Publications Working Group, regularly attended the committee's meetings and received minutes and other communications concerning its decisions and activities.

(e) Pfizer Leadership Team

350. Pfizer's own internal committees also considered matters relating to the development and commercialization of Celebrex and Bextra, including Pfizer's highest-ranking committee, the Pfizer Leadership Team or "PLT." The Pfizer Leadership Team was the Company's ultimate decision-making body. PLT members, as part of their committee responsibilities, received copies of Pfizer press releases for review, comment and approval. At his October 13, 2011 deposition in the Pfizer Securities Class Action, Defendant LaMattina testified that "whenever a press release like this would issue, Andy [McCormick] would send out

[134] *See* 3/19/02 email from J. Vaughan to G. Cawkwell and others, bearing Bates No. Cawkw-G 10001254641-4657 (attached to ECF No. 351-37).

a note out to the leadership team: Please let me know that you reviewed it."[135] At her November 15, 2011 deposition in the Pfizer Securities Class Action, Defendant Katen also admitted that the PLT "was responsible for reviewing and approving press releases before they went out into the market."[136]

351. The Pfizer Leadership Team specifically focused on issues concerning the Company's COX-2 inhibitors, and was responsible for orchestrating every aspect of the acquisition and integration of Pharmacia. In an internal newsletter dated August 14, 2002, Pharmacia's CFO Chris Coughlin "stated clearly that all major decisions during the transition planning process and beyond will ultimately be ***made by the Pfizer Leadership Team…***" In another internal Pfizer newsletter dated August 1, 2002, CFO Sedlarz stated that the role of the PLT was "to make very high-level decisions that have company-wide significance, to resolve issues and conflicts that might arise, and to ensure that the transition is being carried out in a manner that is consistent with Pfizer values and leader behaviors."

352. During the Relevant Period, Defendants McKinnell, LaMattina, and Katen were each members of the PLT.

(f) Pfizer Executive Committee

353. Pfizer also had an Executive Committee that, according to the Company's SEC filings, was responsible for the "strategic direction and operations of the Company," including issues concerning Celebrex and Bextra. During the Relevant Period, Defendant McKinnell was the Chairperson of Pfizer's Executive Committee, and Defendant Katen was a member of the Executive Committee.

[135] *See* 10/13/11 LaMattina Deposition Tr. at 247:7-12 (quoted in ECF No. 420 at 11-12).
[136] *See* 11/15/11 Katen Deposition Tr. at 236:15-22 (quoted in ECF No. 420 at 9).

(g) Pfizer's Development Planning Committee

354. Pfizer's internal "Development Planning Committee" or "DPC" also had a significant role in overseeing Pfizer's development and commercialization of Celebrex and Bextra.

355. In performing its duties, the DPC reviewed and discussed the cardiovascular side effects of Celebrex and Bextra. For example, as detailed above (*see* 180¶), minutes from a May 17, 2000 DPC meeting show that Defendants McKinnell, Katen, LaMattina and Feczko, among other senior Pfizer executives, "reviewed the key changes in the Celebrex development program including dropping Alzheimer's Disease" as a potential indication.[137]

356. In addition, a slide presentation prepared for the October 31, 2001 DPC meeting (*see* ¶273-275) reflects that the Committee discussed the results of the CABG-1 Study, including that "[t]he incidence of thrombo-embolic events with 2x the recommended daily dose of parecoxib/valdecoxib for acute pain was higher than placebo" and that "[Valdecoxib] CABG data adds credence to Cox-2 CV class effect." The same slide presentation shows that the DPC discussed the "Market Impact" associated with the public disclosure of Bextra clinical data, which they concluded (in the case of the CABG Study) would result in a "loss [of] 25%" of Bextra's future sales.

357. During the Relevant Period, Defendants McKinnell, Katen, LaMattina and Feczko served on the Development Planning Committee.

(h) Pfizer's Global Development Review Committee

358. In addition to the DPC, Pfizer's internal "Global Development Review Committee" or "GDRC" also considered matters relating to the development and

[137] *See* 6/13/00 email attaching May 17, 2000 DPC Meeting Minutes, bearing Bates No. Wahba-M 10000200554 – 0557 (quoted in ECF No. 420 at 43-44).

commercialization of Celebrex and Bextra, including issues of disclosure. The GDRC reviewed and discussed COX-2 study results, tracked the status of forthcoming scientific manuscripts, and made disclosure decisions. For example, as detailed above (*see* ¶¶212-213), the Action Minutes from the GDRC's April 15, 2003 meeting show that the committee discussed "the results of the SUCCESS trial," including how "publication [of the SUCCESS trial data] ha[d] taken longer than Pfizer believes [wa]s optimal," in violation of the Company's "obligation to make the results of the study available in a timely manner."[138]

359. During the Relevant Period, Defendants Feczko was the Chairperson of the GDRC and Defendant LaMattina was a Committee member.

2. The Individual Defendants Were Responsible For Reviewing The COX-2 Study Results And Making Disclosure Decisions

360. The Individual Defendants were among Pfizer's most senior officers, and were changed with supervising and monitoring all aspects of the commercialization and development of Celebrex and Bextra. As part of their day-to-day job responsibilities, the Individual Defendants each knew or recklessly disregarded (i) the results of the clinical studies, epidemiological data, and other information regarding the undisclosed cardiovascular risks of Celebrex and Bextra; and (ii) Defendants' related misstatements and omissions.

(a) Defendant McKinnell

361. Defendant McKinnell was Pfizer's President, CEO and Chairman. Defendant McKinnell was also a member of the EMC, PLT, Pfizer Executive Committee, and the DPC, through which (as discussed above, *see* ¶¶337-341; 350-357) he learned and had access to the undisclosed results of Celebrex and Bextra clinical trials.

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[138] *See* 4/30/03 email from M. Sainpy to S. Siberman among others, re: "Apr 15 GDRC Meeting Minutes," bearing Bates No. Silber-S 10000004027-36 (attached to ECF No. 351-34).

362. Defendant McKinnell signed the Co-Promotion Agreement on behalf of Pfizer, and was integrally involved in the creation of the COX-2 Alliance. In addition, as discussed above (*see* ¶268-272), Defendant McKinnell was involved in negotiating the "milestone payments" for the Co-Promotion Agreement. In connection with those negotiations, he was provided "talking points," which discussed (among other things) how "the CABG study data 'raise[d] the possibility that parecoxib is associated with serious, life-threatening adverse events' . . . . and by implication also valdecoxib."[139]

363. Internal Pfizer documents demonstrate Defendant McKinnell's day-to-day role in the development and commercialization of Celebrex and Bextra, including his access to the results of Pfizer and its Co-Promoter's clinical trials. For example, on or about October 31, 2001, a Pfizer employee sent an email to his colleagues specifically noting that "Hank [McKinnell] wanted to see the [CABG safety] data again, which [a Pfizer doctor familiar with the study] presented" at a DPC meeting.

364. Internal Pfizer documents also demonstrate that Defendant McKinnell reviewed, approved, and controlled the contents of the Company's public disclosures. For example, on September 30, 2004, McKinnell emailed Defendants LaMattina, Katen, Feczko and other senior Pfizer officers concerning the "VIOXX Withdrawal," instructing:

> We need to move immediately to avoid collateral damage and to exploit what could be a major opportunity. I see the priorities as the following: 1. Avoid this becoming a class effect. We need a press release out the door before 9 am making it clear that our clinical studies in tens of thousands of patients show no signal of cardiovascular complications. To the contrary we have seen strong signals of beneficial effects in cancer, etc. How to handle Bextra is an interesting problem. I suggest we focus on Celebrex….[140]

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[139] *See* 8/13/01 email from E. Weiner attaching his comments to Talking Points, bearing Bates No. Weiner-E 10000472867-71 (quoted in ECF No. 420 at 100).

[140] *See* email from A. Harris to A. Litwack, H. Crosbie-Foote, bearing Bates No. Litwac-A 1000079025-9026 (quoted in ECF No. 420 at 146-47).

In response to Defendant McKinnell's September 30, 2004 directive, Pfizer issued a press release less than an hour later that falsely assured investors 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."

365. As CEO of Pfizer, Defendant McKinnell was also tasked with overseeing Pfizer's compliance with federal drug laws. In dispatching that responsibility, Defendant McKinnell knew, or was reckless in not knowing, that various domestic and foreign regulators expressed concern about Celebrex's and Bextra's undisclosed cardiovascular safety risks. For example, on February 5, 2001, Defendant McKinnell received an internal Pfizer memorandum attaching and describing the contents of an FDA Warning Letter concerning misrepresentations in Celebrex promotional materials.[141] As noted in the attached Warning Letter, the FDA found that various Celebrex promotions "minimize[ed] important safety information" and contained "unsubstantiated comparative claims vs. NSAIDs and Vioxx."

366. Defendant McKinnell's job responsibilities also included making public statements about Celebrex and Bextra. Through his public statements, Defendant McKinnell professed to know the clinical trial results and safety risks of both drugs. Defendant McKinnell purported to be sufficiently knowledgeable to make specific representations to the media and research analysts concerning Celebrex's and Bextra's cardiovascular safety, including the following:

- July 16, 2002: "Celebrex hasn't been linked to a risk of any heart problems" (*see* ¶¶117; 457);
- November 10, 2004: "The current information we [Pfizer] have on Celebrex shows that it might be protective of the heart" (*see* ¶¶25; 138; 500);

[141] *See* 2/5/01 Memorandum from J. Wolleben to Defendants McKinnell and Katen among others re: FDA WARNING LETTER, bearing Bates No. Cele NDA 20-998 00065450-57 (attached to ECF No. 351-27).

- November 30, 2004: "We [Pfizer] have all kinds of data that shows . . . there [is] no signal of a cardiovascular risk with Celebrex" (*see* ¶502);
- December 20, 2004: "[W]e had lots of data, 10 years of data and over 40,000 patients from controlled clinical studies that showed no evidence of cardiovascular risk" (*see* ¶506); and
- January 4, 2005: "[A]ll of our own clinical data, which include 40,000 patients, show no evidence of cardiovascular risk [for Celebrex]" (*see* ¶¶143; 514; 544).

367. Defendant McKinnell's duties as CEO also included signing and ensuring the accuracy of Pfizer's SEC filings. As discussed herein, Defendant McKinnell signed multiple SEC filings on behalf of Pfizer during the Relevant Period that concerned the Company's development and commercialization of Celebrex and Bextra.[142] In connection with Pfizer's public filings, Defendant McKinnell also signed Pfizer's SEC certifications pursuant to § 302 of the Sarbanes-Oxley Act of 2002, and thereby represented that he reviewed the SEC filings and determined that they contained no misrepresentations or omissions.

(b) Defendant LaMattina

368. Defendant LaMattina was Pfizer's President of Global Research and Development. He was also a member of the Joint Operations Committee, the DPC, and the GDRC, through which (as discussed above, *see* ¶¶336; 342-46; 350-52; 354-59) he learned and had access to undisclosed cardiovascular safety information concerning Celebrex and Bextra. As stated in his online professional profile, LaMattina "oversaw the drug discovery and development efforts of over 12,000 colleagues in the United States, Europe and Asia."

[142] *See* Fiscal Year 2000 Form 10-K405 (filed March 28, 2001); the Fiscal Year 2001 Form 10-K (filed March 28, 2002); the Third Quarter 2002 Form 10-Q (filed November 13, 2002); the 2002 Form 10-K (filed March 27, 2003); the First Quarter 2003 Form 10-Q (filed May 14, 2003); the Second Quarter 2003 Form 10-Q (filed August 13, 2003); the 2003 Form 10-K (filed March 10, 2004); the First Quarter 2004 Form 10-Q (filed May 7, 2004); the Second Quarter 2004 Form 10-Q (filed August 6, 2004); the Third Quarter 2004 Form 10-Q (filed November 5, 2004); the 2004 Form 10-K (filed February 28, 2005); the First Quarter 2005 Form 10-Q (filed May 6, 2005); and the Second Quarter 2005 Form 10-Q (filed August 8, 2005).

369. Defendant LaMattina's job duties included overseeing the development and commercialization of Celebrex and Bextra. In fulfilling his duties, Defendant LaMattina reviewed and analyzed the drugs' clinical trial results and understood their undisclosed safety risks. During the Relevant Period, Defendant LaMattina received numerous emails and other correspondence concerning Celebrex's and Bextra's undisclosed clinical data and cardiovascular side effects, including:

- On July 16, 2001, a Pfizer doctor sent to Defendant LaMattina and others an email that discussed the safety results of the CABG trial, including that the "[s]afety in CABG trial [was] unacceptable due to thromboembolic events, GI events, renal dysfunction."[143]

- On April 16, 2000, Dr. Loose forwarded to Defendant LaMattina and his fellow Pfizer colleagues a presentation containing results from the CLASS Study.

- On July 23, 2004, Ed Harrigan (the global head of Pfizer's regulatory group) forwarded Defendant LaMattina an email concerning the CABG-2 Study, which stated that "possible outcomes" for Bextra included "Stronger Wording" for the Bextra label "[e]ither around CABG OR even perhaps broader risk (CV - general or High Risk patients)," and warned that this "could be the next thing to hit the fan."[144]

370. Defendant LaMattina also attended conferences and meetings to discuss Celebrex's and Bextra's clinical trial results. For example, internal Pfizer documents list Defendant LaMattina as an attendee at a September 18-19, 2000 "Pharmacia/Pfizer Valdecoxib Strategic Summit" (the "Summit"), the purpose of which was to (i) provide the attendees with a "common level of understanding" about Bextra; (ii) review the target product profile and Clinical Development Plan; and (c) review the surrounding regulatory environment.[145] Participants at the

[143] *See* 7/16/01 email from M. Fletcher to S. Ryder, et al., bearing Bates No. Fletch-M 10000692570-72 (quoted in ECF No. 420 at 96).
[144] *See* 7/23/04 email from Harrigan to defendants Feczko and LaMattina, bearing Bates No. Harrig-E 1000012493-2494 (quoted in ECF No. 420 at 146).
[145] *See* "Pharmacia/Pfizer Valdecoxib Strategic Summit," September 18-19, 2000, bearing Bates No. Wahba-M 10000022578-769 (quoted in ECF No. 420 at 186-87).

Summit discussed the results of Bextra's clinical studies, including the 047 Study, the 060 and 061 Studies, and the CABG-1 Study.

371. Defendant LaMattina also had a significant role in formulating Pfizer's disclosures to investors concerning Celebrex and Bextra. Prior to making public disclosures concerning the safety of either drug, Defendants consulted with Defendant LaMattina for his input, review, and approval. As Defendant LaMattina admitted at his October 13, 2011 deposition in the Pfizer Securities Class Action, "[w]henever a press release like this would issue, Andy [McCormick] would send out a note out to the leadership team," which included Defendant LaMattina, asking them to "[p]lease let me know that you reviewed it."[146]

372. In their Answer to the Pfizer Securities Class Action, Defendants, themselves, admitted that Defendant "LaMattina at times reviewed and approved press releases" and was "periodically updated about Pfizer references in the media." For example, as noted above, Defendant McKinnell sent to Defendant LaMattina (among others) an email instructing him to issue "a press release … before 9 am [on October 1, 2004] making it clear that [Pfizer's] clinical studies in tens of thousands of patients show no signal of cardiovascular complications."[147] As another example, on July 23, 2004, a Pfizer employee emailed Defendant LaMattina (as well as Defendants McKinnell and Katen) a draft Form 10-Q for his review and approval that made specific representations about Bextra's "safety."[148]

373. Defendant LaMattina was also actively involved in Defendants' public disclosures during investor conference calls. Defendant Katen testified on November 15, 2011, in the Pfizer Securities Class Action that, during investor conference calls, "John LaMattina would be at the

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[146] *See* 10/13/11 LaMattina Deposition Tr. at 247:7-12 (quoted in ECF No. 420 at 12).
[147] *See* 9/30/04 email from A. Harris to A. Litwack, H. Crosbie-Foote, bearing Bates No. Litwac-A 1000079025-9026 (quoted in ECF No. 420 at 146).
[148] *See* 7/23/04 email from Ryan Starkes to Hank McKinnell, et al., bearing Bates No. McKinn-H 10000006630-6684 (quoted in ECF No. 420 at 144-145).

table," along with Defendants Katen, McKinnell, and Feczko, to help answer questions raised by investors and research analysts. Defendant Katen further testified that "if it was a scientific question, LaMattina would take the lead" in responding.[149]

(c) Defendant Katen

374. Defendant Katen was the former Vice Chairman and President of Pfizer Human Health and, before that, occupied various senior executive positions within the Company. As reported in a June 10, 2005 Pipeline Report by market analyst Life Science Analytics, Inc., "she le[d] the business responsible for the discovery, development, manufacture, distribution and commercialization of prescription medicines; as well as for providing a broad array of innovative human-health services." Former CEO Jeffrey Kindler wrote in an August 15, 2006 internal firm-wide letter that, for "[o]ver more than three decades, [Defendant Katen] played a critical role in the growth of Pfizer to world leadership in pharmaceuticals," including by "le[ading] the introduction of many of Pfizer's most important medicines." During the Relevant Period, Defendant Katen was identified as one of only three potential candidates to succeed Defendant McKinnell as CEO of the Company.

375. Defendant Katen was also a member of various committees tasked with overseeing the commercialization and development of Celebrex and Bextra, including the EMC, PLT, Pfizer's Executive Committee, DPC, and GDRC, through which (as discussed above, *see* ¶¶336-41; 350-59) she learned and had access to undisclosed cardiovascular safety information concerning Celebrex and Bextra. In addition, through her participation on those committees and her day-to-day responsibilities, Katen read, reviewed, and approved Defendants' press releases and other public statements concerning Celebrex and Bextra.

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[149] *See* 11/15/11 Katen Deposition Tr. at 86:17-87:25.

376. As part of her job responsibilities, Defendant Katen was authorized to make public statements on behalf of Pfizer concerning Celebrex's and Bextra's safety profile. During the Relevant Period, Defendant Katen participated in numerous investor conference calls and interviews with the financial press, during which she spoke about the safety risks of these drugs. During those communications, Defendant Katen professed to know about the matters she addressed. For example, during the Relevant Period, Defendant Katen made the following statements during Pfizer earnings conference calls:

- October 17, 2001: "We have not seen any problems with cardiovascular safety with Celebrex" (*see* ¶443);

- July 25, 2003: "An independent analysis that included our entire Celebrex arthritis clinical trial database, found no evidence in increased cardiovascular risk for Celebrex, relative to both conventional, non-psoriatal anti-inflammatory drugs and placebo. As you know there continues to be a shadow of safety concerns about these compounds. So this should eliminate that concern" (*see* ¶470); and

- October 20, 2004: "In a recent FDA-sponsored analysis of 1.4 million patients and in additional clinical studies where patients have been treated for up to four years, patients using Celebrex showed no increased risk of cardiac events" (*see* ¶496).

377. Defendant Katten's job responsibilities also required her to review and analyze clinical data for Celebrex and Bextra, including any safety signals. For example, an internal Pfizer email sent in mid-July 2001 discussed the need "to put together a concise update for [Defendant] Karen Katen" concerning parecoxib, the intravenous form of Bextra that the FDA refused to approve due to safety concerns. As another example, on November 9, 2001, Defendant Cawkwell sent an email to her Pfizer colleagues attaching "Launch Recommendations" for Bextra, which stated that "Karen Katen will be going over this."

(d) Defendant Feczko

378. Defendant Feczko was Pfizer's Chief Medical Officer ("CMO") and, before that, occupied various senior executive roles within the Company. In his capacity as CMO, Feczko

"brought together all aspects of clinical development into a single functioning role," according to his professional profile published with the World Congress. As reported in a June 10, 2005 Pipeline Report prepared by market analyst Life Science Analytics, Inc., Feczko "manage[d] the coordination of medical activities, outcomes research, data management and the complex regulatory requirements critical to global pharmaceutical operations and product development" and was "responsible for the clinical and outcomes research that supports Pfizer's marketed products worldwide." Prior to becoming Pfizer's CMO, Feczko served as Pfizer's President of Worldwide Development, in which he brought "together all aspects of clinical development in both Pfizer Global Research and Development and Pfizer Pharmaceuticals Group into a single function."

379. Feczko was also a member of numerous committees tasked with overseeing the commercialization and development of Celebrex and Bextra, including the Joint Operations Committee, the PLT, Pfizer's Executive Committee, DPC, and GDRC. As discussed above (*see* ¶¶336-46; 350-59), through his participation in those committees, Feczko learned about Celebrex's and Bextra's undisclosed cardiovascular side effects. In addition, through his participation on those committees and his day-to-day responsibilities, Feczko read, reviewed, and approved Defendants' press releases and other public statements concerning Celebrex and Bextra.

380. Defendant Feczko's job responsibilities included supervising the development and commercialization of Celebrex and Bextra. In fulfilling his responsibilities, Feczko was required to know the clinical results of both drugs, including any signs of safety risks. Pfizer's internal documents show that Feczko regularly received information and discussed Celebrex's and Bextra's clinical trial results. For example, Defendant Feczko received the March 4, 2004 Top-

Line Memorandum concerning the CABG-2 Study, which stated that "[t]he results indicate that there may be [a] safety signal that needs to be evaluated especially in light of the results from the earlier CABG surgery study (Study -035) which was conducted at higher doses." [150] As another example, on August 26, 2004, Defendant Feczko emailed Ed Harrigan concerning a "vioxx study," which had shown that drug's adverse cardiovascular risks, with the message "The Bextra implications are concerning."[151]

381. Defendant Feczko's job duties also required him to oversee Pfizer's responses to regulatory agencies. For example, Defendant Feczko received a copy of the DSMC's December 24, 2004 letter concerning the Alzheimer's 001 Study, which stated (among other things) that "review of final data in August 1999 and later showed that there was an indication of excess cardiovascular-related and other risk" and cautioned that the "nominal risk rates [in the study] for cardiovascular events are potentially very high" and "a fairly concerning number, much higher than that that [sic] can be estimated from press reports of the prevention trials."[152] Defendant Feczko also received the FDA's numerous warning letters sent to Pfizer concerning its misleading advertisements about Celebrex's and Bextra's undisclosed safety risks.[153]

382. During the Relevant Period, Defendant Feczko issued numerous public statements concerning Celebrex and Bextra. In his public statements, Feczko claimed to know about Pfizer's clinical trial results and the safety profile of these drugs. For example, Feczko made the following statements during the Relevant Period concerning the safety of Celebrex and Bextra:

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[150] *See* 10/15/04 email from Peter Corr to Andrew McCormick, bearing Bates No. PFE SECURITIES 001024756-4757 (quoted in ECF No. 420 at 160).
[151] *See* 8/26/04 email from J. Feczko to E. Harrigan, bearing Bates No. Feczko-J 10000000170 (quoted in ECF No. 420 at 146).
[152] *See* 12/24/04 letter from the DSMB, attached to email from G. Cawkwell to J. Feczko, bearing Bates No Cawkwe-G 10003250381-0385 (quoted at ECF No. 420 at 172).
[153] *See* 2/5/01 Memorandum from J. Wolleben to Defendants McKinnell and Katen among others re: FDA WARNING LETTER, bearing Bates No. Cele NDA 20-998 00065450-57 (attached to ECF No. 351-27).

- September 30, 2004: "Pfizer is confident in the long-term cardiovascular safety of Celebrex" (*see* ¶483).

- October 4, 2004: "We're even more confident today because the studies have consistently not demonstrated any increased cardiovascular risk with Celebrex" (*see* ¶488).

- October 18, 2004: "Our strong confidence in the CV safety of Celebrex is based on the substantial body of experience that has accumulated over several years in multiple completed studies and ongoing trials." (*see* ¶493).

- February 16, 2005: The data "demonstrates the cardiovascular safety profile of our COX-2 inhibitors, both Celebrex, Bextra and parecoxib" (*see* ¶¶518; 544).

383. Defendant Feczko participated in formulating Pfizer's disclosures to investors concerning Celebrex and Bextra. For example, on January 24, 2000, Feczko was sent an email containing "message points that are/or have been used for the investment community and media" that Searle/Pfizer was "using in response to requests for information on Celebrex/Alzheimer's Disease" for his review and approval.[154] The message points did not include any discussion about the cardiovascular safety risks seen in the Alzheimer's 001 Study.[155]

384. In addition, as part of his professional duties, Defendant Feczko was responsible for creating and overseeing Pfizer's compliance with its disclosure policies. For example, on January 10, 2003, Feczko distributed firm-wide an internal memorandum, which stated that Pfizer "has fully endorsed [the PhRMA Conduct of Clinical Trials and Communication of Clinical Trial Results] of as of October 1, 2002."[156] The PhRMA principles, which were attached to Dr. Feczko's memorandum, required, among other things, Pfizer to make "timely communication of meaningful results of controlled clinical trials of marketed products or investigational products that are approved for marketing, regardless of outcome."

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[154] *See* 1/24/00 email to J. Feczko attaching Alzheimer's Talking Points, bearing Bates No. Kitsis-E 10000012076-78 (quoted at ECF No. 420 at 41).
[155] *Id*.
[156] *See* 1/15/03 email re: Clinical Trial Policies forwarding a 1/10/03 Memorandum from J. Feczko, bearing Bates No. Gandle-M 10001426431-47 (quoted in ECF No. 420 at 41).

(e) Defendant Cawkwell

385. Defendant Cawkwell oversaw on a day-to-day basis the development and commercialization of both Celebrex and Bextra, and was responsible for Defendants' public disclosures. From December 2000 to February 2001, she was the Medical Director of Major Markets, focused on Celebrex. From February 2001 to June 2003, Defendant Cawkwell was a Medical Director, focused on Valdecoxib. Finally, from June 2003 through the end of the Relevant Period, she was Medical Team Leader and Full Development Team Leader, focused on Celebrex.

386. Defendant Cawkwell was also a member of multiple joint committees tasked with overseeing the commercialization and development of Celebrex and Bextra, including the Joint Valdecoxib Product Team and the Joint Bextra Publications Working Group. Through her participation in those committees, she reviewed and discussed the undisclosed cardiovascular risks of Celebrex and Bextra, and made decisions concerning Pfizer's public disclosures. For example, she participated on the Joint Bextra Publications Working Group, which chose to "embargo" Study 047 because "[the] publication of the[] data [047] would be damaging to the product."[157] Through her participation on those committees and her day-to-day responsibilities, Cawkwell read, reviewed, and approved Defendants' press releases and other public statements concerning Celebrex and Bextra.

387. In her role at the Company, Defendant Cawkwell received the undisclosed cardiovascular safety data for Celebrex and Bextra. For example, Defendant Cawkwell received an August 8, 2001 email from Laraine Meyers, a member of Pfizer's regulatory department,

[157] *See* 3/19/03 email from J. Vaughan to T. Burke, et al., attaching meeting minutes from Feb. 5-6, 2002, bearing Bates No. Cawkwe-G 10001254641-57 (quoted in ECF No. 420 at 78).

which stated that "we [Pfizer] know that the safety signals" for Bextra "are thromboembolic events," blood clots causing, among other things, strokes and pulmonary embolisms.[158] In response to an April 23, 2003 email concerning the results of the 040 Cancer Study, Defendant Cawkwell recommended that Pfizer conceal the study's results, noting that Pfizer already has "embargoed a number of celebrex and bextra studies."[159] Defendant Cawkwell was also sent the June 5, 2003 "Cox-2 Strategic Operation Plan," which stated that the "SUCCESS I Publication May Raise Questions" because the results of the study showed that patients provided Celebrex had a "5 X Increase in MIs [myocardial infarctions]."[160] As another example, on March 4, 2004, Defendant Cawkwell received the Top-Line Memorandum concerning the CABG-2 Study, which stated that "[t]he results indicate that there may be [a] safety signal that needs to be evaluated especially in light of the results from the earlier CABG surgery study (Study -035) which was conducted at higher doses."[161]

388. Defendant Cawkwell's job responsibilities also included frequent meetings and communications with regulators and editorial boards of scientific journals concerning Celebrex and Bextra. In connection with these meetings and communications, Defendant Cawkwell reviewed and discussed the drugs' clinical data and undisclosed cardiovascular side effects. For example, as discussed above (*see* ¶216), on September 4, 2003, Defendant Cawkwell received a faxed letter from the NEJM stating that the SUCCESS Study showed "a potential 'signal' that raises the issue of coxib-induced MI's" and that "it looks like such data [showing the number of

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[158] *See* 8/8/01 email from L. Meyers to Cawkwell, et al., bearing Bates No. Cawkwe-G 10001894500 (quoted in ECF No. 420 at 90).
[159] *See* 4/24/03 email from G. Cawkwell to M. Gandelman re: "Publication Committees," bearing Bates No. Gandle-M 10000046442 (attached at ECF No. 351-42).
[160] *See* 6/5/03 "Cox-2 Strategic Operation Plan," bearing Bates No. Cawkwe-G 10003103755-3769 (attached to ECF No. 351-33).
[161] *See* 10/15/04 email from P. Corr to A. McCormick re: Bextra Press Release, bearing Bates No. PFE SECURITIES 001024756-57 (quoted at ECF No. 420 at 160).

heart attacks in the Celebrex treatment group] are being hidden" from Defendants' draft manuscript.[162] As another example, as discussed above (*see* ¶185), Defendant Cawkwell spoke with the DSMC on December 23, 2004, concerning the undisclosed results of the Alzheimer's 001 Study, during which she admitted that "we [Pfizer] recognize that this is a study that had shown unfavorable imbalances of specific CV events."[163]

389. Also as part of her job responsibilities, Defendant Cawkwell spoke to the press and made public statements concerning Celebrex and Bextra during the Relevant Period. In making her public statements, Defendant Cawkwell claimed to know about Pfizer's clinical trial results and the safety profile of these drugs. For example, *The Boston Globe* reported on October 1, 2004, that "[a] Pfizer official, Dr. Gail Cawkwell, said the company knows of no study that shows an increased risk with Celebrex." Five days later, the *Associated Press Online* quoted Defendant Cawkwell as stating that "'there is no evidence' of increased risk of heart problems among the 75 million Americans who have taken Celebrex." Again, on November 12, 2005, *Newsweek* reported that Defendant Cawkwell said that "[w]e [Pfizer] have not seen increased cardiovascular-type risks."

VIII. AFTERMATH: PFIZER FACES A WAVE OF GOVERNMENT INVESTIGATIONS AND CIVIL LAWSUITS, AND PAYS THE LARGEST CRIMINAL FINE IN HISTORY

390. In the fall of 2004, the Department of Justice ("DOJ") commenced an investigation into Pfizer's conduct in marketing COX-2 inhibitors. As discussed above, the FDA had previously denied Pfizer's application to promote Bextra to treat acute pain, basing its decision on various undisclosed safety studies, including the CABG-1 Study, which showed

[162] *See* 9/4/03 SUCCESS rejection letter from the New England Journal of Medicine, bearing Bates No. Cawkwe-G 10000338418-23 (quoted at ECF No. 420 at 59).
[163] *See* 12/23/04 email from Cawkwell to two Pfizer in-house attorneys, bearing Bates No. Cawkwe-G 10003905459 (quoted at ECF No. 420 at 172).

Bextra's significant cardiovascular side effects. Nevertheless, Defendants proceeded with their plan to market Bextra to treat acute pain – an "off-label" use – and concealed the associated cardiovascular safety risks of using Bextra for these purposes. According to the DOJ, ***"approximately 57% of the sales of Bextra were for off-label uses and dosages"*** or over ***$1 billion in net profit.***

391. Defendants' illegal promotional efforts resulted in a criminal plea, Pfizer's payment of the largest criminal fine in history, and the largest ever civil fraud settlement against a pharmaceutical company. On August 31, 2009, a Pfizer subsidiary, Pharmacia & Upjohn Company, Inc. ("Pharmacia Upjohn") agreed to plead guilty to a criminal felony charge of violating the Food, Drug and Cosmetic Act, admitting that it intentionally, and with the intent to deceive and defraud, marketed Bextra for uses and dosages that were not approved by the FDA.

392. To settle the pending criminal charges, Pfizer agreed to pay a fine of $1.195 billion, which, the DOJ stated, was ***"the largest criminal fine ever imposed in the United States for any matter."*** The calculation of the fine was set forth in an August 31, 2009 letter from the prosecuting attorney to Pfizer's counsel. The letter documented the agreement with Pfizer's subsidiary to pay a $1.195 billion fine and $105 million in criminal forfeitures in part because:

> [T]he organization had 5,000 or more employees, and an individual within the high level personnel of the unit participated in or condoned the offense and/or ***tolerance of the offense by substantial authority personnel was pervasive throughout the organization***.

393. The settlement agreement summarizes some of this misconduct, including that "[d]uring the period February 1, 2002, through April 30, 2005 . . . ***Pfizer made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Bextra***."

394. In addition to paying a total of $1.3 billion in criminal fines regarding the illegal promotion and sales practices of Bextra, Pfizer agreed to pay ***another $1 billion*** to settle civil claims by the government that the Company had violated the False Claims Act, including through its prohibited off-label use and dosage promotions, and violations of the Federal anti-kickback statute, with respect to thirteen different drugs. According to the DOJ, this was ***"the largest civil fraud settlement in history against a pharmaceutical company."*** Further, as Assistant Attorney General Tony West commented in connection with the announcement of the settlement, "[t]his civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company ***puts profits ahead of patient welfare***."

395. The deferred prosecution agreement entered between the DOJ and Pfizer, dated August 31, 2009, states that "Pfizer Inc. acknowledges that [Pharmacia & Upjohn] expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information and is in fact guilty of the offense. Pfizer Inc. agrees that it will not make statements inconsistent with this explicit admission of guilty by [its subsidiary] to the crime charged in the Information."

396. On September 21, 2009, Pfizer's Director of Worldwide Programs and US Investigations, Jim Gibney accepted the guilty plea on behalf of Pharmacia Upjohn at a hearing before the Honorable Douglas P. Woodlock, United District Court Judge for the District of Massachusetts (the "Plea Hearing").

397. At the Plea Hearing, U.S. Attorney Sara Bloom stated that Defendants' misconduct ***"was across the corporation and so many people were involved,*** and the astonishing number of e-mails that had 20 people on it, all of whom should have known that [their conduct]

was improper." She further stated that "we certainly think that in this case there were real human beings that ***knew what they were doing was illegal and did it anyway***" and that "many of them were ***following direct instructions from mangers above them***."

398. At the Court's request, U.S. Attorney Bloom then stated the factual basis for the plea, *i.e.*, "what the evidence would be if the case were to go trial." The government would have shown that the FDA made clear to Pfizer the reasons for its decision not to approve Bextra for acute pain, which included "some ***very specific safety concerns*** … based on a study of the use of Bextra in coronary artery bypass graft surgery [*i.e.*, the CABG-1 Study] where the study had used Bextra and an injectable form of Bextra, parecoxib, and had shown ***an increase in cardiovascular thromboembolic events, we're talking primarily heart attacks, in that study in the parecoxib/Bextra arm***." U.S. Attorney Bloom further stated that:

> The evidence would show that, nonetheless, from the time that Bextra was launched in approximately February 2002 and continuing to greater or lesser degree when it was on the market until April of 2005, Pharmacia, and then as it was acquired as part of Pfizer, promoted Bextra for the very uses that the FDA had declined to approve it … ***without disclosing to those to whom it was promoting it the safety issues that the FDA had raised*** and which would be critical to anyone considering using it in such an off-label way….
>
> One of the other things was that sales representatives were making false and misleading claims about the safety and efficacy of Bextra. These included they had ***no dose course increase in hypertension and edema, which was directly contrary to what the FDA had found*** in its approval. Claims about efficacy and safety compared Vioxx, which either ***had not been proven or were contrary to the known evidence….***
>
> The evidence in this case would have included physicians who would say … that had they known about the safety risks identified by the FDA and ***the fact that the FDA had not approved it in surgical use for those safety reasons, they would not have used on their patients, and they felt misled….***

399. In addition, U.S. Attorney Bloom explained at the Plea Hearing the relationship between Pharmacia and Pfizer:

> Pharmacia and Pfizer co-promoted Bextra, as they did Celebrex, from before the time of its launch – and this was a truly joint effort to the point where most of the documents from the planning and marketing have both the Pharmacia and the Pfizer logo on every page…. ***The conduct emanated from headquarters planning and marketing documents.***

400. After U.S. Attorney Bloom stated the factual basis for the plea, the Court asked Mr. Gibney, who was "act[ing] for the corporation [as] the authorized representative," whether Pharmacia Upjohn accepted the plea and admitted that the government had a factual basis for its claims. Mr. Gibney admitted that the government had a factual basis.

401. In a related Sentencing Memorandum, dated October 9, 2009, the DOJ again stated that, based on its extensive investigation, it would have proven at trial that Bextra was promoted "with false and misleading claims of safety, including that Bextra had no dose proportional increase in hypertension and edema, that 'there is not one shred of evidence showing a CV concern with Bextra,' that Bextra had no cardiovascular risks unlike Vioxx, and that Bextra had placebo-like side effects."

402. The Sentencing Memorandum further stated that the government would have shown that ***"the illegal conduct was pervasive throughout the company"*** and that the ***"corporate culture contributed to causing the conduct and allowing it to continue."*** As the government found, and as Pfizer recognized in accepting the plea, Bextra ***did*** have cardiovascular side effects – a fact that Defendants never disclosed to prescribing doctors or investors.

403. At Pfizer's October 16, 2009 sentencing hearing, the Honorable Douglas P. Woodlock, District Judge for the United States Court for the District of Massachusetts, accepted the government's recommended sentence, but expressed the following concern:

> It has, I think, become something of a cost of doing business, a very high cost of doing business, for some of these corporations to ***shed their skin like certain***

> ***animals and leave the skin behind and move on to the future without ultimately giving the public what it is entitled to***, which is the satisfaction of knowing that there has been a full evaluation of the criminal responsibility of the individuals who occupied that skin.

404. In addition to pleading guilty to a felony, paying the largest criminal fine in history, and paying the largest civil settlement by any drug company to the federal government, Pfizer also was forced to pay an additional ***$894 million*** to private litigants and individual states to compensate them for injuries resulting from Pfizer's failure to disclose Celebrex's and Bextra's cardiovascular risks. On October 18, 2008, Pfizer announced that it had "agreed to pay $894 million to settle the bulk of litigation and state government probes surrounding its pain drugs Celebrex and Bextra, which were linked to increased risk for heart attacks and strokes," according to a *Dow Jones* report published that day. "The personal-injury lawsuits generally alleged that use of the drugs caused heart attacks and other problems, and that Pfizer failed to adequately warn of the risks."

405. Of the additional $894 million, Pfizer paid $745 million to resolve the personal injury claims flowing from their failure to disclose Celebrex's and Bextra's cardiovascular risks, $89 million to resolve consumer fraud class action claims, and $60 million to settle claims brought by 33 state attorneys general.[164] In connection with its global settlement with the 33 state attorneys general, Pfizer was also required to adopt various corporate governance changes and to agree to strict limitations on its future promotional activities.

[164] State attorneys general from the following states brought actions against Pfizer, which were resolved by the October 2008 settlement: Alaska, Arizona, Arkansas, California, Connecticut, Florida, District of Columbia, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

IX. PFIZER'S COMPENSATION POLICIES PROVIDED MOTIVE TO COMMIT THE FRAUD

406. Pfizer's compensation policies provided a strong incentive for the Individual Defendants and other members of Pfizer senior management to materially misrepresent, conceal, and recklessly disregard the cardiovascular risks associated with Celebrex and Bextra, and their threat to Pfizer's current and future financial performance. These policies, which were heavily weighted towards incentive and performance-based compensation and were reviewed and approved each year by the Compensation Committee of the board, allowed the Individual Defendants and other senior Pfizer officers to benefit in a substantial, concrete and personal way from the fraud. Defendants McKinnell and Katen, for example, realized over $155 million and $66 million, respectively, in total incentive compensation during the Relevant Period, in addition to millions of dollars in base salary.

407. Pfizer's executive compensation program consisted of three categories: (i) salary; (ii) executive annual incentive awards; and (iii) long-term incentive compensation. During the Relevant Period, the Compensation Committee established the salaries and other compensation of Pfizer's executive officers. According to the Company's proxy statements, in evaluating executive performance during the Relevant Period, the Compensation Committee eschewed established formulas in favor of various considerations, including: (i) the Company's financial performance; (ii) financial, operational and strategic business development, notably "the acquisition of Pharmacia"; (iii) revenue growth versus industry; (iv) earnings per share growth; (v) "ensur[ing] that appropriate strategies and resources are in place to influence the external environment and mitigate any negative impact from increasing regulatory and legislative pressures"; and (vi) the acceptance of the company's product portfolio in the marketplace,

"which drove considerable sales growth, resulting in furthering the Company's position as the number one pharmaceutical company."

408. Pfizer had two distinct incentive-based compensation plans for senior executives and high-ranking employees: (i) the 2001 Stock and Incentive Plan, which was open to all employees of the Company; and (ii) the 2001 Performance-Contingent Share Award Plan, for which Pfizer's 100 highest-ranked employees were eligible to participate. Officers at the senior vice president level and above received half of the value of their annual variable long-term incentive award in the form of performance shares and half in the form of stock options. The performance share awards were based on two performance criteria – 50% diluted earnings per share growth, and 50% total shareholder return – measured over a performance period relative to the performance of a peer group.

409. During the Relevant Period, Defendants McKinnell and Katen each received highly lucrative base compensation, incentive based stock and options awards, performance contingent awards, and significant cash bonuses that made them extremely wealthy, as set forth in the table below:

Year	Base Salary	Annual Incentive Awards	Incentive-Based Stock Awards	Incentive-Based Stock Options[165]	Perform.-Contingent Awards	Total Incentive Comp.	Total Comp.
Henry A. McKinnell							
2000	$984,100	$1,426,900	$1,408,826	$6,836,210	$4,930,892	$14,602,828	$15,586,928
2001	$1,516,667	$2,780,800	$0	$22,811,266	$7,920,000	$33,512,066	$35,028,733
2002	$1,809,900	$3,499,300	$0	$23,376,013	$4,995,648	$31,870,961	$33,680,861
2003	$2,042,700	$4,607,400	$0	$18,445,479	$2,786,978	$25,839,857	$27,882,557
2004	$2,224,900	$3,986,300	$4,292,181	$12,265,804	$5,829,120	$26,373,405	$28,598,305
2005	$2,270,500	$3,700,000	$0	$14,499,795	$5,489,400	$23,689,195	$25,959,695
Total	**$10,848,767**	**$20,000,700**	**$5,701,007**	**$98,234,567**	**$31,952,038**	**$155,888,312**	**$166,737,079**

[165] Minimum Potential Realizable Value, as provided in Pfizer's annual proxy statements for the Relevant Period.

Karen L. Katen							
2000	$698,800	$730,300	$688,282	$3,418,105	$2,408,986	$7,245,673	$7,944,473
2001	$854,625	$1,043,400	$0	$9,409,647	$4,108,500	$14,561,547	$15,416,172
2002	$984,100	$1,240,200	$0	$6,493,337	$2,695,392	$10,428,929	$11,413,029
2003	$1,086,700	$1,434,400	$326,840	$5,072,507	$1,510,448	$8,344,195	$9,430,895
2004	$1,158,300	$1,274,100	$2,326,218	$8,177,202	$3,307,392	$15,084,912	$16,243,212
2005	$1,176,200	$1,535,600	$0	$6,112,982	$3,326,576	$10,975,158	$12,151,358
Total	**$5,958,725**	**$7,258,000**	**$3,341,340**	**$38,683,780**	**$17,357,294**	**$66,640,414**	**$72,599,139**

410. Defendant LaMattina also received lucrative base and incentive compensation during the Relevant Period. From 2002 through 2005, Defendant LaMattina received an aggregate base salary of nearly $3 million, aggregate annual bonuses of over $2.4 million in cash, $1.7 million in restricted stock, over $4.2 million in options, and $3.6 million in long-term incentive payouts all of which were tied to the financial performance of the Company.

411. In addition to the hundreds of millions in executive compensation collectively realized by these Defendants, each generated millions in insider stock sales. During the Relevant Period, Defendant McKinnell disposed of over 800,000 personal shares of Pfizer stock for proceeds in excess of $29.7 million; Defendant Katen disposed of over 375,000 personal shares of Pfizer stock for proceeds in excess of $13.2 million; and Defendant LaMattina disposed of over 67,000 personal shares of Pfizer stock for proceeds of nearly $2 million. Collectively, Defendants McKinnell, Katen and LaMattina sold more than 1,248,743 shares of Pfizer common stock during the Relevant Period, for total proceeds of approximately $45 million.

X. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

412. During and before the Relevant Period, Defendants made numerous untrue statements of material fact regarding the cardiovascular safety of Celebrex and/or Bextra, including that the drugs were safer than Merck's competing COX-2 inhibiter drug, Vioxx, and

numerous material omissions necessary to make such statements not misleading. These statements became part of the total mix of information impacting Pfizer's stock price, and caused Pfizer shares to trade, or continue to trade, at artificially inflated prices throughout the Relevant Period.

413. Similarly, Pfizer's Co-Promoter Searle/Pharmacia made numerous materially false and misleading statements and omissions, including statements made on behalf of Pfizer, during the same period for which Pfizer failed to make corrective or contradictory statements. Pfizer adopted these statements by its Co-Promoter as its own, knowing that they were also impacting the total mix of information related to Celebrex and, by extension, Pfizer's stock price.

414. The materially false and misleading statements made and adopted by Defendants during and before the Relevant Period generally fall within two broad categories. First, Defendants emphasized the cardiovascular safety of Celebrex and Bextra and deliberately concealed or misrepresented materially adverse information concerning significant cardiovascular risks presented by these drugs. Defendants further assured that Celebrex and Bextra were safer than Merck's Vioxx, including through strenuous denials of a "class effect" among COX-2 inhibitors (*i.e.*, that all COX-2 drugs are associated with increased cardiovascular risks) even after Vioxx was withdrawn from the market due to cardiovascular dangers. As set forth in Section VII. above and summarized, in part, in Tables one through six below, such statements and omissions were materially false and misleading when made because they failed to disclose a significant amount of adverse information concerning the cardiovascular safety profile of Celebrex and Bextra, including statistically significant increases in serious cardiovascular safety risks of Celebrex and Bextra compared with a placebo, and associated safety signals.

415. Second, Defendants emphasized the financial performance and commercial importance of Celebrex and Bextra, including their importance to Pfizer's overall financial results, and indicated such performance would continue into the future. As set forth in Section VII. above, such statements were materially false and misleading when made because Defendants failed to disclose that the drugs would not have contributed to Pfizer's financial performance in such manner had the material adverse information known by Pfizer concerning the drugs' significant cardiovascular risks been made public.

416. Pfizer and the Individual Defendants made many such materially false and misleading statements throughout the Relevant Period. At least a dozen of the false and misleading statements set forth below are personally attributable to Defendant McKinnell, more than half a dozen are personally attributable to Defendant Feczko, at least five are personally attributable to Defendant Cawkwell, and several are personally attributable to Defendant Katen.

417. As noted, Defendant McKinnell made numerous public statements concerning Celebrex and Bextra during the Relevant Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Celebrex's and Bextra's medical and commercial viability posed by their cardiovascular risks. These false and misleading statements include those made personally by McKinnell, as well as those made in his presence or at his instruction, including those detailed below on: 10/17/01, 12/18/01, 7/16/02, 7/25/03, 7/23/04, 10/1/04, 10/7/04, 10/20/04, 11/11/04, 11/30/04, 12/1/04, 12/17/04, 12/20/04, 12/21/04, 1/4/05, 2/4/05 and 5/16/05. In addition, Defendant McKinnell signed many of Pfizer's SEC filings during the Relevant Period which contained materially false and misleading statements and omissions, including: (1) the Company's Forms 10-K for each of 2000, 2001, 2002, 2003 and 2004; and (2) the Company's Forms 10-Q for the third quarter of 2002; the first and second

quarters of 2003; the first, second, and third quarters of 2004; and the first and second quarters of 2005.

418. The other Individual Defendants also made numerous public statements concerning Celebrex and Bextra during the Relevant Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Celebrex's and Bextra's medical and commercial viability posed by their cardiovascular risks. These false and misleading statements include those made personally by Defendants Katen, Feczko, and Cawkwell, as well as those made in each of their presence or at their instruction, including those detailed below on: (1) 10/17/01, 12/18/01, 6/18/03, 7/25/03, 10/1/04, 10/7/04, 10/20/04, 11/30/04 and 4/5/05, with respect to Defendant Katen; (2) 9/30/04, 10/1/04, 10/4/04, 10/7/04, 10/18/04, 10/20/04, 11/30/04, 12/17/04 and 2/16-18/05, with respect to Defendant Feczko; and (3) 10/1/04, 10/6/04, 10/19/04, 11/12/04 and 2/1/05, with respect to Defendant Cawkwell.

419. The truth about Celebrex's and Bextra's cardiovascular safety risks was not revealed to the market until late 2004 and 2005, following Vioxx's withdrawal from the market. Even then, the truth about Celebrex and Bextra was only revealed in a series of partial disclosures, many of which were coupled with further misrepresentations and false denials by Defendants. As the truth about the matters previously concealed by Defendants was disclosed, Pfizer's revenues from Celebrex and Bextra fell sharply and the Company's stock price substantially declined.

A. <u>False Statements Before The Relevant Period</u>

420. Prior to the Relevant Period, Pfizer and its Co-Promoter (on behalf of Pfizer) issued a series of press releases and other public statements that misrepresented the safety profile of Celebrex and Bextra through both affirmatively false public statements and by failing to disclose material adverse information then known or recklessly disregarded by Defendants

concerning the significant cardiovascular risks associated with Celebrex. These statements were part of the total mix of information impacting Pfizer's stock price as of the beginning of the Relevant Period.

421. For example, on February 1, 1999, Dr. Needleman gave an interview to the *Philadelphia Inquirer* in which he stated that, "[t]here has been no evidence of extra heart problems in the approximately 9,000 people who have taken Celebrex in trials." Dr. Peter Isakson reiterated that "[i]n fact we'll keep track of all safety around the patients taking the drug," and assured the investors and the public that "[w]e'll monitor cardiovascular just like we monitor all the safety around Celebrex."

422. Similarly, on February 15, 2000, Pfizer issued a press release titled "Newly Published Study Confirms Celebrex® Does Not Interfere With Platelet Function Findings Important for Arthritis Patients Taking Low-Dose Aspirin" (the "February 15, 2000 Press Release"). The February 15, 2000 Press Release stated that "[a] double-blind, randomized, placebo-controlled study published in this month's *Journal of Clinical Pharmacology* concludes that the COX-2 specific inhibitor Celebrex® (celecoxib capsules) does not interfere with platelet function, even at 1200 mg per day, which is six times the recommended daily dose for osteoarthritis." The February 15, 2000 Press Release further stated that, "[t]his benefit meshes nicely with the fact that at recommended doses, ***there doesn't appear to be any dose-related increase in the cardiovascular-related side effects of hypertension of peripheral edema***."

423. On February 22, 2000, Pfizer issued a press release (the "February 22, 2000 Press Release") titled "Celebrex Sets Industry Records in First Year Generating 19 Million Prescriptions: An Estimated Seven Million Patients." The February 22, 2000 Press Release, which was issued on or about the one-year anniversary of Celebrex's launch, boasted that the

launch of Celebrex was "the most successful pharmaceutical launch in U.S. history." The February 22, 2000 Press Release further stated that, "[t]he overwhelming response to Celebrex, including the number of patients who are continuing on the product, ***is a clear signal that this is a safe and effective arthritis medication that can be used for the long term."***

424. Likewise, on February 29, 2000, Pfizer issued a press release (the "February 29, 2000 Press Release") titled "Celebrex® At One Year: Helping Many Return To Daily Activities; Innovative Arthritis Drug Taken By An Estimated Seven Million People." The February 29, 2000 Press Release boasted that Celebrex "in its first year generated an unprecedented 19 million prescriptions, a volume unrivaled by any other prescription drug in its first year." The February 29, 2000 Press Release underscored that this record-setting number of prescriptions was driven by a "motivated patient population" seeking "an effective, well tolerated anti-arthritic medication."

425. On April 6, 2000, Pfizer issued a press release (the "April 6, 2000 Press Release") titled "Celebrex® Study Shows Once-daily Dose As Effective As Twice-daily Dose for Osteoarthritis." The April 6, 2000 Press Release stated that "[a] recently published study of almost 700 osteoarthritis (OA) patients has found that a single daily dose (QD) of 200 mg of Celebrex® (celecoxib capsules) is ***just as effective and safe*** as two daily doses (BID) of 100 mg each for the treatment of the pain and inflammation of OA."

426. On April 17, 2000, Pfizer issued a press release (the "April 17, 2000 Press Release") titled "New Findings Presented on Celebrex® Safety and Tolerability From Long-Term Outcomes Study of 8,000 Arthritis Patients – Long-term safety studied in major organ systems, at 4 times the OA dose – Ibuprofen and diclofenac found to cause significantly greater GI blood loss than Celebrex." The April 17, 2000 Press Release announced that a "landmark"

study to assess the overall long-term safety of Celebrex showed that arthritis patients taking four times the recommended osteoarthritis dose of Celebrex "experienced fewer symptomatic gastrointestinal (GI) ulcers and ulcer complications than patients taking ibuprofen and diclofenac – a difference that was statistically significant based on a combined analysis of Celebrex versus these two traditional nonsteroidal anti-inflammatory drugs." In the April 17, 2000 Press Release, Pfizer emphasized that, "***Importantly, Celebrex showed no increase in thromboembolic or other cardiovascular-related events, even among non-aspirin users."*** The April 17, 2000 Press Release further emphasized that "***Celebrex showed no increases in thromboembolic events (such as myocardial infarctions and stroke) or other cardiovascular adverse events compared with the traditional NSAID comparators,"*** even though "about 40 percent of patients in each arm of the study had a history of cardiovascular disease, and about half of these patients were taking low-dose aspirin."

427. On April 18, 2000, Pfizer issued a press release containing its financial results for the first quarter of 2000 (the "April 18, 2000 Press Release"). In the April 18, 2000 Press Release, Pfizer continued to assure investors that ***"Celebrex showed no increase in thromboembolic or other cardiovascular-related events, even among non-aspirin users."***

428. On April 28, 2000, Pharmacia issued a press release (the "April 28, 2000 Press Release") titled "New Study Validates Safety of Pharmacia Corporation's Celebrex on Stroke, Heart Attack Issues." The April 28, 2000 Press Release discussed the results of another "landmark study" (*i.e.*, the CLASS Study) that "continues to demonstrate a strong safety profile for Celebrex," and denied claims that Celebrex, unlike other COX-2 inhibitors (*viz.*, Vioxx) was associated with stroke and heart attacks. In particular, the April 28, 2000 Press Release reassured investors that while recent news reports associated Vioxx "with stroke and heart attacks" – which

some "suggested" may be an effect "common to COX-2 inhibitor compounds" – new data reaffirmed that "this is not the case" for the "innovative COX-2 specific inhibitor, Celebrex®." The April 28, 2000 Press Release emphasized that "[e]ven at these very high doses, ***Celebrex showed no increases in stroke or heart attack with or without aspirin. The Celebrex data thus indicate that there is no class-related issue on this important safety parameter, suggesting that any potential risk associated with Vioxx may be specific to that compound.***"

429. On May 23, 2000, Pfizer issued a press release (the "May 23, 2000 Press Release") titled "Findings from Celebrex® Safety Study Show Traditional NSAID Comparators Can Cause Serious GI Complications Within First Few Days of Treatment; No Increased Risk of GI Complications Observed for H. Pylori Positive Patients on Celebrex." The May 23, 2000 Press Release emphasized that while "new data" from a Celebrex long-term safety study presented during Digestive Disease Week revealed that (i) "the risk for serious gastrointestinal complications with the NSAID comparators ibuprofen and diclofenac can start within the first few days after treatment begins"; and (ii) "patients who were H. pylori positive had a two times greater risk of developing both symptomatic ulcers and ulcer complications when taking the NSAID comparators than did H. pylori negative patients," and there was "no such increase" observed with patients taking Celebrex, regardless of H. pylori status. The May 23, 2000 Press Release further emphasized that, "***[t]he long-term safety study also indicated that four times the recommended OA dose of Celebrex, taken with or without aspirin, posed no increased risk of heart attacks or strokes compared with ibuprofen and diclofenac."***

430. On June 22, 2000, Pfizer issued a press release (the "June 22, 2000 Press Release") titled "In Large Head-to-Head COX-2 Inhibitor Safety Study, Vioxx® Associated with Significant Increases in Blood Pressure and Edema vs. Celebrex®." The June 22, 2000 Press

Release announced that "[n]ew data derived from the first-ever head-to-head safety study" comparing Celebrex with Vioxx showed that hypertensive osteoarthritis patients taking Vioxx "experienced statistically significantly more increases in edema and systolic blood pressure compared with those taking Celebrex." The June 22, 2000 Press Release emphasized that "Vioxx-treated patients experienced a two-fold increase in clinically significant edema compared to the Celebrex- treated patients" and, "of greater importance, results reveal that within two weeks of the start of the study, significantly more patients on Vioxx had clinically meaningful increases in systolic blood pressure (greater than or equal to 20 mmHg) versus those on Celebrex."

431. At the time the preceding material misstatements were made, high level Pfizer personnel, including the Individual Defendants, knew or recklessly disregarded a variety of adverse information regarding the safety profile of Celebrex and Bextra, as set forth in Section VII above and summarized, in part, in Table 1 below:

TABLE 1

Date	Event	Description
June 1998	ISS Report	Internal summary of safety data from early osteoarthritis and rheumatoid arthritis Celebrex clinical studies shows a statistically significant ***"excess of myocardial infarction (MI) [i.e., heart attacks] in celecoxib-treated elderly patients."*** *See* ¶¶167-172.

Date	Event	Description
June 1998	016 Study	Internal Bextra clinical study conducted on patients suffering rheumatoid arthritis, with patients given Bextra, naproxen, or placebo. Of the twelve patients who experienced adverse events in the Bextra group, six of them were heart attacks, compared to zero heart attacks in patients given a placebo or the active control, naproxen. Dr. Zwillich sent Dr. Wahba an email that he was ***"worried about the safety data,"*** including the "6 MIs [i.e., myocardial infarctions] on valde [i.e., Bextra] vs. 0 on placebo or naproxen." Dr. Wahba also had ***"major concerns"*** about the cardiovascular safety data.
June 1999	Alzheimer's 001 Study	Internal randomized, double-blind placebo-controlled Celebrex study conducted on patients with mild-to-moderate symptoms of the Alzheimer's Disease. The incidence of serious adverse cardiovascular events in the Celebrex treatment group, including stroke and heart failure, was ***337%*** higher than in the placebo group, and the rate of cardiovascular deaths was ***more than twice*** as high in the Celebrex group compared to the placebo group. Pfizer employees internally acknowledged that ***"[w]ith regard to Alzheimer 001, [p]atients treated with 200 mg BID were at greater risk of serious CV thromboembolic adverse events vs. placebo."*** *See* ¶¶173-194.
July 1999	Cardiovascular Safety Summary	Internal summary of safety data from Celebrex clinical studies shows, among other things, that North American patients given Celebrex at 100 and 200 mg doses were ***more than three-times*** more likely to experience adverse cardiovascular events than patients given a placebo, and that this difference was statistically significant. *See* ¶¶195-206.
October 1999	FDA warning letter	FDA sends letter to the President and CEO of Pfizer's Co-Promoter warning that Celebrex promotional materials "present[ed] several unsubstantiated comparative claims to Vioxx," including the "superior safety of Celebrex."
November 1999	Joint Pfizer/Searle presentation to the Senior Management Board	Presentation made to the Senior Management Board shows that, for the Alzheimer's 001 Study, the overall rate of reported cardiovascular adverse events was 9.8% for patients in the Celebrex group, as compared with 2.9% in the placebo group – an over three-times difference that the presentation acknowledged was statistically significant (*i.e.*, with "$p<0.05$ compared to placebo"). *See* ¶¶177-178.

Date	Event	Description
April 2000	SUCCESS Study	Double-blind, randomized trial involving 13,274 osteoarthritis patients that compared the safety of Celebrex to diclofenac and naproxen. The rate of heart attacks in the Celebrex treatment group was ***five times*** higher than compared to the NSAID groups, with ten heart attacks reported in the Celebrex group (0.55 per person/year) and only one heart attack in the combined naproxen/diclofenac group (0.11 per person/year). The medical monitor for the study concluded that "***[t]he rates of myocardial infarction are worrisome."*** *See* ¶¶207-221.
April 2000	CLASS Study	Internal study designed to evaluate Celebrex's safety in treating osteoarthritis and rheumatoid arthritis. The results of the study for rheumatoid arthritis patients reveal a statistically significant result of ***nine*** heart attacks in the Celebrex subgroup versus ***none*** for diclofenac. As noted by Dr. Geis in one internal email, "I think that showing CV events adjusted for time of exposure – from the NDA and then from 024 and CLASS serves to reinforce the story that ***we are seeing a signal."*** Defendants misleadingly publish the results from only six months of the study, concealing the remainder of the study results. *See* ¶¶222-237.
April 2000	FDA warning letter	FDA sends a letter warning that Pfizer and its Co-Promoter's sales aids "misrepresent the safety profile for Celebrex," and that their promotional materials "present[ed] several unsubstantiated comparative claims concerning Celebrex to Vioxx." The FDA further concludes that ***"your representatives continue to engage in violative promotional practices"*** and expressed "concern[] that the activities described [in the letter] demonstrate ***a continuing pattern and practice of violative behaviors that evidence widespread corporate involvement and acquiescence with your employee's activities.***"
May 2000	060 Study	Internal study compares the efficacy and safety of Bextra to naproxen and placebo in 1,089 patients. Based on the results of the study, Dr. Forster concludes that ***"[t]here is clearly an increased incidence of MI with valdecoxib compared to placebo and NSAIDs at this point in the data-base."*** *See* ¶¶248-254.

Date	Event	Description
June 2000	CABG-1 Study	Internal study on coronary artery bypass graft patients for Bextra and parecoxib. Over ***20%*** of the patients in the Bextra treatment group report a serious adverse event, and patients treated with Bextra, as opposed to a placebo, are ***three times*** more likely to report a serious cardiovascular event. The FDA concludes that, ***"[s]afety in CABG trial [was] unacceptable due to thromboembolic events, GI events, renal dysfunction."*** Based on the results of the study, Defendant McKinnell and Pfizer negotiate downward the milestone payments due under the Co-Promotion Agreement. *See* ¶¶255-282.
July 2000	061 Study	Internal study compares the efficacy and safety of Bextra with naproxen and placebo. Participants in the 061 Study were given Bextra, naproxen, or a placebo. Approximately 77% of the total patients that experienced serious cardio-renal events, such as hypertension or congestive heart failure, were in the Bextra treatment group. Commenting on the data, Dr. Forster emails Defendant LaMattina and others, ***"I think the data speak for themselves…. Note the peripheral edema and hypertension at 20mg and 40mg."*** *See* ¶¶248-254.
August 2000	047 Study	Internal six-month long double-blind study compared the safety of Bextra to naproxen (Aleve) on 900 patients. Senior scientist emailed Dr. Verburg about the cardiovascular safety data for the 047 Study, and similarly concluded that "***[t]o me it looks like a small but annoying signal is present."*** *See* ¶¶283-288.

432. Analysts embraced the foregoing materially false and misleading statements. For example a February 7, 2000, report from Morgan Stanley Dean Witter stated that "Celebrex continues to dominate the Cox-2 inhibitor market, with sales forecast to approach $ 2.5 billion in 2000. . . . The addition of WLA's sales force may further augment the muscle behind this blockbuster product…. Based on our forecasts for sales and profit sharing, we expect that PFE will gross peak alliance revenues of around $2 billion from Celebrex and other products in its Cox-2 platform." Similarly, an April 18, 2000 Deutsche Bank Alex Brown analyst report

upgraded Pfizer to a "STRONG BUY," and in its next report on May 2, 2000, stated that "Celebrex is already annualizing at a rate of $2.2 billion, and should benefit from the recently released CLASS trial data which demonstrated the long term safety of the COX-2 inhibitor, as patients on 4 times the recommended dose of Celebrex experienced fewer GI ulcers and ulcer complications than those on ibuprofen or diclofenac. Along with Merck's Vioxx, these drugs are rapidly expanding the arthritis marketplace in dollars as they displace less expensive older NSAIDs. Ultimately, Celebrex could achieve peak sales of $3 billion."

B. False Statements In 2000

433. The Relevant Period begins on October 31, 2000, when Pfizer issued a press release (the "October 31, 2000 Press Release") titled "New Head-to-Head Study Showed CELEBREX® and Vioxx® Comparable In Efficacy for the Treatment of Osteoarthritis – In A Separate Head-To-Head Safety Study, Vioxx Associated With Significant Increases in Blood Pressure and Edema Versus CELEBREX." The October 31, 2000 Press Release stated that:

> In a separate head-to-head safety study, CELEBREX was shown to offer improved renal safety over Vioxx.
>
> * * *
>
> In the study, CELEBREX caused ***significantly fewer adverse renal side effects than Vioxx*** . . . . This study provides ***compelling evidence that CELEBREX and Vioxx affect hypertensive arthritis patients differently***, suggesting that not all COX-2 inhibitors are the same.

434. On November 1, 2000, Pharmacia filed a Form 8-K with the SEC (the "November 1, 2000 8-K") which stated that:

> During the quarter, results of a landmark long-term study of 8,000 patients with osteoarthritis (OA) and adult rheumatoid arthritis were published in the Journal of the American Medical Association (JAMA). The study found that patients treated with Celebrex experienced two-to-threefold fewer gastrointestinal complications than patients treated with two other arthritis medications studied, even at four times the recommended OA dose of Celebrex. Celebrex showed a positive renal

and hepatic profile ***with no increase in thromboembolic or other cardiovascular-related events.***

435. The emphasized portion of the October 31, 2000 Press Release and the November 1, 2000 Form 8-K referenced above regarding the comparative safety of Celebrex over Vioxx were materially false and misleading when made. As set forth above, these statements failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex and falsely claimed that Celebrex showed no increase in thromboembolic or cardiovascular-related events.

C. False Statements In 2001

436. During the course of 2001, Defendants (and Pfizer's Co-Promoter) continued to make and/or caused to issue materially false and misleading statements and/or omissions of material facts related to the safety of Celebrex and Bextra (including studies of COX-2 inhibitors). These material misstatements from 2001 are set forth below.

437. On January 24, 2001, Pfizer issued a press release announcing its fourth quarter 2000 and fiscal year 2000 financial results (the "Fiscal Year 2000 Press Release"). The Fiscal Year 2000 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

Q19) How is Celebrex performing?

A19) Pfizer and Pharmacia Corporation, the company that discovered and developed Celebrex, co-promote this product for relief of the pain and inflammation of osteoarthritis (OA) and adult rheumatoid arthritis (RA) in most major world markets. Celebrex remains the most successful drug launch in the history of the pharmaceutical industry, as measured both by its first year on the market and by its continued performance in its second year. ***Celebrex provides unsurpassed efficacy, outstanding tolerability, and a superior safety profile to Vioxx.***

* * *

> In a long-term outcomes study of 5,800 OA patients and 2,200 RA patients, patients taking four times the recommended OA and twice the recommended RA dose of Celebrex experienced fewer symptomatic gastrointestinal ulcers and ulcer complications than patients taking ibuprofen and diclofenac, a difference that was statistically significant. ***Celebrex showed no increase in thromboembolic or other cardiovascular-related events, even among non-aspirin users.*** Celebrex also was associated with a significantly lower incidence of blood loss than ibuprofen or diclofenac, an event that can often signal serious hidden damage throughout the GI tract.

438. On April 18, 2001, Pfizer issued a press release announcing its first quarter 2001 financial results (the "First Quarter 2001 Press Release"). The First Quarter 2001 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Q16) How is Celebrex performing?
>
> A16) Pfizer and Pharmacia Corporation, the company that discovered and developed Celebrex, co-promote this product for relief of the pain and inflammation of osteoarthritis (OA) and adult rheumatoid arthritis (RA) in most major world markets. Celebrex remains the most successful drug launch in the history of the pharmaceutical industry, as measured by both its first and second years on the market. ***Celebrex provides unsurpassed efficacy, outstanding tolerability, and a superior safety profile to Vioxx.***
>
> * * *
>
> Celebrex was tested in more than 50 clinical trials that involved more than 13,000 patients and healthy volunteers in 23 countries. In these trials, Celebrex was shown to be as effective as the maximum recommended dose of the prescription-strength nonsteroidal anti-inflammatory drugs (NSAID) naproxen and ibuprofen in treating arthritis pain and inflammation.
>
> * * *
>
> Q17) What is the status of revised labeling for Celebrex reflecting the results of the CLASS Study?
>
> A17) Pfizer and Pharmacia have received an approvable letter from the FDA for revised labeling for Celebrex. The approvable letter is in response to the Supplemental New Drug Application seeking changes to the prescribing information to include results of the CLASS trial. Pfizer

> and Pharmacia are confident that all previous studies, including CLASS, comparing Celebrex to traditional NSAIDs in approximately 20,000 patients, as well as post-marketing surveillance in more than 12 million patients and nearly 2 million patient-years of exposure, have demonstrated that ***Celebrex is effective and well tolerated and offers an excellent GI safety profile.***

439. On August 21, 2001, Pharmacia and Pfizer issued a joint press release which stated:

> Pharmacia and Pfizer strongly support the cardiovascular safety profile of CELEBREX®. . . . The article in JAMA is not based upon any new clinical study. The companies believe it is essential to exercise extreme caution in drawing any conclusions from this type of analysis. Furthermore, it is inconsistent with the clinical experience of CELEBREX.
>
> ***"Celebrex studies have consistently shown no increased risk for heart attack and stroke compared to traditional NSAIDs studied . . . ."***

440. The next day, on August 22, 2001, Pfizer and Pharmacia followed up with a joint press release which stated:

> Celebrex has an excellent, well-documented gastrointestinal and cardiorenal safety profile. The safety of Celebrex has been fully demonstrated in the extensive clinical trials reviewed by the FDA as part of the approval of Celebrex and confirmed ***in numerous post-approval clinical settings that have been widely published,*** as well as in real world use, 21.5 million patients to date . . . .
>
> In contrast to the analysis presented in the JAMA article, properly conducted, well-controlled clinical trials have consistently shown that Celebrex poses no increased risk for heart attack compared to the traditional NSAIDs studied….
>
> Celebrex does not affect platelet function….

441. Between August and October 2001, Pfizer and Pharmacia issued numerous additional materially false and misleading statements to the media regarding their "strong support" for Celebrex's supposed cardiovascular safety profile, including:

> (a) an August 21, 2001 joint Pfizer/Pharmacia press release on *PR Newswire* that stated: "CELEBREX studies have consistently shown no increased risk for heart attack and stroke, compared to traditional NSAIDs studied. . . .

The cardiovascular safety profile of CELEBREX was carefully considered at the February 7, 2001 Food and Drug Administration . . . Arthritis Advisory Committee meeting, which concluded that CELEBREX demonstrated no increased cardiovascular risk in comparison to NSAIDs studied.";

(b) an August 22, 2001 *Akron Beacon Journal* article which states: "'We have not seen ***any signal at all*** suggesting there could be a cardiovascular risk with Celebrex,' Geis said.";

(c) an August 22, 2001 *Wall Street Journal Europe* article and an August 27, 2001 *Asian Wall Street Journal* article, each of which quotes Dr. Geis as follows: ***"We have never seen in any of our databases that Celebrex has a higher rate of cardiovascular events"***;

(d) an August 24, 2001 article in *The Dominion* in which Dr. Chris Fenn, a Pharmacia regional medical director, is quoted as follows: "We believe Celebrex does not cause any higher or any more problems with regard to heart attacks than the older drugs which have been around for donkey's years **-- *all the clinical trials show no difference"***; and

(e) an October 9, 2001 *The New York Times* article which quotes Dr. Geis as stating "Pharmacia's studies never showed any increase in heart attacks or strokes in patients taking Celebrex…. 'We systematically go through our data,' he said, and he carefully explains again that the Celebrex studies found no such effect."

442. On October 17, 2001, Pfizer issued a press release announcing its third quarter 2001 results (the "Third Quarter 2001 Press Release"). The Third Quarter 2001 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

Q18) How is Celebrex performing?

A18) Celebrex continues to perform very well. Celebrex remains the most successful drug launch in the history of the pharmaceutical industry, as measured by both its first and second years on the market. Celebrex is receiving more than 440,000 average weekly total U.S. prescriptions, which make it the #1 prescribed arthritis brand in the U.S. . . . ***Celebrex provides strong efficacy, outstanding tolerability, and a superior safety profile to Vioxx.***

* * *

Celebrex has an excellent, well-documented gastrointestinal and cardiorenal safety profile. The safety of Celebrex has been fully demonstrated in the extensive clinical trials reviewed by the FDA as part of the approval of Celebrex and confirmed in numerous post-approval clinical settings that have been widely

published, as well as in real world use, including more than 21 million patients to date. ***Properly conducted, well-controlled clinical trials have consistently shown that Celebrex poses no increased risk for heart attack compared to the traditional NSAIDs studied,*** medications that have been widely used to treat arthritis for decades. The FDA reviewed these studies, and has concluded that Celebrex is not associated with a greater cardiovascular risk compared to traditional NSAIDs studied.

We have conducted two large studies in almost 2,000 elderly patients who had stable hypertension. We observed that significantly more patients on Vioxx as compared to Celebrex had clinically significant increases in peripheral edema. Additionally, significantly more patients in the Vioxx treatment group demonstrated clinically significant increases in their systolic blood pressure. Also, patients on Vioxx have an approximate 3 mm/Hg increase in systolic blood pressure compared to Celebrex. Cardiologists have told us that a rise in the mean systolic blood pressure of as little as 3mm/Hg, if sustained, could increase the risk of a person having a heart attack, stroke, or other cardiovascular events. There were no statistically significant differences between treatments for diastolic blood pressure.

443. During Pfizer's October 17, 2001 earnings conference call, Defendant Katen stated: "We have not seen any problems with cardiovascular safety with Celebrex."

444. Similarly, during Pfizer's October 17, 2001 earnings conference call, Defendant McKinnell stated: "There's never been a cardiovascular issue raised around Celebrex other than by inference, which we think is faulty science and analysis."

445. On November 13, 2001, Pfizer issued a press release (the "November 13, 2001 Press Release") titled "Analysis of Celebrex® Safety Data Show No Increased Risk of Cardiovascular Adverse Events Compared to NSAIDs Studied®." The November 13, 2001 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> An analysis of safety data, representing over 13,000 patients from the new drug application (NDA) and 8,000 patients in the Celecoxib Long-term Arthritis Safety Study (CLASS), supports that ***CELEBREX® (celecoxib capsules) is not associated with an increased risk of cardiovascular (CV) adverse events compared to the NSAIDs studied.***

446. On November 19, 2001, Pfizer in a press release announced the approval of its second-generation COX-2 inhibitor, Bextra (the "Bextra Approval Press Release"). The Bextra Approval Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Pharmacia Corporation (NYSE: PHA) and Pfizer Inc (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has approved BEXTRA® (valdecoxib tablets), a COX-2 specific inhibitor, for treating the signs and symptoms of osteoarthritis (OA) and adult rheumatoid arthritis (RA); and the treatment of pain associated with menstrual cramping.
>
> BEXTRA, which is indicated for arthritis in a once-a-day 10 mg dose, offers 24-hour arthritis pain relief. In global clinical trials involving more than 5,000 patients, BEXTRA demonstrated comparable efficacy while offering an improved gastrointestinal safety and tolerability profile versus conventional NSAIDs studied, specifically naproxen, ibuprofen and diclofenac. In controlled arthritis trials, ***the use of BEXTRA at the recommended dose has not been associated with any increased risk of cardiovascular or renal complications versus NSAIDs studied.*** For menstrual pain, the recommended dose of BEXTRA is 20 mg, administered twice daily as needed. Approximately 80 percent of women in the clinical trials required only one dose of medication within the first 24 hours.

447. Pfizer issued the following statement reported by *PR Newswire* on December 18, 2001 (the "December 18, 2001 *PR Newswire*"):

> Bextra provides an important, 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 non-steroidal anti-inflammatory drugs.

448. Pfizer also issued a press release on December 18, 2001, reporting on a Wall Street analysts meeting (which was attended by Defendants McKinnell, Katen, and other senior Pfizer executives) that stated: (a) "Pfizer also received regulatory approval for Bextra . . . for the treatment of … OA, … RA and menstrual pain"; (b) "Co-promoted with Pharmacia, Bextra provides an important, new, once-daily option for people with OA and RA;" and (c) "It offers improved gastrointestinal toleration, with ***no increase in renal or cardiovascular risk*** versus

traditional non-steroidal anti-inflammatory drugs. It represents an important addition to Pfizer's arthritis/pain franchise."

449. The above-referenced 2001 statements (including the emphasized portions) were materially false and misleading when made. As set forth in Section VII. above and summarized, in part, in Table 1 above and Table 2 below, these statements failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex and/or Bextra and falsely claimed that Celebrex and/or Bextra showed no increase in thromboembolic or cardiovascular-related events.

TABLE 2

Date	Event	Description
February 2001	FDA Warning Letter	FDA sends a warning letter to Pharmacia and Pfizer ordering it to "[i]mmediately ceas[e] the dissemination of all promotional activities and materials for Celebrex that contain violations like those outlined in this letter," including unsubstantiated safety comparisons to Vioxx. The same FDA warning letter, with an accompanying memorandum, is sent directly to Defendants McKinnell and Feczko. *See* ¶¶325-334.
September 2001	WHO Safety Signal Warning	WHO notifies Pfizer and its Co-Promoter about a Celebrex ***"safety signal"*** for myocardial infarctions. The UMC's database shows "48 cases where celecoxib [is] listed as the only drug suspected of association with MI [*i.e.*, a myocardial infarction]." The UMC concludes that, "[i]n view of … the evidence of possible causality proved by the reviewed case reports[,] ***Myocardial infarction observed with celecoxib should be regarded as a serious signal.***" *See* ¶¶304-307.
November 2001	Valdecoxib Joint Product Team Meeting to Discuss CABG-1 Study	Meeting minutes reflect that disclosure of the results "will affect managed care perceptions of the portfolio, possibly raising safety concerns about Celebrex" and ***"Merck might use CABG as ammo."*** *See* ¶¶276-278.
November	FDA Rejection of	FDA rejects Pfizer and its Co-Promoter's application for an

Date	Event	Description
2001	Bextra Acute Pain Indication Based On CABG-1 Study	acute pain indication for Bextra. FDA identifies "Safety" as the first "deficienc[y]" preventing approval, and further states that "safety of valdecoxib for the management of acute pain in the peri-operative setting has not been established based on the findings of study 035 (CABG)." *See* ¶¶278-282.

450. Analysts reacted positively to the foregoing false and misleading statements made and/or adopted by Defendants in 2001. For example, on October 17, 2001, Bear Stearns issued a report on Pfizer that rated the Company's shares as "Attractive" and set a target price of $45-48. Embracing Defendants' false statements, the Bear Stearns report highlighted that "PFE [Pfizer] management stated they were confident that the upcoming label changes for Celebrex would be differentiated from Vioxx (Merck), potentially conveying a marketing advantage."

D. <u>False Statements In 2002</u>

451. During the course of 2002, Defendants continued to make, cause to issue and/or adopt materially false and misleading statements and/or omissions of material facts related to the safety of Celebrex and Bextra (including studies of COX-2 inhibitors), as well as false advertisements to the general public. These material misstatements from 2002 are set forth below.

452. On January 23, 2002, Pfizer issued a press release announcing its fourth quarter and full-year 2001 financial results (the "Full Year 2001 Press Release"). The Full Year 2001 Press Release included, *inter alia,* the following materially false and misleading statements and/or omissions of material fact:

> Q20) How is Celebrex performing?
>
> A20) . . . ***Celebrex provides strong efficacy, outstanding tolerability, and a superior safety profile to Vioxx.*** These advantages have translated into a higher

refill rate, higher patient satisfaction level, and higher persistence of use for Celebrex. With the recent approval for acute pain and primary dysmenorrhea in the U.S., Celebrex is now the selective COX-2 inhibitor approved to treat the broadest range of painful conditions.

* * *

While the issue of cardiovascular safety has been raised for Vioxx, we thoroughly reviewed our Celebrex NDA database for such findings and found no evidence. In CLASS, a long-term outcome trial of more than 8,000 patients conducted at a Celebrex dose that was four times the recommended dose for osteoarthritis, Celebrex demonstrated no increased incidence of myocardial infarction, cerebral vascular accidents, hypertension, or peripheral edema when compared to ibuprofen and diclofenac.

*** * ***

Q22) What is the status of Bextra?

A22) Bextra was approved by the FDA on November 16, 2001, for the relief of pain and inflammation of osteoarthritis (OA), adult rheumatoid arthritis (RA), and primary dysmenorrhea. Bextra offers once-daily dosing for OA and RA patients. The product has a significantly lower incidence of gastroduodenal ulcers vs. traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia vs. naproxen.

453. On March 25, 2002, *The Wall Street Journal* quoted Dr. Geis of Pharmacia as stating that a study in the *American Journal of Cardiology* in February did not identify, "'any difference in the incidence of serious cardiac events with Celebrex vs. traditional nonsteroidal anti-inflammatories. We don't see a signal of cardiac problems with Celebrex'.... Data has shown that Celebrex has a better gastrointestinal profile, a lower incidence of ulcers. It definitely is safer.'"

454. On June 7, 2002, Pfizer issued a press release (the "June 7, 2002 Press Release") titled "FDA Approves New CELEBREX® Prescribing Information; New Data Included From CLASS Study." The June 7, 2002 Press Release contained the following false and misleading statements and/or omissions of material fact:

New label reaffirms the GI and CV safety profile of CELEBREX

> Specifically, the new prescribing information includes additional GI safety data from CLASS. ***Importantly, the revised label also includes data indicating that there was no increased risk for serious CV [cardiovascular] adverse events observed compared to the non-specific NSAID comparators (diclofenac and ibuprofen). These CV events included heart attack, stroke and unstable angina.***
>
> * * *
>
> ***The revised label reaffirms the cardiovascular safety profile of CELEBREX. Analysis of the safety data from CLASS shows there were no significant differences between treatment groups in the overall incidence of serious CV thromboembolic adverse events, such as heart attack, stroke and unstable angina.***

455. On June 8, 2002, *The New York Times* published an article based on an interview with Dr. Steven Geis of Pharmacia, which stated: "He [Geis] said that study also ***proved that Celebrex was safe on the heart.*** Even when patients in the study were given twice the highest recommended dose of Celebrex, he said, the study showed there was ***no higher risk of heart attack compared with patients taking diclofenac or ibuprofen."*** Also on June 8, 2002, an article in the *The Record* attributed the following statements to Dr. Geis: "I think the ***whole picture*** validates and confirms the superior GI safety profile of Celebrex, ***confirms there's no cardiovascular risk of Celebrex,*** and reinforces the whole safety profile that we have seen in the past."

456. On July 15, 2002, Pfizer announced its financial results for the second quarter of 2002, which was also filed with the SEC as a Form 425 (the "Second Quarter 2002 Press Release"). The Second Quarter 2002 Press Release titled "Pfizer Announces Second Quarter 2002 Results, Reaffirms Strong Outlook for Full-Year 2002" contained the following materially false and misleading statements and/or omissions of material fact:

> Q11) HOW IS CELEBREX PERFORMING?
>
> A11) . . . In June, after a comprehensive review of the Celecoxib Long-term Arthritis Safety Study (CLASS) data, the FDA approved revised labeling for Celebrex. The new prescribing information includes additional gastrointestinal

(GI) safety data showing the estimated cumulative incidence of upper GI ulcer complications and symptomatic ulcers for Celebrex patients at 0.78% versus an annual NSAID category rate of 2-4%. ***Additionally, the revised label also includes data indicating that there was no increased risk for serious cardiovascular (CV) adverse events observed compared to the non-specific NSAID comparators (diclofenac and ibuprofen). These CV events included heart attack, stroke, and unstable angina.***

* * *

Q20) HOW IS THE BEXTRA LAUNCH GOING?

A20) Bextra was launched in the U.S. in April 2002 for the relief of pain and inflammation of osteoarthritis (OA), adult rheumatoid arthritis (RA), and primary dysmenorrhea . . . . Pfizer and Pharmacia Corporation, the company that discovered and developed Bextra, co-promote this product in most major world markets . . . . The product has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen. In controlled comparative arthritis trials of up to 26 weeks, Bextra in daily doses of 10 mg or 20 mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs.

457. On July 16, 2002, *The Wall Street Journal* published an article (the "July 16, 2002 *Wall Street Journal* Article") attributing the following statements to Defendant McKinnell:

[T]he company will press more aggressively what he believes is the drug's major advantage over its biggest competitor, Merck & Co.'s Vioxx: ***Celebrex hasn't been linked to a risk of any heart problems,*** while the Merck pill has.

* * *

"We have to communicate that cardiovascular safety is critical differentiation between Celebrex and Vioxx."

458. On July 29, 2002, Defendant McKinnell stated in an interview with *The Pink Sheets*: "'I think the naproxen cardioprotection story is thoroughly debunked. . . . ***There is no cardiovascular issue with Celebrex, clearly.*** We need to do a better job communicating that. I think I'd rather put, as a comparator in this study, Vioxx to show what the difference really is."

459. On August 13, 2002, Pfizer filed its Form 10-Q for the second quarter of 2002 with the SEC (the "Second Quarter 2002 Form 10-Q"). The Second Quarter 2002 Form 10-Q

contained the following materially false and misleading statements and/or omissions of material fact:

> Celebrex, discovered and developed by our alliance partner Pharmacia Corporation (Pharmacia), is used for relief of the pain and inflammation of osteoarthritis (OA), adult rheumatoid arthritis (RA), acute pain and primary dysmenorrhea (menstrual pain) in adults. In addition, Celebrex is approved to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis, a rare genetic disease that may result in colorectal cancer. With the approval for acute pain and primary dysmenorrhea in the U.S., Celebrex is the COX-2 specific inhibitor approved to treat the broadest range of conditions. In June 2002, the FDA approved revised labeling for Celebrex. ***The new prescribing information includes additional gastrointestinal safety data and data indicating that there was no increased risk for serious cardiovascular adverse events observed.*** These cardiovascular adverse events include heart attack, stroke and unstable angina.

460. On October 16, 2002, Pfizer issued a press release, which was filed with the SEC as a Form 425, announcing its second quarter 2002 financial results (the "October 16, 2002 Press Release"). The October 16, 2002 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Q12) HOW IS CELEBREX PERFORMING?
>
> A12) Celebrex is the #1 branded NSAID and the #1 COX-2-specific inhibitor in the world. Pfizer and Pharmacia Corporation, the company that discovered and developed Celebrex, co-promote this product in more than 60 countries . . . . ***Celebrex provides strong efficacy, excellent tolerability, and a proven safety profile.*** With the recent approval for acute pain and primary dysmenorrhea in the U.S., Celebrex is now the COX-2-specific inhibitor approved to treat the broadest range of conditions.
>
> * * *
>
> Q13) HOW IS BEXTRA PERFORMING?
>
> A13) Bextra was launched in the U.S. in April 2002 for the relief of pain and inflammation of osteoarthritis (OA), adult rheumatoid arthritis (RA), and primary dysmenorrhea . . . . The product has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen. In controlled comparative arthritis trials of up to 26 weeks, Bextra in

> daily doses of 10 mg or 20 mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs.

461. On October 28, 2002, Pfizer issued a press release titled "Data Confirm Gastrointestinal Safety Profile of COX-2 Specific Inhibitor BEXTRA® versus Non-Specific Comparator NSAIDs in Arthritis Patients, Separate Analysis Affirm Cardiovascular Safety Profile" (the "October 28, 2002 Press Release"). The October 28, 2002 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Analyses of pooled study results for the COX-2 specific inhibitor BEXTRA® (valdecoxib tablets), presented at this year's annual scientific meeting of the American College of Rheumatology (ACR), ***underscored its improved upper gastrointestinal (GI) safety as well as its cardiovascular safety profile.***
>
> * * *
>
> ***"Our analysis suggests that valdecoxib shows no greater incidence of cardiovascular events than either naproxen or placebo,"*** said lead author Andrew Whelton, MD, Adjunct Professor of Medicine, Johns Hopkins University, Baltimore, Maryland. "While more data are necessary to confirm this conclusion, our findings suggest that valdecoxib demonstrates a cardiovascular safety profile similar to that of placebo or naproxen."

462. On November 13, 2002, Pfizer filed its Form 10-Q for the third quarter of 2002 with the SEC (the "Third Quarter 2002 Form 10-Q"). The Third Quarter 2002 Form 10-Q contained the following materially false and misleading statements and/or omissions of material fact:

> In June 2002, the FDA approved revised labeling for Celebrex. The new prescribing information includes additional gastrointestinal safety data and ***data indicating that there was no increased risk for serious cardiovascular adverse events observed, including heart attack, stroke and unstable angina.***

463. The above-referenced 2002 statements (including the emphasized portions) were materially false and misleading when made. As set forth in Section VII. and summarized in Tables 1 and 2 above and Table 3 below, these statements failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex and/or Bextra by

falsely claiming that Celebrex and/or Bextra showed no increase in thromboembolic or cardiovascular-related events, by failing to publish study results in a timely or complete fashion, and by making comparisons to Vioxx, NSAIDS or other traditional arthritis medications that omitted such material information.

TABLE 3

Date	Event	Description
January 2002	040 Cancer Study	Internal Bextra study conducted on cancer patients. A statistically significant higher number of cancer patients treated with Bextra suffered peripheral edema, and over 22% of the patients in the Bextra group died during the treatment (as compared with only 10% in the placebo group). Defendant Cawkwell instructs Pfizer to embargo the publication of the study's results. *See* ¶¶289-293.
February 2002	Defendants Embargo Publication of the 047 Study	Bextra Publications Working Group decides at a team meeting that the results of the 047 Study should be ***embargoed"*** because their publication would be ***"damaging to the product."*** *See* ¶¶287-288.

464. Analysts reacted positively to Pfizer's false and misleading statements in 2002. For example, on April 12, 2002, Bear Stearns issued a bullish report on Pfizer that stated: "COX-2 sales rebounding and Bextra appears to be incremental to the COX-2 family, taking share from Vioxx. Pharma sales driven by . . . Celebrex (+22%)." Similarly, on July 16, 2002, Deutsche Bank-North America issued a report on Pfizer that rated the Company's shares a "Strong Buy" and underscored that the Celebrex/Bextra franchise was "winning" a "fierce" marketing battle with Vioxx due, in part, to "positive" Celebrex label changes that were "more favorable on CV risks" than Vioxx and "nagging concerns around CV safety that focus primarily on Vioxx."

E. <u>False Statements In 2003</u>

465. During the course of 2003, Defendants continued to make and/or cause to issue materially false and misleading statements and/or omissions of material facts related to the safety

of Celebrex and Bextra (including studies of COX-2 inhibitors), as well as false advertisements to the general public. These material misstatements and omissions from 2003 are set forth below.

466. On January 22, 2003, Pfizer issued a press release (the "January 22, 2003 Press Release") announcing 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." The January 22, 2003 Press Release was also filed as an exhibit to a Form 8-K with the SEC.

467. On April 22, 2003, Pfizer issued a press release announcing its first quarter 2003 financial results (the "First Quarter 2003 Press Release"). The First Quarter 2003 Press Release, which was also filed as an exhibit to a Form 8-K with the SEC, contained the following materially false and misleading statements and/or omissions of material fact:

> Q13) How is Celebrex performing?
>
> A13) Celebrex is the #1 branded non-steroidal anti-inflammatory drug (NSAID) and the #1 COX-2-specific inhibitor in the world . . . . ***Celebrex provides strong efficacy, excellent tolerability, and a proven safety profile.*** Celebrex is now the COX-2-specific inhibitor approved to treat the broadest range of conditions.
>
> * * *
>
> Q14) How is Bextra performing?
>
> A14) . . . Bextra . . . has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen. In controlled comparative arthritis trials of up to 26 weeks, ***Bextra in daily doses of 10 mg or 20 mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs.***

468. On June 18, 2003, the *Waymaker* published an article titled "Pfizer Sees Strong Prospects Based on Rapid Integration of Pharmacia and Expanded Product and R&D

Opportunities." The article described the success achieved by Celebrex and Bextra and predicted considerable growth:

> Pfizer's COX-2 portfolio, consisting of the arthritis medicines Celebrex and Bextra, continues to post impressive gains.
>
> * * *
>
> Pfizer anticipates further benefits from the unified team that now supports the portfolio and from a steady stream of data from important studies now under way. ***To conclusively demonstrate the COX-2s safety superiority over NSAIDs,*** Pfizer has undertaken a series of major global studies that include a far broader patient population than those believed to be at high risk for gastrointestinal side effects.

469. On July 25, 2003, Pfizer filed with the SEC an exhibit to its press release announcing its second quarter 2003 financial results (the "Second Quarter 2003 Press Release"). The Second Quarter 2003 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Q9) How is Celebrex performing?
>
> A9) Celebrex is the #1 COX-2-specific inhibitor in the world, having the broadest range of approved indications. ***Celebrex provides strong efficacy, excellent tolerability, and a proven safety profile in providing relief for the pain and inflammation of osteoarthritis (OA) and adult rheumatoid arthritis (RA) and treatment of acute pain and primary dysmenorrhea in adults.***
>
> * * *
>
> ***We 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.***
>
> * * *
>
> Q10) How is Bextra performing?
>
> A10) . . . Bextra . . . has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen. In controlled comparative arthritis trials of up to 26 weeks, Bextra in daily doses of 10 mg or 20

mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs.

470. Also on July 25, 2003, Pfizer held a conference call with securities analysts to discuss the Company's second quarter 2003 financial results (the "Second Quarter 2003 Conference Call"). During the Second Quarter 2003 Conference Call, in which Defendants McKinnell, Katen and other Pfizer executives participated, Defendant Katen made the following materially false and misleading statements and/or omissions of material fact:

> KATEN: . . . An independent analysis that included our entire Celebrex arthritis clinical trial database, found no evidence in increased cardiovascular risk for Celebrex, relative to both conventional, non-psoriatal anti-inflammatory drugs and placebo. ***As you know there continues to be a shadow of safety concerns about these compounds. So this should eliminate that concern.***

471. On October 22, 2003, Pfizer issued a press release (the "Third Quarter 2003 Press Release"), which was also filed with the SEC as an exhibit to a Form 8-K. The Third Quarter 2003 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Q9) How is Celebrex performing?
>
> A9) . . . Celebrex is the number 1 COX-2-specific inhibitor in the world, having the broadest range of approved indications. ***It provides strong efficacy, excellent tolerability, and a proven safety profile in providing relief for the pain and inflammation of osteoarthritis (OA) and adult rheumatoid arthritis (RA) and treatment of acute pain and primary dysmenorrhea in adults.***
>
> * * *
>
> ***We 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.***
>
> * * *
>
> Q10) How is Bextra performing?
>
> A10) . . . Bextra . . . has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and

diclofenac) and significantly less dyspepsia versus naproxen. In controlled comparative arthritis trials of up to 26 weeks, ***Bextra in daily doses of 10 mg or 20 mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs.***

472. The above-referenced 2003 statements (including the emphasized portions) were materially false and misleading when made. As set forth in Section VII. above and summarized, in part, in Tables 1–3 above and Table 4 below, these statements failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex and/or Bextra by falsely claiming that Celebrex and/or Bextra showed no increase in thromboembolic or cardiovascular-related events, by failing to publish study results in a timely or complete fashion and by making comparisons to Vioxx, NSAIDs or other traditional arthritis medications that were inherently misleading without including this material information.

TABLE 4

Date	Event	Description
February 2003	Rapporteur's Report	Germany's equivalent of the FDA sends to Pfizer a confidential report that shows that taking Celebrex increases the likelihood that a patient will suffer an adverse cardiovascular event by over 2.3 times. The Rapporteur Report concludes that ***"there is still a clear signal for an increased risk of myocardial infarctions with celecoxib [i.e., Celebrex] in comparison to (some) non-selective NSAIDs"*** and that "available findings from CLASS and SUCCESS shows that ***in both studies a clear trend towards an increased risk for MI [myocardial infarctions]."*** *See* ¶¶308-313.
April 2003	GDRC Meeting to discuss the SUCCESS Study	Action Minutes from GDRC meeting attended by Defendant Feczko (the chair of the committee), Defendant LaMattina, and Ian Read (Pfizer's current CEO), show that the GDRC acknowledged that "[t]he question of the safety of COX-2s in [coronary artery disorder] patients has ***remained an issue***" interfering with Pfizer's "ability to differentiate Celebrex and Bextra from other COX-2s" – a "key to expanding their market share." The "team

Date	Event	Description
		reminded GDRC of the results of the SUCCESS trial and ***the concern that publication has taken longer than Pfizer believes is optimal,"*** and the GDRC acknowledged that there was ***"an obligation to make the results of the study available in a timely manner."*** *See* ¶¶212-213.
June 2003	COX-2 Strategic Operations Plan	The COX-2 Strategic Operations Plan is sent to Defendant Cawkwell and other Pfizer officers, expressly cautioning that the ***"SUCCESS I Publication May Raise Questions"*** because the Study showed that patients provided Celebrex had a ***"5 X Increase in MIs [myocardial infarctions]."*** *See* ¶¶214-221.
September 2003	NEJM rejection of Pfizer SUCCESS manuscript	NEJM editor rejects draft manuscript, stating that the SUCCESS showed a potential safety "'signal'" and, in light of the undisclosed study results, ***"[i]t is unacceptable to state that the MI [myocardial infarction] rates were statistically similar [for Celebrex and traditional NSAIDs]."*** *See* ¶¶216-221.

473. Analysts continued to embrace Pfizer's representations about the efficacy and cardiovascular safety of Celebrex and Bextra, including the Company's efforts to cast its Cox-2 franchise as having a comparative safety advantage over Merck's Vioxx. On March 7, 2003, for example, analysts from SG Cowen reported that "Pharmacia/Pfizer has delivered on its goal of adding market share points on a global basis with Bextra without cannibalizing Celebrex. Indeed, Celebrex/Bextra has gained about 11 percentage points of share since January 2002. This share gain is due in part to Bextra's profile, which features powerful efficacy and good safety, and a fierce marketing battle in which Pfizer/Pharmacia have gained the upper hand by portraying Vioxx as capable of inducing cardiovascular risk."

F. False Statements In 2004

474. During the course of 2004, Defendants continued to make and/or cause to issue materially false and misleading statements and/or omissions of material facts related to the safety of Celebrex and Bextra (including studies of COX-2 inhibitors), as well as false advertisements to the general public. These material misstatements from 2004 are set forth below.

475. On January 22, 2004, Pfizer issued a press release announcing its fourth quarter and fiscal year 2003 financial results (the "Full Year 2003 Press Release"). The Full Year 2003 Press Release, which was filed with the SEC as an exhibit to a Form 8-K, contained the following materially false and misleading statements and/or omissions of material fact:

> Q12) How is Celebrex performing?
>
> A12) . . . Celebrex is the number 1 COX-2-specific inhibitor in the world, having the broadest range of approved indications. ***It provides strong efficacy, excellent tolerability, and a proven safety profile in providing relief for the pain and inflammation of osteoarthritis (OA), rheumatoid arthritis (RA), acute pain, and primary dysmenorrhea.***
>
> * * *
>
> We 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.***
>
> * * *
>
> Q13) How is Bextra performing?
>
> A13) . . . Bextra . . . has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen. ***In controlled comparative arthritis trials of up to 26 weeks, Bextra in daily doses of 10 mg or 20 mg demonstrated an incidence of edema and hypertension similar to comparator NSAIDs.***

476. On April 20, 2004, Pfizer issued a press release announcing its first quarter 2004 financial results (the "First Quarter 2004 Press Release"). The First Quarter 2004 Press Release,

which was filed with the SEC as an exhibit to a Form 8-K, contained the following materially false and misleading statements and/or omissions of material fact:

> Q12) How is Celebrex performing?
>
> A12) . . . Celebrex is the #1 COX-2-specific inhibitor in the world, having the broadest range of approved indications. ***It provides strong efficacy, excellent tolerability, and a proven safety profile in providing relief for the pain and inflammation of osteoarthritis (OA), rheumatoid arthritis (RA), acute pain, and primary dysmenorrhea.***
>
> * * *
>
> A recent study published in the Journal of Rheumatology demonstrated that Celebrex had a significantly longer duration of use than both Vioxx and nonselective NSAIDs. Patients taking Celebrex stayed on medication two months longer than those taking Vioxx and five months longer than nonselective NSAID users, which, the authors assert, "can be an indication of treatment effectiveness and/or drug acceptability."
>
> Q13) How is Bextra performing?
>
> A13) . . . Bextra . . . has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen.

477. On May 7, 2004, Pfizer filed its Form 10-Q for the first quarter of 2004 with the SEC (the "First Quarter 2004 Form 10-Q"). The First Quarter 2004 Form 10-Q contained the following materially false and misleading statements and/or omissions of material fact:

> Celebrex is the No. 1 COX-2-specific inhibitor in the world, having the broadest range of approved indications. ***It provides strong efficacy, excellent tolerability, and a proven safety profile in providing relief for the pain and inflammation of osteoarthritis, rheumatoid arthritis, acute pain, and primary dysmenorrhea.*** Since its launch in 1999, Celebrex has accumulated more than 10 million patient years of use and more than 149 million prescriptions worldwide, demonstrating efficacy and tolerability among a patient population whose need for long-term, effective relief of pain and inflammation is great and growing.

478. On June 13, 2004, Pfizer issued a press release (the "June 13, 2004 Press Release") titled "Greater Tolerability of CELEBREX® in Elderly Europeans With Osteoarthritis Of the Hip or Knee May be a Measure of Overall Improved Effectiveness and Greater Cost

Effectiveness Compared to Diclofenac Mean Treatment Costs Were Lower for CELEBREX than Diclofenac." The June 13, 2004 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> New research on elderly patients with osteoarthritis of the hip or knee treated with CELEBREX® (celecoxib) ***shows that they have a significantly lower risk of safety problems,*** intolerability, and discontinuation due to adverse events (AEs) compared with patients treated with a moderate dose of diclofenac.

479. On July 21, 2004, Pfizer filed as an exhibit to its Form 8-K a press release announcing its second quarter 2004 financial results (the "Second Quarter 2004 Press Release"). The Second Quarter 2004 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Q12) How is Celebrex performing?
>
> A12) . . . In May 2004, European regulators completed a safety review and reaffirmed the use of COX-2-specific inhibitors such as Celebrex in a broad range of patients. The May 29, 2004, issue of The Lancet included an independent study by the Institute for Clinical Evaluative Sciences, which provided ***further evidence of the cardiovascular safety of Celebrex.*** In this study, patients taking Celebrex had the same rate of hospitalization for congestive heart failure as people who weren't using any NSAIDs at all. Patients taking older NSAIDs, such as ibuprofen, had a 40% increase in such hospitalizations compared with a community control group not taking any of the drugs in the study.
>
> * * *
>
> Q13) How is Bextra performing?
>
> A13) . . . Bextra . . . has a significantly lower incidence of endoscopically detected gastroduodenal ulcers versus traditional comparator NSAIDs (naproxen, ibuprofen, and diclofenac) and significantly less dyspepsia versus naproxen.

480. On August 6, 2004, Pfizer filed with the SEC its Form 10-Q for the second quarter of 2004 (the "Second Quarter 2004 Form 10-Q"). The Second Quarter 2004 Form 10-Q contained the following materially false and misleading statements and/or omissions of material fact:

> Celebrex is the No. 1 COX-2-specific inhibitor in the world, having the broadest range of approved indications. ***It provides strong efficacy, excellent tolerability, and a proven safety profile in providing relief for the pain and inflammation of osteoarthritis, rheumatoid arthritis, acute pain, and primary dysmenorrhea. In May 2004, European regulators completed a safety review and reaffirmed the use of COX-2-specific inhibitors such as Celebrex in a broad range of patients.***

481. The above-referenced statements and those identified below made in 2004 (including the emphasized portions) were materially false and misleading when made. As set forth in Section VII. above, and summarized, in part, in Tables 1-4 above and Table 5 below, these statements failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex and/or Bextra by falsely claiming that Celebrex and/or Bextra showed no increase in thromboembolic or cardiovascular-related events, by failing to publish study results in a timely or complete fashion and by making comparisons to Vioxx, NSAIDs or other traditional arthritis medications that were inherently misleading without including this material information.

TABLE 5

Date	Event	Description
January 2004	CABG-2 Study	Second internal Bextra clinical study on coronary artery bypass graft patients. Four times the number of patients treated with Bextra experience adverse CV events compared to patients taking placebo. As noted by Dr. Verburg in an email to his colleague, "***Need your help. Cardiovascular signal was still evident in the second parecoxib/valdecoxib CABG surgery study."*** *See* ¶¶294-302.
March 2004	Top-Line Memorandum	Internal Pfizer report sent to over 30 employees, including Defendants Cawkwell and Feczko, concerning the CABG-2 Study states that "***[t]he results indicate that there may be [a] safety signal that needs to be evaluated in light of the results from the early CABG surgery study (Study -035) which was conducted at higher doses."*** *See* ¶¶380-389.

Date	Event	Description
September 2004	MPA Health Authority Contact	Sweden's equivalent of the FDA sends Pfizer a "Health Authority Contact" directing it to submit "long-term cardiovascular (CV) safety data for Celebrex."
November 2004	Aetna provides Pfizer with its retrospective epidemiological study of its claims data	Aetna sent Pfizer a retrospective epidemiological study of its claims data for the period beginning January 2002 and ending May 2004 showing that a statistically significant larger number of Celebrex users suffered acute myocardial infarctions compared with those given no treatment, and that certain subgroups treated with Celebrex suffered a larger number of acute myocardial infarctions compared with those treated with other NSAIDs.
December 2004	DSMC contacts Pfizer re: Alzheimer's 001 Study	DSMC calls Pfizer to "express some ***potential safety concern*** that can be seen in the [Alzheimer's 001] study itself…. Specifically, they noted that there were ***numeric imbalance in CV events*** including CV SAEs [*i.e.*, Cardiovascular Serious Adverse Events] previously noted, including between 6-10 CV events in drug group vs. almost none in placebo group." *See* ¶¶185-194.

482. On August 26, 2004, *The Wall Street Journal* reported on a major safety study by the FDA, announced the prior day, which found that patients taking Vioxx at the highest recommended daily dosage had a threefold higher risk of heart attack and sudden cardiac death than those who had been taking a placebo. The article reported that in response to news of the study showing that "Vioxx appeared to have a stronger association with [patients' risk of a heart attack or sudden cardiac death] than Celebrex," Pfizer's world-wide medical director for Celebrex stated: "We feel that for Celebrex this is excellent news."

483. On September 30, 2004, Merck announced it was withdrawing Vioxx from the market because of a proven increase in adverse cardiac events. This event should have alerted Pfizer to promptly disclose the cardiovascular risks of Celebrex and Bextra that it had been

concealing. However, at the insistence of Defendant McKinnell, Pfizer opportunistically seized on Vioxx's withdrawal to market its COX-2 drugs without any serious competition. Indeed, on the very same day of Defendant McKinnell's instruction, Pfizer issued a press release (the "September 30, 2004 Press Release") that falsely asserted the cardiovascular safety of Celebrex and Bextra and denied the existence of a class-wide COX-2 cardiovascular effect:

> In response to Merck & Co.'s announcement today of the worldwide withdrawal of its COX-2 medicine Vioxx, Pfizer Inc. issued the following statement:
>
> * * *
>
> ***"Pfizer is confident in the long-term cardiovascular safety of Celebrex,"*** said Dr. Joe Feczko, Pfizer's president of worldwide development.
>
> In a recent FDA-sponsored study of 1.4 million patients, those who received Celebrex demonstrated ***no increased risk of cardiac events.***
>
> "Patients taking COX-2 inhibitors may be confused and should speak with their doctors," Dr. Feczko said. "Because of its ***outstanding long-term safety profile*** and broad indication base including osteoarthritis, rheumatoid arthritis and acute pain, ***Celebrex is an appropriate treatment alternative…."***
>
> ***Bextra's cardiovascular safety profile is also well established in long-term studies.***

484. On October 1, 2004, the *St. Louis Post-Dispatch* published an article titled "Pfizer's Celebrex may get boost from Merck's decision to pull Vioxx." In the article, Defendant Cawkwell attempted to distinguish the safety concerns for Vioxx and Celebrex:

> ***"There's a spectrum of cardiovascular safety, and Vioxx falls at one end and Celebrex at the other,"*** said Gail Cawkwell, a physician on New York-based Pfizer's Celebrex medical team.
>
> "The (drugs) are different in molecular structure, in some of the ways that they act and interact in the body," she said.

485. Also on October 1, 2004, Pfizer issued a press release again falsely asserting the cardiovascular safety of its COX-2 inhibitors (the "October 1, 2004 Press Release"). The October

1, 2004 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> ***Data demonstrate[s] that Celebrex does not increase the risk of heart attack or stroke in patients with arthritis and pain, even at higher-than-recommended doses[.]***
>
> * * *
>
> Pfizer Inc. said today that three large long-term Celebrex (celecoxib capsules) studies involving more than 6,000 patients have not shown any significant safety issues and are expected to continue to completion.
>
> * * *
>
> ***The 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, the world's most prescribed arthritis and pain relief brand.***
>
> "Each Cox-2 inhibitor has a distinct chemical structure and we would not expect them to have the same side effect profile," said Dr. Joe Feczko, Pfizer's president of worldwide development. "The data we've accumulated over time demonstrate that Celebrex does not increase the risk of serious cardiovascular events in patients with arthritis and pain, even at higher-than-recommended doses."

486. On October 1, 2004, the *Boston Globe* published an article quoting Defendant Cawkwell for stating that "the company knows of ***no study*** that shows an increased heart risk with Celebrex. . . ."

487. The August 26, 2004 statement by Defendant Feczko published in *The Wall Street Journal*, the September 30, 2004 Press Release, the October 1, 2004 Press Release, and Defendant Cawkwell's statements published in *St. Louis Post-Dispatch* and the *Boston Globe* articles on October 1, 2004, were each materially false and misleading when made. These statements failed to disclose material adverse information known by or recklessly disregarded by Defendants concerning the cardiovascular risks associated with Celebrex and Bextra demonstrated by, among other things, a variety of clinical studies that were either embargoed,

manipulated or misrepresented, including the Alzheimer's 001 Study, the SUCCESS Study, the CLASS Study, the 047 Study, the 060 and 061 Studies, the 016 Study, the 040 Study as well as the CABG-1 Study and most recently, the CABG-2 Study. These statements were also materially false and misleading in their comparison to Merck's Vioxx and associated safety issues.

488. On October 4, 2004, *The Wall Street Journal* reported that Defendant Feczko stated, "[w]e're even more confident today because ***the studies have consistently not demonstrated any increased cardiovascular risk with Celebrex.***" This statement by Defendant Feczko was false and misleading when made because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented that Pfizer studies had consistently not demonstrated any increased cardiovascular risk with Celebrex.

489. On October 6, 2004, the *Associated Press Online* reported the following based on statements attributed to Defendant Cawkwell:

> "The data for Celebrex is robust and exceeds, in the length of patients in studies and in the size of studies, the data Vioxx has."
>
> She called Fitzgerald's contention "an interesting theory," but said, "***there is no evidence" of increased risk of heart problems among the 75 million Americans who have taken Celebrex."***

This statement by Defendant Cawkwell was false and misleading because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented

that there was no evidence of increased risk or heart problems among the 75 million Americans who have taken Celebrex.

490. On October 7, 2004, Pfizer ran an advertisement in *The New York Times* that stated: (a) "Important patient studies with Celebrex show strong cardiovascular safety"; (b) "numerous studies of Celebrex show no increased risk of heart attacks or strokes"; and (c) "Patients treated in clinical studies of up to 4 years show no increased cardiovascular safety concerns." (underlining in original) These statements were false and misleading when made because they failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because they misrepresented that there were no studies showing increased cardiovascular safety concerns.

491. On October 12, 2004, Pfizer again responded to the withdrawal of Vioxx by posting the following statements on the website, www.celebrex.com (the "October 12, 2004 Statement"). The October 12, 2004 Statement contained the following materially false and misleading statements and/or omissions of material fact:

> For years, CELEBREX has been helping people with pain and arthritis feel better. Now we'd like to put your mind at ease, too. As you've probably heard, VIOXX®, a COX-2 drug for arthritis and pain, has been withdrawn from the market because it increased the risk of heart attacks and strokes. But, the information below should make you feel good about CELEBREX, which is also a COX-2 drug.
>
> * * *
>
> Does CELEBREX increase the risk of stroke, heart attack, or death by effects on the heart or blood vessels?
>
> ***In numerous studies, CELEBREX did not increase the risk of heart attack, stroke, or death caused by heart attack or stroke compared to patients taking traditional arthritis medications or a sugar pill.***

* * *

> What does recent patient data show?
>
> In one study, people preferred once daily CELEBREX to 4 times a day acetaminophen (the main ingredient in Tylenol®). And in a six month study of nearly 800,000 patients, more people stayed with CELEBREX than naproxen (used in Aleve®) or ibuprofen (Motrin®).

The referenced portions of the October 12, 2004 Statement were false and misleading when made because they failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because the statements misrepresented that Celebrex did not increase the risk of heart attack, stroke, or death caused by heart attack or stroke compared to patients taking traditional NSAIDs or a placebo.

492. On October 15, 2004, Pfizer issued a press release (the "October 15, 2004 Press Release") announcing plans to conduct further Bextra cardiovascular safety studies. The October 15, 2004 Press Release, which was also filed with the SEC as an exhibit to a Form 8-K, contained the following materially false and misleading statements and/or omissions of material fact:

> PFIZER PROVIDES INFORMATION TO HEALTHCARE PROFESSIONALS ABOUT ITS COX-2 MEDICINE BEXTRA® (VALDECOXIB)
>
> In the letter to healthcare professionals, Pfizer . . . reviewed information about the cardiovascular profile of Bextra. The information is based on analyses of a comprehensive clinical trial database of nearly 8,000 patients treated with Bextra for durations ranging from six to 52 weeks. ***Available clinical information for Bextra suggests there is no increased risk of cardiovascular thromboembolic events in people treated for osteoarthritis (OA) and rheumatoid arthritis (RA).***
>
> ***In addition, Bextra has been studied in several surgical settings. In studies in general surgery, Bextra in combination with the investigational drug parecoxib (an IV formulation) showed no increased risk of cardiovascular thromboembolic events.***

The referenced statements in the October 15, 2004 Press Release were false and misleading when made because they failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Bextra, demonstrated by the CABG-1 Study, the CABG-2 Study and the other studies detailed above, and by falsely claiming that available clinical information showed no increased risk of cardiovascular thromboembolic events in patients taking Bextra.

493. On October 18, 2004, Pfizer issued a press release titled "Pfizer to Sponsor Major New Celebrex Clinical Trial" (the "October 18, 2004 Press Release"). The October 18, 2004 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Pfizer Inc announced today it is sponsoring a major clinical study to further assess its COX-2 medication CELEBREX® (celecoxib) in osteoarthritis (OA) patients at high risk for cardiovascular disease.
>
> * * *
>
> ***"Our strong confidence in the CV safety of Celebrex is based on the substantial body of experience that has accumulated over several years in multiple completed studies and ongoing trials,"*** said Dr. Joseph Feczko, MD, president of worldwide development at Pfizer. "In fact, small mechanistic studies suggest that Celebrex's anti-inflammatory properties as well as additional unique Celebrex-specific characteristics may improve vascular function in patients with established coronary artery disease. That is why we feel it is important at this time to announce our plans to conduct the first large-scale clinical study involving the use of a COX-2 specific inhibitor to look at inflammation and CV events in osteoarthritis patients at high risk for cardiovascular disease."
>
> Celebrex has a strong long-term safety profile and broad indication base including osteoarthritis, rheumatoid arthritis and acute pain, backed up by observational data and ongoing trials.
>
> ***Pfizer remains confident in the long-term cardiovascular safety of Celebrex.*** The CV safety profile of Celebrex is supported by extensive clinical and widespread post-marketing experience. More than 27 million patients in the US have been prescribed Celebrex, which was approved by the U.S. Food and Drug Administration in 1998 – even more patients have used Celebrex in over 60

> countries worldwide. Patients treated in clinical studies of up to 4 years show no increased CV safety concerns.

The referenced statements in the October 18, 2004 Press Release were false and misleading when made because they failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, by deceptively reaffirming the long term safety of Celebrex.

494. On October 19, 2004, *The New York Times* published an article titled, "A New Trial of Celebrex, and Questions on Its Timing" (the "October 19, 2004 *New York Times* Article"), which stated:

> Less than three weeks after Merck withdrew its arthritis painkiller Vioxx from the market because it increased the risk of heart attacks, Pfizer announced plans yesterday to test if its best-selling painkiller Celebrex, which is in the same class of drugs as Vioxx, can do the opposite - help prevent heart attacks. But Pfizer's announcement is raising questions. For one, Pfizer warned only last Friday that Bextra, another of its drugs in the same class as Vioxx and Celebrex, increased the risks of heart attack and stroke in patients undergoing coronary-bypass surgery. So the timing of the announcement of the new Celebrex trial could divert attention from the warning about Bextra.... Besides questions about the new trial, there are also questions about why Pfizer did not disclose the data on Bextra earlier. Dr. Cawkwell acknowledged that Pfizer knew the results of the Bextra trial in bypass patients ***two months ago*.**

495. The October 19, 2004 *New York Times* Article included false and misleading statements that failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Bextra, demonstrated by the CABG-1 Study, the CABG-2 Study and the other studies detailed above, and also because Defendant Cawkwell falsely claimed that Pfizer knew the results of the CABG-2 Study two months before the article when, in fact, Pfizer (and Defendant Cawkwell) knew the results at least by March 2, 2004, more than seven months earlier.

496. On October 20, 2004, Pfizer held a conference call with securities analysts to discuss the Company's third quarter 2004 financial results (the "Third Quarter 2004 Conference Call"). The Third Quarter 2004 Conference Call, in which Defendants McKinnell, Katen, Feczko and other Pfizer executives participated, contained the following materially false and misleading statements and/or omissions of material fact:

> KATEN: . . . Finally, our COX-2-specific inhibitor medicines are responding to new challenges as well. Both Celebrex and Bextra continue to perform well by exceeding year-to-date sales projections, and we fully expect this trend to continue as more doctors and patients consider them as effective, appropriate treatment alternatives. ***No other prescription medicine is as widely used for arthritis and pain relief as is Celebrex, thanks to its outstanding efficacy, long-term safety profile and broad range of use.***
>
> ***In a recent FDA-sponsored analysis of 1.4 million patients and in additional clinical studies where patients have been treated for up to four years, patients using Celebrex showed no increased risk of cardiac events.*** This past Monday, we announced response from a major clinical study to further evaluate the potential cardiovascular benefit of Celebrex in osteoarthritis patients at high risk for cardiovascular disease. This new global study will begin in early '05 and will further explore evidence that certain properties of Celebrex may improve vascular function in patients with established coronary artery disease.
>
> * * *
>
> And now a word about our other COX-2, Bextra . . . . ***Available clinical evidence for Bextra, based on nearly 8,000 patients, suggest no increased risk of cardiovascular thrombolic events in patients with OA and RA.***
>
> * * *
>
> TIMOTHY ANDERSON, ANALYST, PRUDENTIAL: . . . Then on the COX category again, you guys seem pretty confident in the cardiovascular profile of Bextra, so I'm wondering why there is not a Bextra arm in this Celebrex trial you've announced, being as we really don't have any long-term data with that product. Then on para-COX, I'm wondering when and where we can expect to see the full results of that second cabbage study.
>
> * * *
>
> FECZKO: Yeah. Couple things there. We are – we will be working with the FDA on talking about what kind of data they want on Bextra. ***The Celebrex cardiovascular study had been in the makings for quite a long time now, and***

> ***was based on looking at – based on a lot of the epidemiological studies we had that actually showed a trend toward some kind of beneficial effects seen on vasculature.*** So as part of what we're doing here – this isn't strictly a safety study, we're looking at improvement in inflammatory markers for cardiovascular disease and another aspect that improve its function.

The emphasized statements during the Third Quarter 2004 Conference Call regarding the cardiovascular safety of Celebrex were materially false and misleading when made. These statements failed to disclose material adverse information then known by or recklessly disregarded by Defendants concerning the cardiovascular risks associated with Celebrex, as demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above. Similarly, the statements that Celebrex has an outstanding long-term safety profile were false and misleading when made. Finally, the emphasized statements regarding the cardiovascular safety of Bextra were also materially false and misleading when made because Defendants failed to disclose material adverse information then known by or recklessly disregarded concerning the cardiovascular risks associated with Bextra, as demonstrated by the CABG-1 Study, the CABG-2 Study and the other studies detailed above. Defendants also falsely claimed that available clinical evidence for Bextra showed no increased risk of cardiovascular thrombotic events in patients with OA and RA.

497. Also on October 20, 2004, Pfizer issued a press release (the "October 20, 2004 Press Release") announcing its third quarter 2004 financial results. The October 20, 2004 Press Release, which was filed with the SEC as an exhibit to a Form 8-K, contained the following statements and/or omissions of material fact:

> Q14) How is Celebrex performing?
>
> A14) . . . Celebrex . . . provides proven lasting strength for the pain and inflammation of osteoarthritis (OA), rheumatoid arthritis (RA), acute pain, and primary dysmenorrhea, ***with a low risk of gastrointestinal bleeding compared to non-steroidal anti inflammatory drugs (NSAIDs) and established cardiovascular safety.***

> Following the global withdrawal of Merck's Vioxx from the market on September 30, Pfizer has been communicating with business partners, including wholesalers, pharmacy chains, pharmacy benefit managers, and other managed-care organizations to assure them of the availability of Celebrex to meet potential patient need. Pfizer has reaffirmed its confidence in the well-documented cardiovascular safety of Celebrex and has released information citing that there is no evidence of a cardiovascular safety signal for Celebrex in long-term clinical trials of more than 6,000 patients.
>
> * * *
>
> Q15) How is Bextra performing?
>
> A15) . . . The clinical efficacy of Bextra has been well established by studies in more than 11,000 patients and its use by more than 10 million patients worldwide. It is indicated for osteoarthritis (OA), rheumatoid arthritis (RA), and primary dysmenorrheal. Its efficacy is also shown in OA and RA flares, which makes Bextra a valuable therapeutic option for tough-to-treat arthritis patients.
>
> A recent analysis published in the American Journal of Therapeutics supports the cardiovascular safety of Bextra based on an analysis of a comprehensive clinical-trial database of nearly 8,000 patients ***treated with Bextra for durations ranging from six to 52 weeks. Available clinical information for Bextra suggests there is no increased risk of cardiovascular thromboembolic events in people treated for OA and RA.*** 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.
>
> ***In studies in general surgery, Bextra in combination with the investigational drug parecoxib (an intravenous formulation) showed no increased risk of cardiovascular thromboembolic events.***

These statements from the October 20, 2004 Press Release constituted misrepresentations for the same reasons as the referenced statements from the Third Quarter 2004 Conference Call.

498. On November 4, 2004, Pfizer issued a press release titled "Pfizer Affirms Celebrex Safety" (the "November 4, 2004 Press Release"), which responded to a report in Canada's *National Post.* The November 4, 2004 Press Release contained the following materially false and misleading statements and/or omissions of material fact regarding Celebrex's cardiovascular safety:

> Pfizer Inc. today issued the following statement in response to a report in Canada's National Post newspaper concerning the cardiovascular safety of Celebrex:
>
> The news report, based on voluntary spontaneous event reporting to Canadian Health authorities, is misleading. The story is not supported by any clinical or epidemiological studies and has the potential to cause undue confusion among patients and physicians.
>
> ***The safety profile for Celebrex is well-established and is supported by extensive clinical studies in Canada and around the world.***
>
> Voluntary spontaneous event reporting to health authorities is not designed and cannot be used to determine cause and effect. It is essential to remember that the information provided is uncontrolled and may be second-hand or incomplete.
>
> Health Canada has acknowledged these limitations, noting "there hasn't been a causal link established". The agency has also noted that these data contain no information about patients' underlying medical conditions.
>
> ***Millions of patients have been prescribed Celebrex since its first approval in 1998 and large-scale clinical studies of up to four years showed no increased cardiovascular safety risk.***

The referenced statements in the November 4, 2004 Press Release were false and misleading when made because Defendants failed to disclose material adverse information they knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above. Defendants also misrepresented that Celebrex has a well-established safety profile showing no increased cardiovascular risks.

499. On November 5, 2004, Pfizer filed its Form 10-Q for the third quarter of 2004 with the SEC (the "Third Quarter 2004 Form 10-Q"). The Third Quarter 2004 Form 10-Q contained the following materially false and misleading statements and/or omissions of material fact:

> Celebrex is the world's most-prescribed arthritis and pain-relief brand. It provides proven lasting relief for the pain and inflammation of osteoarthritis (OA), rheumatoid arthritis (RA), acute pain, and primary dysmenorrhea, with a

> low risk of gastrointestinal bleeding compared to non-steroidal anti inflammatory drugs (NSAIDs) and an established cardiovascular safety profile. . . . ***We have reaffirmed our confidence in the well-documented cardiovascular safety of Celebrex, and we have released information citing that there is no evidence of a cardiovascular safety signal for Celebrex in ongoing, long-term clinical trials involving more than 6,000 patients.***
>
> * * *
>
> Bextra is an important therapeutic option for tough-to-treat arthritis pain, offering patients effective once-daily dosing and powerful relief. Available clinical information for Bextra, based on a recent pooled analysis of nearly 8,000 patients treated with Bextra for periods ranging from six weeks to one year, suggests ***no increased risk of cardiovascular thromboembolic events in patients with OA and RA.*** 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.
>
> ***In studies in general surgery, Bextra (valdecoxib) in combination with the investigational drug parecoxib (an intravenous formulation of valdecoxib) showed no increased risk of cardiovascular thromboembolic events.***

The emphasized statements were materially false and misleading for the same reasons described above regarding the November 4, 2004 Press Release.

500. On November 10, 2004, the *Nightly Business Report* broadcast included an interview of Defendant McKinnell. During that interview, Defendant McKinnell made the following materially false and misleading statements and/or omissions of material fact to the interviewer, Stephanie Woods:

> WOODS: Two of Pfizer's biggest drugs, Bextra (ph) and Celebrex have come under a cloud of uncertainty about their safety and effectiveness. How can you guarantee people that these drugs are safe and effective?
>
> McKINNELL: Well, they haven't really come under a cloud. Different drugs are different chemical entities. Vioxx has been shown to raise blood pressure and raise cardiovascular risk. ***We don't have that kind of evidence for Celebrex and Bextra. In fact the current information we have on Celebrex shows that it might be protective of the heart*** and we've just launched a two-year study to show that hopefully that this drug is cardio-protective.
>
> WOODS: There is some concern about some studies that were done in Canada showing a correlation of cardiac risk.

> McKINNELL: The FDA reviews all the data. They review all the events that are spontaneously reported and their judgment is these drugs are safe and effective when used as recommended.

Defendant McKinnell's statements during this *Nightly Business Report* broadcast were false and misleading because he failed to disclose material adverse information that Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above and the CABG-1 Study, the CABG-2 Study and the other studies detailed above, and because he misrepresented that Celebrex and Bextra were safe and that Celebrex might even offer cardio-protective benefits.

501. On November 12, 2004, *Newsweek* reported that Defendant Cawkwell made the following statement: "We have not seen increased cardiovascular-type risks." This statement was false and misleading because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented that Pfizer had not seen increased cardiovascular-type risks.

502. On November 30, 2004, Pfizer held a conference call with securities analysts (the "November 30, 2004 Conference Call"). The November 30, 2004 Conference Call, in which Defendants McKinnell, Katen, Feczko and other Pfizer executives participated, contained the following materially false and misleading statements and/or omissions of material fact:

> FECKZO: . . . Celebrex is a unique molecule. As a matter of fact, there has been a lot of noise and literature about trying to get unifying hypotheses about why COX-2s may have similar side effect profiles. I wish to point out that both Celebrex and Bextra come from unique chemical classes that are different from the chemical class in Vioxx and Arcoxia came from. These chemical class differences are noticeable at the molecular level, where they interact differently with cell membranes, their ability to introduce free radical reduction and oxidative

intermediates, which may have an effect on abnormal vascular endothelium. They also have differences that manifest clinically, especially in the propensity to cause hypertension and cell retention.

Bextra, we note in long clinical trials, is very similar to traditional NSAIDs in its ability to promote cell-retention or cause hypertension, and Celebrex actually has less of a propensity for hypertensiveness and cell-retention than traditional NSAIDs. This is not the same with Vioxx.

This unique molecule in Celebrex, with the proven strength and safety profile, makes it the world's most prescribed arthritis and pain-relief treatment. Pfizer is confident in the safety and reliability of Celebrex as an appropriate treatment. Our confidence in the cardiovascular safety of Celebrex is based on the substantial body of experience it has accumulated over several years in multiple completed studies and in ongoing trials, including trials that have lasted for up to four years.

In addition, we are now sponsoring a major clinical study to further assess Celebrex in osteoarthritis patients at high risk for cardiovascular disease. This study is part of a larger cardiovascular exploration program with Celebrex that started more than 18 months ago. This new clinical trial, which will be conducted at major universities and hospitals around the world, is expected to start early in 2005. As I mentioned, early mechanistic studies suggest that Celebrex's anti-inflammatory properties are unique and may in fact improve vascular function in patients with heart disease, so we are conducting a large-scale clinical study to examine potential cardiovascular benefits in osteoarthritis patients with cardiovascular disease.

Bextra, our second COX-2 inhibitor, is an important therapeutic option for tough-to-treat arthritis patients in the appropriate patient. Bextra offers patients powerful relief and once-daily dosing. Available clinical information from a recently pooled analysis of OA and RA clinical trials involving nearly 8000 patients with dosing intervals ranging from 6 to 52 weeks in duration suggest no increased risk of cardiovascular thrombotic events in patients with osteoarthritis and rheumatoid arthritis.

* * *

MARA GOLDSTEIN, ANALYST, CIBC: Mara Goldstein with CIBC. A question on Bextra. Can you comment whether or not you have had a chance to look at the meta analysis that was presented at AHA and when indeed you might be able to comment on that analysis?

* * *

McKINNELL: . . . On the meta analysis, I'll ask Joe to talk about that in the future. But I guess my comment would be get a grip here. Because as Karen showed there is a reason the COX-2 agents were developed. It's a sad fact that more Americans die each year from non-steroidal induced GI bleeds than die from

AIDS. They number about 16,500 versus about 15,000. So there are serious side effects to the traditional non-steroidals.

We tend to think because these are older, well-known agents, we've all taken them, that they're safe. Wrong. We know about the GI risk. What we are exploring is the cardiovascular profile with each of these agents, ***and you can bet they're not going to be the same.***

* * *

We have all kinds of data that shows not only is there no signal of a cardiovascular risk with Celebrex, and you have heard us say we have over 6000 patients going out beyond 3 years and many of those now beyond 4 years with no signal of a cardiovascular risk, but from some of the other meta analysis we've seen, it looks like Celebrex may even have a lower risk than any of the other non-steroidal agents. We've now launched a study to try to demonstrate that. So out of all this will come a much greater understanding of how all the various non-steroidals, new and old, COX-2s and the old version, stack up on a controlled clinical study on both GI safety and cardiovascular risk. ***And we're extremely confident that when this all plays out, which will take a couple of years, Celebrex is going to be the clear winner emerging from all of this.***

* * *

FECKZO: . . . ***We have published – and it was published in the study I referred to, which was the analysis of all RA and OA patients with Bextra was posted about a year and a bit ago – I think it was the summer of '03 – that showed no increased cardiovascular risk. And again, those studies were not long, but they were all-inclusive of everything that's been done on Bextra in OA/RA.***

The emphasized portions of the November 30, 2004 Conference Call were materially false and misleading statements when made. These statements failed to disclose material adverse information that Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex and Bextra, as demonstrated by the Alzheimer's 001 Study, the CABG-1 Study, and the CABG-2 Study and the other studies and information detailed above.

503. On December 1, 2004, Defendant McKinnell was quoted in an interview (the "December 1, 2004 McKinnell Interview") with Neil Cavuto published on the *Fox News*

Network. The December 1, 2004 McKinnell Interview contained the following materially false and misleading statements and/or omissions of material fact:

> McKINNELL: Well, let's go back to the beginning here and why these drugs were invented in the first place. It's tragically true that more Americans die each year from the use of the old non- steroidal anti-inflammatories, the ibuprofens, naproxens, the prophenact (ph), than die of AIDS every year. The number is about 16,500 for non-steroidal anti-inflammatory induced G.I. bleeds to about 15,000 for – for those dying – dying from AIDS or AIDS complications. These drugs were developed for a very important reason. It is true that Vioxx showed in extensive clinical studies to increase cardiovascular risk. ***But with Celebrex, for example, we have over 6,000 patients in controlled clinical studies beyond three years, and the most encouraging thing we've seen in some analyses of data, which aren't as good as controlled clinical studies. We've seen a protective effect, possibly, for Celebrex.*** And we are now launching a program to determine if that is the case or not.

The December 1, 2004 McKinnell Interview included false and misleading statements regarding the cardiovascular safety of Celebrex and failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and misrepresented that Celebrex was safe and might even offer cardio-protective benefits.

504. On December 17, 2004, the results of the APC Study were released by the National Institute of Health revealing that this long-term, placebo-controlled study in cancer patients showed increased cardiovascular risk for Celebrex versus a placebo. In response to the APC Study results, Pfizer executives attempted to downplay the cardiovascular risks associated with Celebrex. For example, in an interview published in the *Associated Press* titled "Pfizer Finds Celebrex Heart Attack Risk," Defendant Feczko stated that "it has not [been] shown in totality that it [Celebrex] increases the risk of heart attacks." Similarly, in a *Nightly Business Report* interview, Defendant McKinnell engaged in the following exchange with correspondent Jeff Yastine:

YASTINE: I'm told the company has no plans to pull Celebrex off the market. Why not?

McKINNELL: A decision to withdraw a drug is made in the context of all the information known about this drug. These two high dose long-term studies, they contradict each other to begin with and the one showing cardiovascular risk also contradicts the great body of evidence we have around the long term use of Celebrex when used as recommended.

YASTINE: Would anything happen or what would have to happen to perhaps change your mind, to change Pfizer's mind about Celebrex? Why not pull it off the market just as a preliminary cautionary measure?

McKINNELL: Well, we have to remember why this class of medicines was developed in the first place. It's tragically true that more Americans die of GI bleeds induced by traditional non- steroidals than die of AIDS in this country, 16,500 versus about 15,000. There's a very important medical need for safe, effective treatment of the pain and inflammation of arthritis.

YASTINE: Is there any concern on your part just from a financial perspective? I was reading in the "New York Times" they said about 11 percent of all new prescriptions that are written by primary care physicians are for Celebrex. Some people, it might be a cynical comment, some people might say this is the reason why you're not pulling the drug off the market.

McKINNELL: This is a very important medicine, meeting unmet medical needs of millions of patients in the United States and Canada and in Europe. It's a needed medicine. Physicians need to be fully informed. Patients need to discuss the risks and benefits of this class of medicines with their physicians and many times they will choose Celebrex as the best choice.

YASTINE: Let's move on to Bextra which is another Cox 2 inhibitor. The "New England Journal of Medicine" had an article, physicians there are recommending that physicians stop prescribing your Bextra drug and I believe the FDA last week required a warning label for folks with heart ailments to be careful using Bextra. Is that another concern for Pfizer, for you?

McKINNELL: Well, that's not really correct. What we included with the FDA and the Bextra label was a unique group of patients, those who have just come off coronary artery bypass grafts who have been on heart lung machines, who have been treated with an injectable form Bextra not yet approved in the United States and very high doses of oral Bextra and of course Bextra's not approved in the United States for this indication.

YASTINE: Well, give us some perspective then on this. I mean there might be a concern about folks jumping to the conclusion that between Vioxx, Bextra and Celebrex that that's it for Cox 2 inhibitors. Give us some perspective as to why

> you think that obviously these drugs still have a great deal of value for patients and for Pfizer.
>
> McKINNELL: Well, these are very different chemical agents. Vioxx and Celebrex and Bextra are from different chemical classes. They affect the body in different ways. We have very large bodies of evidence around the safety and effectiveness of these agents when they're used as recommended. The key of course is to have physicians and patients fully informed of the benefits and the risks of treatment with any of these agents, and then we leave to it the physician and patient to choose what's in the best interest of the patient.

505. Defendant McKinnell's referenced statements regarding the cardiovascular safety of Celebrex and Bextra in the December 17, 2004 *Associated Press* interview and the *Nightly Business Report* interview were false and misleading when made. These statements failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study, the CABG-1 Study, the CABG-2 Study and the other studies and information detailed above, and misrepresented that Celebrex and Bextra posed no increased cardiovascular risks.

506. In a December 20, 2004 broadcast of CNBC's *Kudlow & Cramer*, Defendant McKinnell made the following statements:

> ***Larry, we had lots of data, 10 years of data and over 40,000 patients from controlled clinical studies that showed no evidence of cardiovascular risk.*** There's also been five very large published reports of our database and other people's databases since the drug was introduced. Five out of five show cardiovascular risk less than any other treatment option…. That was the first time we had that kind of information.

This statement was false and misleading when made because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented that Pfizer's controlled clinical trials showed no evidence of cardiovascular risk.

507. On December 20, 2004, *The Wall Street Journal* reported that Defendant McKinnell made the following statement:

> Vioxx made us alert to this risk. We had early signals of cardiovascular risk with Vioxx. We saw none of that in our data for Celebrex.

This statement was false and misleading when made because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented that Pfizer had not seen any early signals of cardiovascular risk in Pfizer's data for Celebrex.

508. On December 21, 2004, Pfizer issued the following statement as reported on the *PR Newswire*:

> The National Institutes of Health has reported in an Alzheimer's disease prevention study that there was no increased cardiovascular risk seen in elderly patients taking Celebrex (400 mg daily) for up to three years. These results are consistent with the large body of Celebrex scientific evidence that has accumulated over 10 years in more than 40,000 patients.

This statement was false and misleading when made because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented that the results of the National Institutes of Health Alzheimer's disease prevention study were consistent with Pfizer's results, including the Alzheimer's 001 Study results.

509. Throughout 2004, analysts followed Defendants' public statements and announcements closely in connection with reporting Company developments to investors. Analysts routinely parroted the Defendants' materially false and misleading statements. However, all of Defendants' statements failed to disclose material facts of the serious

cardiovascular risks that Celebrex and Bextra posed. Nonetheless, the analysts relied on the Defendants' statements as the basis for recommending that investors purchase the Company's stock. For example:

- On September 30, 2004, William Blair & Co., L.L.C. issued a report on Pfizer, stating in part, "Merck (MRK $45.07) announced a voluntary, worldwide withdrawal of Vioxx (rofecoxib), its COX-2 inhibitor for arthritis and acute pain. The decision, effective immediately, is the result of new data from a three-year prospective, randomized and placebo-controlled clinical trial, APPROVe (Adenomatous Polyp Prevention on Vioxx), originally intended to add labeling to reduce intestinal polyps to compete with Pfizer's Celebrex labeling. . . . We view this as positive for Pfizer's COX-2 inhibitors, Celebrex and Bextra, which generated greater than $4 billion in last-12-months' revenue."

- On October 7, 2004, analysts from Citigroup Smith Barney reassured investors stating that, "we continue to believe the Vioxx withdrawal remains an incremental positive for PFE. Based on our analysis of available information, Celebrex cardiac safety profile appears much better than that of Vioxx . . . . We forecast 2005 WW Celebrex sales of $3.2 bill (6% of sales) & $1.3 bill (2% of sales) for Bextra, w/ total COX-2 EPS contrib of approx $0.42. If PFE gains 20-60% of Vioxx sales, we expect 2005 EPS to increase $0.05-0.15."

- Also on October 7, 2004, analysts from SunTrust Robinson Humphrey reported that "with the market removal of Vioxx, we believe Celebrex (celecoxib) and Bextra (valdecoxib) are in prime position to gain the Vioxx market share. On October 4, we therefore boosted our Celebrex estimates by $195 million in 2004 (due to the 4Q), by $1.1 billion in 2005, by $1.325 billion in 2006, and by $1.425 billion in 2007 (see our note from last week). We stand by our recent Celebrex and Bextra revenue estimate increases. We reiterate our Buy rating on shares of PFE."

510. Reflecting the success of Pfizer's strategy of concealing the cardiovascular risks of Celebrex and Bextra, and reflecting how that disinformation campaign distorted the market, on October 21, 2004, A.G. Edwards & Sons, Inc. issued a report on Pfizer stating:

> ***PFE recently reviewed the cardiovascular profile of Bextra with healthcare professionals, reiterating that there is no increased risk of cardiovascular thromboembolic events*** in people treated for osteoarthritis (OA) and rheumatoid arthritis (RA). This was based on a clinical trial database of 8,000 patients treated with Bextra for a range of 6 to 52 weeks. PFE had also announced results from studies with Bextra in surgical settings (for which the product is not approved). (1) In general surgery Bextra in combination with parecoxib (IV formulation) showed no increase in cardiovascular thromboembolic events.

511. Similarly, in an October 7, 2004 report pertaining to Pfizer, analysts remained optimistic, stating that "Our EPS estimates remain unchanged…. [W]e continue to believe the Vioxx withdrawal remains an incremental positive for PFE. Based on our analysis of available information, Celebrex cardiac safety profile appears much better than that of Vioxx (see discussion below), & PFE could capture an important proportion of Vioxx sales." The report summarized several recent safety studies and concluded that the results were "promising."

512. On December 17, 2004, immediately following the announcement by the National Cancer Institute that it would be canceling its Celebrex study due to concerns over cardiovascular risk, analysts at Deutsche Bank reaffirmed their "Buy" rating, stating that the risk for Celebrex was "not quite like Vioxx." A report released the same day by analysts at Bear Stearns acknowledged that the cardiovascular risk was "statistically significant," but stated that the "Bigger Challenge for Pfizer is Replacing $14 Billion in Potential Generic Erosion Over Next Several Years."

G. False Statements In 2005

513. Notwithstanding the revelations in late 2004 concerning the safety of Celebrex and Bextra and Merck's withdrawal of Vioxx, through much of 2005 Pfizer continued to mislead investors and the general public by falsely attempting to distinguish Celebrex from Vioxx and otherwise concealing or deceptively minimizing the truth that Celebrex posed serious cardiovascular risks and by implication, would suffer declining sales. These material misstatements from 2005 are set forth below.

514. On January 4, 2005, *USA Today* published an article titled "Pfizer leader steps up to plate for Celebrex," in which Defendant McKinnell was interviewed by Ron Insana. During that interview, Defendant McKinnell affirmatively misrepresented Celebrex's cardiovascular safety risks, including risks that were well known by Defendants:

[Ron] Insana: Is there a serious risk to people who use Celebrex on a regular basis?

[Hank] McKinnell: We still believe that Celebrex, when used as recommended, which does not mean 800 milligrams a day continuously for three years, is safe and effective. We've had discussions with the FDA. They haven't taken a formal position, but what they've said publicly is that physicians should be considering alternatives for treatment of arthritis and pain and that if Celebrex is the alternative they select, then it should be at the minimally effective dose, and that's good medicine. We agree.

Insana: Given the described cardiac risks for Celebrex, why should it still be on the market and Vioxx be off?

McKinnell: There are two major differences. One is they are different chemical families. They both target the COX-2 enzyme, but they're different molecules. They affect the body differently. Secondly, ***all of our own clinical data,*** which include 40,000 patients, ***show no evidence of cardiovascular risk.*** In these large patient-test studies, they show consistently that Celebrex actually has less cardiovascular risk than people receiving no treatment at all.

Insana: A recent colon polyp study, using Celebrex as a cancer preventive, turned up a greater incidence of heart risk among Celebrex users than had been previously discovered. How did that happen?

McKinnell: ***That's the $3.6 billion question. We can't really understand it.*** It was a large, well-controlled study, 2,200 patients. There were a very small number of events, 41 in total. There were six cardiac events in the no-treatment group, 15 in the 400-milligram (dosage) group and 20 in the 800-milligram group. That's an increase in risk from 1% to 2%. So absolutely it's a small number, ***but it is a significant finding.*** We don't want to underestimate it. It is exactly contradicted, however, by a second study, also large, also well-controlled, that we're running, adjudicated by the same group of cardiologist specialists who found no risk. It's an anomaly. It doesn't fit with anything that we know.

Insana: What if the FDA decides that COX-2 inhibitors, as a class, are not suitable for public consumption? What do you do as a company?

McKinnell: We have to obviously remove the drug from the market. That would be a shame for the millions of people who rely on Celebrex as their best option, or in some cases, their only option to live a normal life.

Defendant McKinnell's statements in the *USA Today* article regarding the cardiovascular safety of Celebrex were false and misleading when made because they misrepresented clinical data for Celebrex as showing no evidence of cardiovascular risk, and failed to disclose material adverse

information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above.

515. On January 19, 2005, Pfizer issued a press release announcing its financial results for the fourth quarter of 2004 (the "January 19, 2005 Press Release"). The January 19, 2005 Press Release, which was also filed with the SEC as a Form 8-K, contained the following material misrepresentations and omissions:

> Q27) What are the implications for Pfizer of the FDA's upcoming Advisory Committee meeting concerning the safety of COX-2- specific medicines?
>
> A27) . . . We will be participating in the Advisory Committee meeting, and we look forward to a reasoned scientific discussion in which we will provide data in support of our belief that Celebrex and Bextra present a cardiovascular risk profile comparable to that of non-selective non-steroidal anti-inflammatory drugs and are important therapeutic options. Pfizer's submission to the FDA will be posted on the FDA website.

516. Further, in the January 19, 2005 Press Release, Pfizer misleadingly characterized as "new news" requiring "considerable additional analysis" the issue of increased cardiovascular risks of Celebrex and Bextra:

> Q28) What new cardiovascular information has been obtained about Celebrex?
>
> A28) In December 2004, three controlled prevention studies involving Celebrex were halted. These three studies provide preliminary but inconsistent information. More specifically, on December 16, 2004, Pfizer learned of new information concerning two of these studies – large, well-controlled cancer-prevention studies involving patients who took high doses of Celebrex. One study, sponsored by the National Cancer Institute and involving patients taking 400 mg/day and 800 mg/day of Celebrex, showed an increase in overall cardiovascular events, such as heart attack, stroke, and death, compared to placebo. The second study, sponsored by Pfizer and involving patients taking 400 mg/day of Celebrex, did not show an increased overall cardiovascular risk over placebo. A third large, well-controlled Alzheimer's prevention study sponsored and conducted by the National Institute on Aging, a part of the National Institutes of Health, reported preliminary information on December 20, 2004. This third study had enrolled more than 2,400 patients over the previous 3 1/2 years to determine if Celebrex 400 mg/day or Aleve (naproxen sodium) 440 mg/day were effective treatments to prevent the

> development of Alzheimer's disease in people at risk of developing this serious disease. Preliminary safety results from the study indicated in part "an apparent increase in cardiovascular and cerebrovascular events among the participants taking naproxen sodium when compared with those on placebo." No increased cardiovascular risk was seen in patients taking Celebrex relative to placebo. We believe these three studies require considerable additional analysis before any conclusions can be reached.

517. These statements in the January 19, 2005 Press Release were false and misleading when made because they misrepresented that Celebrex and Bextra were safe and failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study, the CABG-1 Study, the CABG-2 Study and the other studies and information detailed above.

518. On February 16-18, 2005, the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees held a joint meeting concerning, among other things, the safety profile of Celebrex and Bextra. During those meetings Defendant Feczko made the following materially false and misleading statements and/or omissions of material fact:

> [T]he data "demonstrates the cardiovascular safety profile of our COX-2 inhibitors, both Celebrex, Bextra and parecoxib."
>
> * * *
>
> ***We believe that this data shows that the cardiovascular safety of Celebrex is at least on a par with therapeutic alternatives such as the non-selective NSAIDs***.
>
> In conclusion, I continue to be confident that Celebrex and Bextra have important treatment options for arthritis patients. I actually believe that there is no effective treatment for arthritis patients that is safer than Celebrex.

Defendant Feczko's statements at the joint meeting of the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees were false and misleading when made because they misrepresented that available data supported Celebrex's and Bextra's cardiovascular safety profile and failed to disclose material adverse information Defendants knew or recklessly

disregarded concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study, the CABG-1 Study, the CABG-2 Study and the other studies of information detailed above.

519. On April 5, 2005, Pfizer issued a press release (the "April 5, 2005 Press Release"), which was filed also filed with the SEC on Form 8-K. Although it referred to "uncertainties" that included "the outlook for our COX-2 franchise," the April 5, 2005 Press Release misleadingly failed to disclose Pfizer's knowledge that its COX-2 franchise was based on dangerous products that were sure to be investigated and either banned, strictly limited or further regulated and labeled. Indeed, rather than fully and accurately disclose the truth that Celebrex posed substantial risks of serious cardiovascular harms, Pfizer continued to conceal this critical information and instead claimed that COX-2's "needed more study:"

> For the COX-2 portfolio, Pfizer looks forward to finalizing changes to its U.S. labeling with the U.S. Food and Drug Administration (FDA) as well as moving ahead with plans for clinical studies to further explore the benefits as well as the risks of the COX-2 specific medicines compared to older, non-selective medicines. In the interim, Pfizer remains focused on the importance of these products for millions of patients around the world. "We believe that, with continued clinical work and appropriate labeling, these medicines will remain important treatment options for patients and doctors for many years to come," Katen said.

The April 5, 2005 Press Release was false and misleading because it misrepresented that Celebrex and Bextra were safe and failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study, the CABG-1 Study, the CABG-2 Study and other concealed study data and other information detailed above.

520. A May 16, 2005 article in *UPI* titled "Future of Bextra in doubt" reported that: "Pfizer Chief Executive Officer Hank McKinnell hopes Bextra gets FDA re-approval for at least limited use. He told the *Boston Globe* FDA reviewers saw unpredictable skin reactions in Bextra

users ***but had not seen 'increased cardiovascular risk,'*** the problem seen with Merck's Vioxx, which was pulled from the market last fall." This statement by McKinnell was false and misleading because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Bextra, demonstrated by the CABG-1 and CABG-2 Studies and other concealed study data and other information detailed above. In addition, this statement misrepresented that FDA reviewers had not seen increased cardiovascular risk for Bextra when an earlier April 6, 2005 FDA memo that precipitated Bextra's withdrawal from the market states: "The three approved COX-2 selective NSAIDs (i.e., celecoxib, rofecoxib, ***and valdecoxib [i.e., Bextra]***) are associated with an ***increased risk of serious adverse CV events*** compared to placebo."

521. During the June 24, 2005 broadcast of the *Charlie Rose Show,* McKinnell made the following statement: "Celebrex actually produces the same or less cardiovascular risk than the older agents." This statement was false and misleading because it failed to disclose material adverse information Defendants knew or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information detailed above, and because it misrepresented that Celebrex produces the same or less cardiovascular risk than older arthritis medicines.

522. The above-referenced statements made in 2005 (including the emphasized portions) were materially false and misleading when made. As set forth in Section VII. above, and summarized, in part, in Tables 1 – 5 above and Table 6 below, these statements failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex and/or Bextra by falsely claiming that Celebrex and/or Bextra showed no increase in thromboembolic or cardiovascular-related events, by failing to publish study results in a timely

or complete fashion and by making comparisons to Vioxx, NSAIDs or other traditional arthritis medications that were inherently misleading without including this material information.

TABLE 6

Date	Event	Description
January 2005	Pfizer Revises Response to the MPA	Defendants send the MPA a report that includes cardiovascular safety data that they omitted from their original report. They admit that, with regard to the Alzheimer's 001 Study "patients treated with celecoxib 200 mg BID ***had greater incidence of serious cardiovascular thromboembolic adverse events compared to patients treated with placebo."*** *See* ¶¶317-318.
April 2005	Pfizer Celebrex Meta-Analysis	Internal Pfizer meta-analysis of 41 controlled clinical trials shows a ***seven times, statistically significant*** increase in "myocardial thromboembolic" events for Celebrex 400 mg compared to placebo. *See* ¶¶238-240.

XI. DEFENDANTS FAILED TO MAKE DISCLOSURES REQUIRED BY REGULATION S-K

523. As discussed above, Defendants knew material adverse information about their two blockbuster drugs, Celebrex and Bextra. Specifically, they knew that these two drugs had serious cardiovascular side effects that were unknown to the medical community and investors. In addition, Defendants knew that sales of these two drugs would decline substantially (and the drugs might even be pulled from the market) if the public learned of their cardiovascular safety risks. Defendants also knew that a drop in sales in Celebrex and Bextra – two of their most important marketable pharmaceutical products – could severely impact Pfizer's financial condition and future outlook. Nevertheless, Defendants did not disclose these known risks and uncertainties in any of their public reports filed with the SEC.

524. Defendants' failure to disclose these risks and uncertainties in their reports filed with the SEC violated Regulation S-K. *See* 17 C.F.R. § 229.10, *et seq.* Regulation S-K provides, in part, that annual and period reports must contain a section entitled "Management's discussion and analysis of financial condition and results of operations" (the "Management Discussion").

525. Item 303 of Regulation S-K, 17 C.F.R. § 229.303 ("Item 303"), specifies what Defendants were required to include in the Management Discussion. In addition to disclosing Pfizer's financial results, Item 303 required Defendants to "provide such other information that the registrant believes to be necessary to an understanding of its financial condition, changes in financial condition and results of operations." It also required Defendants to describe any known "uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." As explained in the instructions to Item 303, "[t]he discussion and analysis shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

526. Notwithstanding Regulation S-K's clear instruction, Defendants never once disclosed in any of their periodic or annual reports that there was a risk that Pfizer's financial condition may change when the cardiovascular risks associated with Celebrex and Bextra were realized. Defendants' failure to warn investors of this risk rendered the following periodic and annual filings incomplete, false and misleading: the November 1, 2000 Form 8-K; January 24, 2001 Form 8-K; March 28, 2001 Form 10-K405; November 13, 2001 Form 10-Q; July 15, 2002 Form 425; August 13, 2002 Form 10-Q; October 16, 2002 Form 425 (press release); November 13, 2002 Form 10-Q; March 27, 2003 Form 10-K; April 22, 2003 Form 8-K; May 14, 2003 Form

10-Q; July 25, 2003 Form 8-K; October 22, 2003 Form 8-K; January 22, 2004 Form 8-K; April 20, 2004 Form 8-K; May 7, 2004 Form 10-Q; July 21, 2004 Form 8-K; August 6, 2004 Form 10-Q; October 15, 2004 Form 8-K; October 20, 2004 Form 8-K; November 5, 2004 Form 10-Q; January 19, 2005 Form 8-K; February 28, 2005 Form 10-K; April 5, 2005 Form 8-K; April 19, 2005 Form 8-K; May 6, 2005 Form 10-Q; July 20, 2005 Form 8-K; and August 8, 2005 Form 10-Q.

XII. PLAINTIFFS RELIED UPON DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

527. At all relevant times, the market for Pfizer's common stock was efficient. Plaintiffs are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine for the following reasons, among others:

(a) Pfizer's stock met the requirements for listing and was listed and actively traded on the New York Stock Exchange, a presumptively efficient market;

(b) Pfizer's securities volume was substantial. The Company had between 6.2 billion and 8.2 billion shares outstanding, and an average weekly trading volume of 1.3%. Additionally, the annual average weekly trading volume as a percentage of Pfizer shares outstanding in each year of the Relevant Period was 1.0%, 1.2%, 1.3%, 1.2%, and 1.9%, respectively;

(c) Institutional investors held a substantial majority of Pfizer shares, ranging from 55% to 70%;

(d) Pfizer was eligible to file registration statements with the SEC on Form S-3. To be S-3 eligible, a company had to have $75 million in stock held by non-affiliates, and had to have filed financial reports with the SEC for

at least one year. The value of the shares held by nonaffiliates of Pfizer greatly exceeded the $75 million threshold. Moreover, as a regulated issuer, Pfizer regularly filed annual, periodic, and interim public reports with the SEC.

(e) Pfizer also regularly communicated with public investors via other established market communication mechanisms, including through press releases that were carried by the media, newswires and on the internet, as well as through presentations to investors and analysts, and conference calls with analysts;

(f) Over 35 different firms followed Pfizer, including Citigroup Inc., Credit Suisse First Boston, Deutsche Bank, Morgan Stanley, SG Cowen, and UBS, which collectively issued more than 1,300 analyst reports concerning Pfizer;

(g) The market reacted promptly to public information disseminated by Pfizer, as Defendants' market efficiency expert, Professor Paul A. Gompers, conceded in the Pfizer Securities Class Action;

(h) The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Pfizer's securities; and

(i) Without knowledge of the misrepresented or omitted material facts alleged herein, Plaintiffs purchased or acquired Pfizer common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed.

528. As a result of the foregoing, the markets for Pfizer common stock promptly reacted to current information regarding Pfizer from publicly available sources and reflected such information in the trading price of Pfizer common stock. Under these circumstances, a presumption of reliance applies.

529. In addition, Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are also predicated upon omissions of material fact which there was a duty to disclose.

530. Indeed, in granting class certification in the Pfizer Securities Class Action, the court held that the foregoing facts provide "sufficient evidence to establish that Pfizer's public statements about the safety profiles of Celebrex and Bextra were material, and that Pfizer stock traded on an efficient market. Therefore, the fraud-on-the-market presumption applies and Plaintiffs need not establish individualized reliance." *See* Pfizer Securities Class Action, Opinion dated March 29, 2012, at 27 [ECF. No. 358]. As a result, the presumption of reliance is established under principles of *res judicata.*

XIII. DEFENDANTS' CONDUCT CAUSED PLAINTIFFS' LOSSES

531. The market price of Pfizer's common stock was artificially inflated by the material misstatements and omissions complained of herein.

532. The artificial inflation in Pfizer's common stock was removed when the conditions and risks misstated and omitted by Defendants were revealed to the market. The corrective information was disseminated through several partial disclosures that revealed the truth during the Relevant Period. These disclosures, more particularly described below, reduced the price of Pfizer's common stock, causing economic injury to Plaintiffs.

533. None of the disclosures was sufficient on its own to fully remove the inflation from Pfizer's common stock, because each only partially revealed the risks and conditions that had been concealed from investors.

534. Further, the corrective impact of the disclosures alleged herein was tempered by Defendants' continued misstatements and omissions about Celebrex and Bextra. These continued misrepresentations maintained the prices of Pfizer's publicly traded securities at levels that were artificially inflated and, in some cases, induced Plaintiffs to continue purchasing Pfizer common stock even after the truth began to partially enter the market. Further price declines that caused additional injury to Plaintiffs occurred upon the disclosure of additional information about Celebrex and Bextra.

535. As discussed in detail above, both prior to and during the Relevant Period, Defendants made many materially false and misleading statements and omissions regarding the cardiovascular safety of Celebrex and/or Bextra that caused the price of Pfizer securities to trade (or remain) at artificially inflated levels. Among other things, these misstatements maintained the false impression in the marketplace that Celebrex and Bextra were free of cardiovascular safety risks.

536. Pfizer's stock experienced a series of statistically significant drops from the close of trading on October 6, 2004, the day before the first partial disclosure, to October 19, 2005, the day prior to Pfizer's announcement of its earnings results for the third-quarter. Over this period of time, the price of Pfizer's stock fell substantially, by $9.28 per share (or 29.7%), from $31.18 per share to $21.90 per share, erasing over $74 billion in market capitalization.

537. The first partial corrective disclosure occurred on October 7, 2004. On that date, *Reuters* reported that "an editorial in *The New England Journal of Medicine* published late on

[October 6, 2004] . . . questioned the safety of [COX-2] arthritis drugs, including Pfizer Inc.'s (PFE.N) Celebrex and Bextra, which are members of the same class of treatments as Vioxx." The editorial, published one week after Vioxx was pulled from the market, revealed new concerns about the safety of Celebrex and Bextra because Pfizer previously denied that the drugs were associated with any cardiovascular risk. This news caused a statistically significant drop in Pfizer's shares. As the *Dow Jones News Service* reported that day, "Pfizer shares drop 6% as a report in the New England Journal of Medicine raises concerns about Celebrex . . . ."

538. Approximately one week later, prior to the stock market's opening on October 15, 2004, *Reuters* published another report titled "Pfizer warns on arthritis drug Bextra." This report disclosed for the first time that Pfizer's two CABG studies showed Bextra was associated with a higher risk of cardiovascular events: "Pfizer Inc. on Friday said two clinical trials [the CABG studies] showed patients taking its anti-inflammatory drug Bextra had a higher risk of cardiovascular events during high-risk coronary bypass surgery." In response to this latest revelation, Pfizer's stock price again declined by a statistically significant amount. As research analysts at CIBC World Markets reported the same day, "concern regarding adverse events in CABG . . . has knocked 4% off [Pfizer's] shares today."

539. On November 4, 2004, *The National Post* of Canada published an article titled, "Alternative to Vioxx is connected to 14 deaths: Company argues Health Canada data is not definitive," that revealed further news about the cardiovascular risks of Celebrex. The article revealed that Celebrex, which had been "touted as the safe alternative to Vioxx after that medicine was pulled from the shelves," was "itself suspected of contributing to at least 14 deaths and numerous heart and brain-related side effects." While Pfizer publicly refuted that any link could be drawn from this data, Pfizer's denial that Celebrex was not associated with the reported

adverse cardiovascular events was less credible because Merck had recently pulled Vioxx from the market. In response to this latest revelation, shares of Pfizer common stock again declined by a statistically significant amount. *Reuters* reported that day that "Pfizer Inc.'s shares fell as much as 6.2 percent . . . after a report in a Canadian newspaper said the company's arthritis drug Celebrex was linked to 14 deaths." That same day, *Reuters* reported in another article "Celebrex has been touted as the safe alternative to Vioxx after that medicine was pulled from the shelves after a study showed increase risk of heart attack and stroke."

540. Ten days later, prior to the opening of the market on November 10, 2004, *The New York Times* published an article titled "New Study Links Pfizer's Bextra, Similar To Vioxx, To Heart Attacks." The article revealed that "[t]he 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 discussed in *The New York Times* article was an aggregation of data from twelve Bextra studies (including CABG-1 and CABG-2, the full results of which had not been timely disclosed to the market), which had never been previously analyzed and disclosed in the aggregate.[166] Following the publication of the *New York Times* article, Pfizer's shares again dropped by a statistically significant amount. *Reuters* reported that "Drugmaker Pfizer Inc. (PFE.N) slipped 2 percent to $27.45 after a *New York Times* article reported results from a study that showed the incidence of heart attacks and strokes among patients given Pfizer's painkiller, Bextra, was more than double that of those given placebos."

541. Again, on December 17, 2004, shares of Pfizer stock declined substantially following a Pfizer press release that disclosed additional information concerning the

[166] It was not until Pfizer published an amended prescribing label for Bextra later in November 2004 that the Company disclosed the complete, statistically significant CABG-1 safety results.

cardiovascular risks associated with Celebrex that had previously been concealed by Defendants. In the press release, "Pfizer Inc said it received new information last night about the cardiovascular safety of its COX-2 inhibitor Celebrex (celecoxib) based on an analysis of two long-term cancer trials." The press release further revealed that, "[b]ased on these statistically significant findings, the sponsor of the trial, the NCI [*i.e.*, National Cancer Institute], has suspended the dosing of Celebrex in the study." These revelations swiftly and significantly impacted the price of Pfizer's stock. As reported in *Reuters* that day, "[s]hares of Pfizer Inc. (PFE.N), the world's largest drugmaker, on Friday fell 12 percent in composite trading after trial data for its popular arthritis drug Celebrex showed increased risk of heart attack."

542. On Friday, December 17, 2004, the National Institutes of Health disclosed its finding that Celebrex was linked to an increased risk of heart attack. The market again responded to this latest revelation. By the close of trading on the next business day after the corrective disclosure, Pfizer's shares plummeted by $4.69 per share (or 16.2%) and wiped out more than $35.3 billion in market capitalization.

543. On Sunday, December 20, 2004, *Reuters* reported that, at the insistence of the FDA, "Pfizer Inc. <PFE.N> has agreed to suspend advertisements for arthritis drug Celebrex while U.S. regulators review new data that link the drug to an elevated risk of heart attacks." In response to this news – which was another materialization of Celebrex's cardiovascular risk that Defendants had previously hid and denied – Pfizer's stock price fell the next business day by a statistically significant amount. As the *Wall Street Journal* reported, "Pfizer continued to fall [on December 20, 2004], shedding 1.46, or 5.7%, to 24.29 after the Food and Drug Administration told it to stop advertising Celebrex, its pain treatment, to consumers. This came after a study

linked high doses of Celebrex to a greater risk of heart attack, which led to an 11% drop in Pfizer's stock Friday."

544. Notwithstanding the above partial disclosures, Pfizer's stock price still remained artificially inflated because Defendants continued to minimize and misrepresent the true cardiovascular risks associated with Celebrex and Bextra. For example, Defendant McKinnell was quoted in a January 4, 2005 *USA Today* report as stating that ***"all of our own clinical data, which include 40,000 patients, show no evidence of cardiovascular risk."*** Likewise, Defendant Feczko stated on or about February 16, 2005, that the data "demonstrates the cardiovascular safety profile of our COX-2 inhibitors, both Celebrex, Bextra and parecoxib."

545. On October 20, 2005, Pfizer was forced to disclose additional material adverse information concerning the cardiovascular risks of Celebrex and Bextra, *viz.*, the impact of the previously concealed heart risks on sales of the "blockbuster" drugs and the Company's overall financial results. In releasing its financial results for the third quarter of 2005, Pfizer stated that "[t]he regulatory actions relating to Celebrex and the suspension of sales of Bextra," which resulted from the cardiovascular safety risks of the drugs, "have contributed to an additional decline in third-quarter 2005 selective COX-2 inhibitor worldwide revenues of $754 million (down 67%) and year-to date selective COX-2 inhibitor worldwide revenues of $2.0 billion (down 62%) in comparison to the same periods in the prior year." Later that day, the *Dow Jones News Service* reported that Pfizer Inc.'s (PFE) third-quarter earnings fell by more than half, "hurt by . . . a loss of sales from its blockbuster Cox-2 family of drugs." Discussing the Company's disclosures the following day, *The New York Times* reported that Pfizer, "[f]acing increasing . . . concerns about the heart risks of Celebrex, its once-popular painkiller . . . said yesterday that sales in the third quarter fell 5 percent compared with the period in 2004," which "report led

Pfizer's battered shares to plunge $2.07 to $21.90." This drop in Pfizer's stock price was again statistically significant and a direct result of the materialization of the cardiovascular risks of Celebrex and Bextra that were concealed from investors and the public during the Relevant Period.

XIV. INAPPLICABILITY OF STATUTORY SAFE HARBOR

546. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded in this Complaint. First, the statements complained of herein were historical statements or statements of current facts and conditions at the time the statements were made. Second, the statutory safe harbor does not apply to statements included in financial statements that purport to have been prepared in accordance with Generally Accepted Accounting Principles ("GAAP"). Further, to the extent that any of the false or misleading statements alleged herein can be construed as forward-looking, the statements were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements.

547. Alternatively, to the extent the statutory safe harbor otherwise would apply to any forward-looking statements pleaded herein, Defendants are liable for those false and misleading forward-looking statements because at the time each of those statements was made, the speakers knew the statement was false or misleading, or the statement was authorized or approved by an executive officer of Pfizer who knew that the statement was materially false or misleading when made.

XV. TOLLING OF THE STATUTE OF LIMITATIONS

548. On December 15, 2004, L. Norman Showers, on behalf of himself and all others similarly situated, filed a class action complaint on behalf of purchasers of publicly traded Pfizer common stock against Defendants Pfizer and McKinnell alleging violations of Sections 10(b) and 20(a) of the Exchange Act. *See L. Norman Showers v. Pfizer., Inc., et al.,* No. l:04-cv-9866 (S.D.N.Y.). During the next two months, at least ten additional class action complaints were filed in this District and other federal Districts on behalf of purchasers of publicly traded Pfizer common stock against Defendants alleging violations of Sections 10(b) and 20(a) of the Exchange Act and relating to the same or substantially similar misconduct, including, but not limited to: *John Haggerty v. Pfizer, Inc., et al.,* No. 1:04-cv-10001 (S.D.N.Y.); *Philip Morabito v. Pfizer, Inc., et al.,* No. 1:04-cv-9967 (S.D.N.Y.); *Sheldon Miller P.C. Defined Benefit Plant Dated November 1, 2001 v. Pfizer, Inc., el al.,* No. 1:04-cv-10224 (S.D.N.Y.); *Shirley Schaffer, et al., v. Pfizer, Inc., et al.,* No. 1:04-cv-10296 (S.D.N.Y.); *Ronald Hodge v. Pfizer, Inc., et al.,* No. 1:05-cv-0125 (S.D.N.Y.); and *Amalgamated Bank, et al. v. Pfizer, lnc., et al,* No. 1:05-cv-2076 (S.D.N.Y.).

549. On October 21, 2005, these actions were consolidated by the Court in *In re Pfizer Inc. Securities Litigation,* Case. No. 1:04-cv-09866. On February 16, 2006, the court-appointed Lead Plaintiff in the Pfizer Securities Class Action filed a Consolidated Class Action Complaint ("Consolidated Complaint") against Defendant Pfizer and the Individual Defendants asserting claims under Sections 10(b), 20(a), and 20(A) of the Exchange Act. The Consolidated Complaint alleged that Pfizer and the Individual Defendants made materially false and misleading statements and omitted material information from Pfizer's public reports and documents about the cardiovascular risks associated with Celebrex and Bextra. As a result of these misrepresentations, Lead Plaintiff alleged that the price of Pfizer common stock during the

putative class period was artificially inflated, and that once the truth about these cardiovascular risks began to emerge, the price of Pfizer common stock declined in value and class members suffered losses. On July 1, 2008, United States District Judge Laura T. Swain substantially denied Defendants' motions to dismiss the Consolidated Complaint, including Lead Plaintiff's claims for violations of Section 10(b) and 20(a) of the Exchange Act.

550. On March 27, 2012, Lead Plaintiff filed an Amended Consolidated Class Action Complaint asserting the same claims as those sustained from the Consolidated Complaint.

551. On March 29, 2012, Judge Swain granted class certification (including with respect to the claims alleged herein) and, on April 6, 2012, the Court issued its Amended Order Granting Motion For Class Certification (the "Pfizer Class Certification Order"). Pursuant to the Pfizer Class Certification Order, on July 3, 2012, Judge Swain approved notice to the class of the pendency of the class action. On September 7, 2012, Plaintiffs timely submitted their requests for exclusion from the Pfizer Securities Class Action.

552. The class action complaints referenced above, including all of the class action complaints listed in Paragraph 548, were filed less than two years after Plaintiffs discovered or reasonably could have discovered the facts upon which the claims asserted herein are based. In addition, these class action complaints were all filed less than five years after the date the misrepresentations upon which the claims asserted herein are based were made. The filing of these class action complaints, or some of them, served to toll any applicable statute of limitations and repose for the claims set forth in this Complaint pursuant to the doctrine announced in *Am. Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 552 (1974).

XVI. CLAIMS FOR RELIEF

COUNT I

VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

553. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

554. This Count is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all of the Defendants.

555. Throughout the Relevant Period, Defendants, individually and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce and/or of the United States mail, engaged and participated in a continuous course of conduct to conceal adverse material information about the cardiovascular safety risks of Celebrex and Bextra, as specified herein, thus materially misrepresenting Celebrex's and Bextra's medical and commercial viability. This plan, scheme and course of conduct was intended to and, throughout the Relevant Period, did: (a) deceive the investing public, including Plaintiffs, as alleged herein; (b) artificially inflate the market price of Pfizer securities; and (c) cause Plaintiffs to purchase Pfizer securities at artificially inflated prices.

556. In furtherance of this unlawful scheme, plan and course of conduct, the Defendants, individually and jointly, consistently made materially false and misleading statements and omitted to state material facts regarding the cardiovascular dangers that Celebrex and Bextra posed during the Relevant Period, thus materially misrepresenting Celebrex's and Bextra's medical and commercial viability. While in possession of material, adverse non-public information, the Defendants (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the

statements made not misleading; (c) sold shares while in possession of material, adverse non-public information; and (d) engaged in acts, practices and a course of conduct which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to create and maintain artificially high market prices for Pfizer's common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Each of these Defendants was a direct, necessary and substantial participant in the common course of conduct alleged herein.

557. The Defendants carried out a deliberate scheme to protect the extraordinary revenue source that Celebrex and Bextra represented for Pfizer, and the Defendants knew that Celebrex's and Bextra's sales results would be incorporated into Pfizer's quarterly and annual financial statements and publicly disseminated reports to investors. Defendants knew or, but for their deliberate recklessness, should have known, that their statements concerning the Company's business operations and future prospects, as disseminated to the investing public during the Relevant Period, were materially misstated. Further, Defendants knew of existing adverse facts which undermined their representations about Pfizer's existing business operations and prospects during the Relevant Period.

558. As a result of their making and/or their substantial participation in the creation of affirmative statements and reports to the investing public, the Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-K (17 C.F.R. § 229.10, *et seq.*) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and performance so that the market prices of the Company's common stock would be based on truthful, complete and accurate information. With regard to

the efficacy and medical and commercial viability of Celebrex and Bextra, the Defendants consistently failed to perform this duty.

559. Defendants acted with scienter throughout the Relevant Period. The Defendants' own internal information concerning Celebrex and Bextra provided the Defendants with statistically significant information showing that Celebrex and Bextra carried severe cardiovascular risks, such that the medical and commercial viability of the drug, as well as the revenue stream associated with it, was consistently threatened during the Relevant Period. The Defendants knew or recklessly disregarded that the financial results publicly disseminated to investors during the Relevant Period were significantly driven by sales of Celebrex and Bextra all over the world and that this material source of Company revenues remained at risk because of the dangers that Celebrex and Bextra posed to people taking the drug.

560. In addition to having actual knowledge and/or recklessly disregarding the fraudulent nature of their statements and conduct, each of the Defendants also had a strong motive to engage in the fraudulent scheme set forth herein. Maintaining a strong stock price was essential to Pfizer's ability to expand its markets as well as to maintain the artificially inflated value of each of the Individual Defendants' holdings of Pfizer shares. Notwithstanding these Defendants' knowledge that Celebrex and Bextra posed severe cardiovascular risks to patients taking the drug, the Defendants knowingly and/or recklessly failed to disclose such material risks. Disclosure of the true facts concerning Celebrex and Bextra would have seriously impaired Pfizer's position in the pharmaceuticals marketplace. In addition, bonuses and other incentive compensation available to the Individual Defendants were heavily dependent on meeting the ever growing financial targets set by Pfizer.

561. Defendants are liable as direct participants in the wrongs complained of herein. Through their positions of control and authority as officers of the Company, each of these Defendants was able to and did control the content of the public statements disseminated by Pfizer. With knowledge of the falsity and/or misleading nature of the statements contained therein and in reckless disregard of the true business operations and future prospects of the Company, these Defendants caused the heretofore complained of public statements to contain misstatements and omissions of material facts as alleged herein.

562. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Pfizer common stock was artificially inflated during the Relevant Period. In ignorance of the fact that market prices of Pfizer's publicly traded common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock traded, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Relevant Period, Plaintiffs acquired Pfizer common stock during the Relevant Period at artificially high prices and were damaged thereby.

563. At the time of said misrepresentations and omissions, Plaintiffs were ignorant of their falsity, and believed the false statements to be true. Had Plaintiffs known that Celebrex and Bextra presented such severe cardiovascular risks, facts which were misrepresented and/or not disclosed by the Defendants, Plaintiffs would not have purchased Pfizer common stock at all or would not have done so at the artificially inflated prices that they paid.

564. The Defendants' materially false and misleading statements and omissions of material fact caused Plaintiffs to suffer losses in connection with their investments in Pfizer

common stock. Pfizer's stock price collapsed as the truth was revealed over time regarding the medical and commercial viability of Celebrex and Bextra. By October 20, 2005, the disclosure of Pfizer's Celebrex and Bextra-related fraud reduced the share price by more than $21 per share.

565. By reason of the foregoing, the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder, and are liable to Plaintiffs for damages suffered in connection with purchases of Pfizer common stock during the Relevant Period.

COUNT II

VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

566. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

567. This Count is asserted against the Individual Defendants pursuant to Section 20(a) of the Exchange Act.

568. The Individual Defendants acted as controlling persons of Pfizer within the meaning of Section 20(a) of the Exchange Act, as alleged herein. By virtue of their respective high-level positions and active participation in and/or awareness of the day-to-day operations at Pfizer, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various public statements and SEC filings that Plaintiffs allege were false and misleading. The Individual Defendants were provided with, or had unlimited access to, copies of reports, clinical studies, press releases, public filings and other statements alleged herein to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

569. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company, and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

570. As set forth above, Pfizer and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are also liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct Plaintiffs suffered damages in connection with their purchases of the Company's common stock during the Relevant Period.

COUNT III

VIOLATIONS OF SECTION 20A OF THE EXCHANGE ACT AGAINST DEFENDANTS MCKINNELL, LAMATTINA AND KATEN

571. Plaintiffs repeat and re-allege each and every allegation above as if fully set forth herein.

572. This Count is asserted pursuant to Section 20A of the Exchange Act against Defendants McKinnell, LaMattina and Katen, by Plaintiffs Texas Teachers, CalPERS, CalSTRS, The UC Regents, Arizona SRS, La Caisse, Thrivent Financial, American Century funds, Alger Management funds, Janus funds, and TIAA-CREF funds that purchased Pfizer common stock contemporaneously with the sale of Pfizer common stock by either McKinnell, LaMattina or Katen during the Relevant Period, and who were damaged thereby (the "Section 20A Plaintiffs").

573. During the Relevant Period, McKinnell, LaMattina and Katen occupied positions within Pfizer that made them privy to confidential information about Pfizer, as well as Pfizer's operations, finances, financial condition and future business prospects, including, but not limited

to, the materially false and misleading financial statements disseminated to the investing public alleged herein. Notwithstanding their duty to refrain from trading in Pfizer common stock unless they disclosed the foregoing material adverse facts, and in violation of their fiduciary duties to Plaintiffs, during the Relevant Period, McKinnell, LaMattina and Katen sold their Pfizer common stock contemporaneously with Plaintiffs' purchases of Pfizer common stock.

574. Defendant McKinnell sold 809,134 shares of his Pfizer common stock on October 26, 2000, October 23, 2001, February 27, 2003, February 25, 2004, and August 26, 2005, while in possession of material, nonpublic information for total proceeds of approximately $29,755,919 at market prices artificially inflated by the non-disclosure of material adverse non-public facts, misrepresentations of fact, and the public statements released during the Relevant Period.

575. All of the Section 20A Plaintiffs purchased shares of Pfizer common stock contemporaneously with some or all of the foregoing sales of Pfizer common stock by Defendant McKinnell.

576. Defendant LaMattina sold 67,073 shares of his Pfizer common stock on February 26, 2004, February 24, 2005, and May 6, 2005, while in possession of material, nonpublic information for total proceeds of approximately $1,883,452 at market prices artificially inflated by the non-disclosure of material adverse non-public facts, misrepresentations of fact, and the public statements released during the Relevant Period.

577. All of the Section 20A Plaintiffs purchased shares of Pfizer common stock contemporaneously with some or all of the foregoing sales of Pfizer common stock by Defendant LaMattina.

578. Defendant Katen sold 372,536 shares of her Pfizer common stock on August 18, 2000, November 6, 2000, October 19, 2001, February 21 and 25, 2002, February 27, 2003,

November 18, 2003, February 26, 2004, February 24, 2005, and May 10, 2005, while in possession of material, nonpublic information for total proceeds of approximately $13,264,107 at market prices artificially inflated by the non-disclosure of material adverse non-public facts, misrepresentations of fact, and the public statements released during the Relevant Period.

579. All of the Section 20A Plaintiffs purchased shares of Pfizer common stock contemporaneously with some or all of the foregoing sales of Pfizer common stock by Defendant Katen.

580. At the time of the above-referenced sales, Defendants McKinnell, LaMattina and Katen knew that they were in possession of material adverse information that was not known to the investing public, including Plaintiffs. Before selling their stock to the public, Defendants McKinnell, LaMattina and Katen were obligated to disclose the material non-public adverse information to Plaintiffs and other members of the investing public.

581. By reason of the foregoing, Defendants McKinnell, LaMattina and Katen, directly and indirectly, by use and means of instrumentalities of interstate commerce, electronic communications mailing, and the facilities of a national securities exchange, employed devices, schemes, and artifices to defraud, and engaged in acts and transactions and a course of business which operated as a fraud or deceit upon members of the investing public who purchased Pfizer common stock contemporaneously with the sale of such stock by McKinnell, LaMattina or Katen.

582. The Section 20A Plaintiffs have suffered damages because, in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of Section 10(b) and 20(a) of the Exchange Act as alleged herein. The Section 20A Plaintiffs would not have purchased the shares at the prices they paid, or at all, if they had been aware that the market

prices had been artificially inflated by the Defendants' false and misleading statements and concealment. At the time of the purchases of the Pfizer shares by these Plaintiffs, the fair and true market value of the securities was substantially less than the price paid by the Plaintiffs.

XVII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

583. Awarding Plaintiffs compensatory damages against all of the Defendants, jointly and severally, for all losses and damages suffered as a result of Defendants' wrongdoing alleged herein, in an amount to be determined at trial;

584. Awarding Plaintiffs pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees and other costs;

585. Awarding punitive and exemplary damages; and

586. Awarding such other relief as this Court may deem just and proper.

XVIII. JURY DEMAND

Plaintiffs hereby demand a jury trial as provided by Rule 38(a) of the Federal Rules of Civil Procedure.

Dated: November 15, 2012

Respectfully submitted,

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