GRANT & EISENHOFER P.A.
Jay W. Eisenhofer
Richard S. Schiffrin
James J. Sabella
Charles T. Caliendo
Brenda F. Szydlo
485 Lexington Avenue, 29th Floor
New York, New York 10017
Telephone: (646) 722-8500
Facsimile: (646) 722-8501

and

Geoffrey C. Jarvis
Mary S. Thomas
Michele S. Carino
Ned C. Weinberger
123 Justison Street
Wilmington, DE 19801
Telephone: (302) 622-7000
Facsimile: (302) 622-7100

Attorneys for Lead Plaintiff The Teachers' Retirement System of Louisiana

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

IN RE PFIZER INC. SECURITIES LITIGATION	04 Civ. 9866 (LTS) (HBP)
	JURY TRIAL DEMANDED

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

This is a securities class action brought by the Teachers' Retirement System of Louisiana ("Lead Plaintiff" or "TRSL") by and through its attorneys Grant & Eisenhofer P.A., and Named Plaintiffs Christine Fleckles, Julie Perusse and Alden Chace, by and through their attorneys, Kessler Topaz Meltzer & Check, LLP, on behalf of all persons and entities who purchased or otherwise acquired securities issued by Pfizer Inc. ("Pfizer" or the "Company"), between and including October 31, 2000 through October 19, 2005 (the "Class Period") (Lead Plaintiff, other named plaintiffs, and the class and subclass (as defined below) are collectively referred to as "Plaintiffs").

Plaintiffs allege the following upon information and belief, except as to those allegations concerning Lead Plaintiff and the additional named plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their investigation, conducted by and through their attorneys, into the facts and circumstances alleged herein including, without limitation: (a) review and analysis of certain filings made by Pfizer with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of certain press releases, public statements, news articles, medical studies, and other publications disseminated by or concerning the Defendants named herein and related parties; (c) review and analysis of certain Pfizer press conferences, analyst conference calls and conferences, and the corporate website of Pfizer; (d) review and analysis of securities analyst reports concerning Pfizer and its operations; (e) review and analysis of prepared statements and other testimony given before the United States Food and Drug Administration's ("FDA") Arthritis Advisory Committee and Drug Safety and Risk Management Committee; (f) review and analysis of certain other information, documents, and materials concerning Pfizer and the other Defendants named herein; (g) interviews with former Pfizer, Pharmacia Corporation ("Pharmacia") and/or G.D. Searle & Co. ("Searle") employees and other industry professionals; (h) review and analysis of

Pfizer's Class Period internet advertising and other promotional materials as they influenced investors; (i) documents and information produced by the Company in response to Plaintiffs' discovery demands in this litgation, including, without limitation, deposition testimony of current or former Pfizer employees (or former employees of Pfizer's predecessors-in-interest, Pharmacia and/or Searle) in *In re: Bextra and Celebrex Marketing and Sales Practices, and Product Liability Litigation*, No. 05-CV-01699, MDL No. 1699, U.S.D.C. for the Northern District of California, San Francisco Division) and in the *Carter v. Pfizer* and *Grutka v. Pfizer* litigations in New Jersey state court; (j) deposition testimony of current or former Pfizer employees (or former employees of certain of Pfizer's predecessors-in-interest as identified more fully below) in this litigation; (k) the guilty plea agreement dated August 31, 2009 between Pfizer subsidiary Pharmacia & Upjohn Company, Inc., in which Pharmacia & Upjohn Company, Inc. pled guilty to a felony violation of the Food, Drug and Cosmetic Act, Title 21, U.S.C. Sections 331(a), 333(a)(2) and 352(f)(1), arising in significant part out of false and misleading safety claims concerning Bextra and resulting in a criminal fine in the amount of $1,195,000,000 and forfeiture of $105,000,000; (l) the deferred prosecution agreement between Pfizer and the United States Department of Justice ("DOJ") dated August 31, 2009, approved by Pfizer's board of directors, wherein Pfizer agreed to settle its federal False Claims Act and other civil liability for $1,000,000,000, with payments to federal and state Medicaid fraud control units of $503,000,000, all arising out of the unlawful promotion of Bextra; and (m) the Sentencing Memorandum dated October 9, 2009 in *United States of America v. Pharmacia & Upjohn Company, Inc.*, Criminal No. 09 CR 10258-DPW, U.S.D.C. for the District of Massachusetts, and other related agreements.

Plaintiffs continue to gather evidence and believe that substantial additional evidence will exist to support the allegations in this Amended Consolidated Class Action Complaint (the

"Complaint") at the time of trial, gathered in part from examination of sources including Company-wide databases and other centralized filing systems known as "eRooms" that existed during and following the Class Period, and which were only recently acknowledged to exist by Defendants. Additional facts supporting the allegations contained herein are still known only to the Defendants or are exclusively within their custody and/or control.

I. BASIS OF ALLEGATIONS

1. Plaintiffs bring this securities fraud action against Pfizer and current or former Pfizer executives Henry A. McKinnell, John L. LaMattina, Karen L. Katen, Joseph M. Feczko and Gail Cawkwell (collectively, the "Defendants") to recover damages sustained in connection with the Defendants' fraudulent material misrepresentations and omissions regarding the safety of two of Pfizer's pain-relieving drugs – Celebrex (celecoxib) and Bextra (valdecoxib). These drugs belong to a class of drugs known as Cyclooxygenase 2 ("COX-2") inhibitors. COX-2 inhibitors are primarily used to treat, among other things, pain resulting from arthritis and were designed as an alternative to older drugs such as aspirin, ibuprofen and naproxen. As a result of the fraud alleged herein, Plaintiffs suffered significant losses in connection with their purchases of the Company's common stock on the New York Stock Exchange ("NYSE") during the Class Period.

2. Celebrex was a blockbuster drug. As the most successful product launch in the history of the pharmaceutical industry, 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, approximately $2.5 billion in 2003, and $3.3 billion in 2004. Bextra also had a successful debut. Bextra generated revenues of $470 million in 2002, approximately $875 million in 2003, and over $1.2 billion in 2004. The joint sales of Celebrex and Bextra constituted between 6% and 11% of Pfizer's total sales from 2002 to 2004.

3. Pfizer and its co-promoter Searle and later Pharmacia (together, "Co-Promoter") achieved these results by, for more than five years, consistently misrepresenting Celebrex and Bextra as completely free of any cardiovascular risk. They repeatedly touted internal safety data which they claimed demonstrated cardiovascular safety and claimed to have no evidence of cardiovascular risk. They touted the drugs' allegedly superior cardiovascular safety profile as compared to its primary COX-2 competitor, Merck Inc.'s Vioxx. Defendant McKinnell (Pfizer's CEO during the relevant time) even recognized that this allegedly superior cardiovascular safety profile was the primary marketing advantage Celebrex possessed over Vioxx.

4. Unbeknownst to investors in Pfizer's common stock, however, from at least as early as 1999, and in stark contrast to their cardiovascular safety statements, Defendants were in possession of completed drug safety studies and other data and information which documented the serious cardiovascular risks of Celebrex and/or Bextra. These materials flatly contradicted or rendered false or misleading statements made by or on behalf of the Defendants throughout the Class Period. Once the truth – which was known to Pfizer since no later than the beginning of the Class Period – 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 precipitously.

5. It is clear that the information concerning the safety of Celebrex and Bextra concealed from the investing public, was well-known by the Company since as early as 1999. Thus, far from having "no evidence" of cardiovascular risk, as Defendants and the Co-Promoter consistently proclaimed throughout the Class Period, Defendants knew or had access to the following material information:

> (a) findings from the Integrated Summary of Safety for Celecoxib dated June 1998, which stated that there was a statistically significant increase in heart attacks for elderly patients taking Celebrex versus elderly patients taking placebo (*see infra* § VII.A.);

(b) a cardiovascular safety summary distributed in a July 14, 1999 memo by a then-senior doctor in Searle's clinical study department (who subsequently became a senior doctor in Pharmacia's and Pfizer's research departments) addressed to several Searle and Pfizer employees that reflected, among other things, statistically significant increases for patients using Celebrex as compared with those given placebo for all cardiovascular events in North American arthritis trials (*see infra* § VII.C.);

(c) findings of statistical significance based on at least 27 cardiovascular adverse events in patients taking Celebrex versus 1 for patients taking placebo in a clinical study on the effects of Celebrex on the progression of Alzheimer's disease (known as the "Alzheimer's 001 Study") that was completed before the Class Period began in 1999 (*see infra* § VII.D.);

(d) findings from a large, unpublished clinical trial completed in April 2000 (known as the "SUCCESS Study") that revealed a 10 to 1 increase in myocardial infarctions (heart attacks) for patients taking Celebrex versus those taking two traditional arthritis medicines (*see infra* § VII.F.);

(e) the full results from a large clinical trial completed in March 2000 (known as the "CLASS Study"), which were falsely portrayed to the market because, in publishing the study, Pfizer and Pharmacia purposefully misrepresented and concealed the cardiovascular safety data (*see infra* § VII.G.);

(f) a September 2001 letter from the World Health Organization received by the Co-Promoter and Pfizer that stated "myocardial infarction observed with celecoxib [in post-marketing adverse event databases] should be regarded as a serious signal" (*see infra* § VII.H.);

(g) a February 7, 2003 preliminary assessment report prepared by a representative (known as a "Rapporteur") of a foreign (German) regulator that detailed an increased risk for heart attack with Celebrex-treated patients compared to traditional arthritis medicines (*see infra* § VII.I.);

(h) a January 2003 meta-analysis of Celebrex arthritis studies prepared by a representative of the German Rapporteur that, according to an internal Pharmacia email, showed "a Relative Risk of 2.3 for cele[coxib] v. diclofenac [i.e., a traditional arthritis medicine] for thromboembolic events" or, in other words, that it was 2.3 times more likely that, in the arthritis studies analyzed, Celebrex would result in a thromboembolic event than would diclofenac, and a subsequent September 2003 internal meta-analysis prepared by a Pharmacia statician that showed an increased risk for heart attacks in Celebrex users versus diclofenac users (*see infra* § VII.I.);

(i) safety signals in clinical studies relating to Bextra (specifically, the "047 Study" and "060 and 061 Studies"), as evidenced by, among other things, numerous emails discussing cardiovascular and cardio-renal study results that

acknowledge safety signals and/or Bextra's "Vioxx-like" safety profile (*see infra* § VII.J.);

(j) a decision by Pfizer in March 2002 to "embargo" (conceal) the publication of a Bextra study (the "047 Study") that revealed "Vioxx-like" cardiovascular issues and a cardiovascular (hypertension) safety signal, because publication of the results in a medical journal would damage the product (*see infra* § VII.K.);

(k) the findings from an unpublished study (known as "Study 016") that revealed a six to zero difference in heart attacks in rheumatoid arthritis patients taking Bextra versus patients taking a traditional arthritis medicine or a placebo (*see infra* § VII.L.);

(l) the findings from an unpublished study in patients with chronic cancer pain (known as the "040 Cancer Pain Study") that revealed a nearly two to one increase in serious adverse events for patients taking Bextra versus placebo patients and a statistically significant increased mortality rate for patients taking Bextra versus patients taking placebo (*see infra* § VII.M.);

(m) the results of a clinical study (completed in June 2000) involving Bextra and coronary artery bypass graft patients (known as the "CABG-1 Study") that revealed a cardiovascular safety signal – the complete results of which were not published in a medical journal until late 2004 (*see infra* § VII.O.);

(n) the results of a second clinical study involving Bextra and coronary artery bypass graft patients (known as the "CABG-2 Study"), which was completed in early 2004, that also revealed a cardiovascular safety signal (*see infra* § VII.P.); and

(o) a May 2005 pooled-analysis of all its studies done by Pfizer that showed a seven times, statistically significant increase in cardiovascular risk for Celebrex patients versus patients taking placebo. (*See infra* ¶15).

6. In addition, from the initial approval of Celebrex by the FDA on December 31, 1998, and the subsequent FDA approval of Bextra in 2001, through April 2005, Pfizer's website never publicly provided any warning about the cardiovascular dangers associated with the use of Celebrex and Bextra that it knew existed. Today, Bextra is no longer on the market 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."*** (Emphasis added).

7. In February 2001, FDA Advisory Committee hearings were held to consider the cardiovascular safety of Celebrex and Vioxx. The Feburary 2001 Advisory Committee hearings

resulted in a cardiovascular warning for Vioxx, but not for Celebrex. (As discussed below, Pfizer's submission in advance of those hearings failed to mention the cardiovascular safety results of the Alzheimer's 001 Study or the SUCCESS Study or the July 14, 1999 memo showing statistically significant increases in cardiovascular events for Celebrex users.) This difference in cardiovascular safety profiles between Celebrex and Vioxx gave Pfizer and its Co-Promoter a powerful marketing advantage over Vioxx, and Pfizer and its Co-Promoter exploited the differing cardiovascular safety profiles in their marketing efforts for years thereafter.

8. On September 30, 2004, Merck announced that it was withdrawing Vioxx from the market due to cardiovascular risks associated with the drug. Shortly thereafter, an October 6, 2004 editorial in *The New England Journal of Medicine* questioned the safety of all COX-2 drugs, including Celebrex and Bextra. Pfizer knew it had been concealing the results of numerous studies that revealed cardiovascular risk, including (at this point) the CABG-2 Study results which had been widely disseminated within the Company on March 2, 2004, more than six months before Vioxx was withdrawn. But, after Vioxx was withdrawn from the market, rather than disclosing prior existing, completed studies and other information in its possession that revealed increased cardiovascular risk for Celebrex and Bextra, Pfizer's then CEO (defendant McKinnell) issued a directive to Pfizer's senior managers (including defendants Katen, LaMattina and Feczko, who were senior officers of the Company) to seize upon the withdrawal of Vioxx as a marketing opportunity for its own COX-2 inhibitors. Thus, 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 (emphasis added):

> 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….

9. In fact, Pfizer had privately challenged the cardiovascular safety of Bextra in a private arbitration with Pharmacia in 2001. Pfizer – through defendants McKinnell and Katen – challenged the amounts Pfizer owed Pharmacia for the rights to Bextra under the co-promote agreement between the companies because of Pfizer's concerns about cardiovascular risk with Bextra.

10. Following CEO McKinnell's September 30, 2004 directive, Pfizer released a statement continuing to proclaim that none of its Celebrex studies had ever shown any increased cardiovascular risk, despite, among other things, the fact that the unpublished cardiovascular results from the Alzheimer's 001 Study and SUCCESS Study that had been completed years earlier clearly showed such risk. With respect to handling the "interesting problem" with Bextra, Pfizer's press release following the withdrawal of Vioxx stated only "Bextra's cardiovascular safety profile is also well established in long-term studies," with no mention whatsoever of the cardiovascular safety signal seen in the CABG-1 Study results, which was recognized internally no later than September 2000 and in the CABG-2 Study results disseminated within Pfizer on March 2, 2004, or any of the other cardiovascular issues known to Pfizer.

11. On October 15, 2004, Pfizer finally revealed the cardiovascular safety results in the CABG-2 Study in a letter to health care professionals. Pfizer continued to lie to the market, however, by falsely claiming that the CABG-2 study had only been "recently" completed when, in reality, Pfizer had the results for more than seven months. With respect to Celebrex, Pfizer continued to conceal the results of the Alzheimer's 001 Study, the SUCCESS Study and other information evidencing cardiovascular risk for Celebrex from the market.

12. In December 2004, however, Pfizer began to lose control over the study information it had concealed from the market relating to the increased cardiovascular risks for

Celebrex. On December 17, 2004, the National Institute of Health (not Pfizer) released the results of a study of Celebrex use in treating cancer patients that showed increased cardiovascular risk for Celebrex patients relative to placebo. Once again, rather than admit that it had been concealing evidence of increased cardiovascular risk, Pfizer continued to lie by maintaining publicly that the increased cardiovascular risk seen in this cancer study was an isolated event and that no prior cardiovascular risk signals had been seen in its studies.

13. Privately, however, in October 2004 after the Vioxx withdrawal, the FDA had contacted Pfizer seeking more information regarding the Alzheimer's 001 Study. Pfizer then began preparing a supplement to the report on the Alzheimer's 001 Study that had originally been submitted to the FDA in June 2001. The original report contained the false conclusion that Celebrex was safe and well tolerated in the Alzheimer's study population. In late December 2004, it was Pfizer's plan to supplement the report with additional information about the study, but the supplement was going to retain the original false conclusion and exclude a statement that there had been statistically significant differences in cardiovascular events seen in the study. But the independent safety committee for the Alzheimer's 001 Study (known as the "Data Safety Monitoring Board" or "DSMB") contacted Pfizer just before Pfizer was going to file the supplemental report. In a December 23, 2004 phone conversation with DSMB members and a subsequent letter dated December 24, 2004 from the DSMB, the DSMB "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 were unpublished. Pfizer became concerned that the DSMB might go public with its concerns over the unpublished results of the Alzheimer's 001 Study.

14. After these communications with the DSMB, Pfizer changed the supplemental report it had been planning to submit to the FDA prior to contact with the DSMB. The

supplemental report was filed with the FDA on January 5, 2005. The revised text of the report now stated that there were statistically significant increases for cardiovascular occurrences in the study. In addition, the conclusion in the original report submitted to the FDA in June 2001 which had previously stated (emphasis added) "the results of this study ***demonstrate***" that Celebrex was "generally safe and well tolerated in this elderly, debilitated [Alzheimer's] population," now stated in the supplemental report that (emphasis added) "[t]he safety and tolerability of [Celebrex]…, compared to placebo, in this elderly, debilitated population **cannot be decisively concluded** from this study." Even still, Pfizer failed to fully disclose what it knew regarding the cardiovascular safety of its COX-2 inhibitors. Despite the intense scrutiny and public interest surrounding cardiovascular risk related to the use of COX-2's at this time, Pfizer did not publicly disclose that it had filed a supplemental FDA report.

15. Instead, 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 on January 24, 2005 with no surrounding publicity. The "synopsis" was discovered by a health advocacy group and ultimately brought to light in an early February 2005 *New York Times* article that detailed how Pfizer had concealed these results since 1999. Nevertheless, Defendants continued to misrepresent the cardiovascular safety profile of Celebrex and Bextra through the end of the Class Period in October 2005, claiming that the studies showing increased cardiovascular risk for Celebrex were isolated or aberrations. Pfizer continued to hide the substantial other evidence of cardiovascular risk it had in its possession for years. In fact, Pfizer had in its possession an undisclosed pooled-analysis conducted in May 2005 of all its studies during the Class Period that showed a **seven times, statistically signficant** increase in cardiovascular risk for Celebrex patients. This was <u>never</u> disclosed.

16. Revenues from Celebrex fell from $2.294 billion for the first nine months of 2004 to $1.258 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 over $2 billion compared to the first nine months of 2004, a decline of 63%.

17. As a result of these and other belated disclosures of increased cardiovascular risk and the impact that such risk had on sales of Celebrex and Bextra (discussed more fully below), Pfizer's common stock price fell dramatically throughout the corrective disclosure portion of the Class Period. In this respect, from the close of trading on October 6, 2004, through and including October 19, 2005, the day preceding Pfizer's pre-market opening announcement of third quarter earnings, Pfizer's stock fell from $31.18 per share to $21.90, a decline of $9.28 per share or 29.7%, representing a loss in market capitalization of $68.39 billion.

18. Moreover, in the fall of 2004, the DOJ commenced an investigation into Pfizer's conduct in marketing COX-2 inhibitors. The DOJ investigation culminated in an agreement dated August 31, 2009 between Pfizer and the Government pursuant to which a Pfizer subsidiary pled guilty to a felony violation of the Food, Drug and Cosmetic Act, Title 21, U.S.C. Sections 331(a), 333(a)(2) and 352(f)(1), arising in significant part out of false and misleading safety claims relating to Bextra's cardiovascular safety, and paid a criminal fine of $1,195,000,000 and forfeiture of $105,000,000. In a related deferred prosecution agreement between Pfizer and the DOJ dated August 31, 2009 and approved by Pfizer's board of directors, Pfizer agreed to settle numerous lawsuits filed against it under the federal False Claims Act and other civil liability for a total amount of $1,000,000,000, including payment to federal and state Medicaid fraud control units of $503,000,000 with respect to the unlawful promotion of Bextra. In the related Sentencing Memorandum dated October 9, 2009, the DOJ found, among other things, that (emphasis added):

(a) "[T]he evidence showed that **tolerance of the illegal conduct** by substantial authority personnel **was pervasive throughout the organization**. Indeed,…, the conduct was **not just tolerated** by the senior marketing members within [the Pfizer subsidiary's] headquarters, but also **urged by them**…." and

(b) "[T]he **illegal conduct was pervasive throughout the company** and stemmed from messages created at **high levels** within the national marketing team."

II. JURISDICTION AND VENUE

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

20. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, 28 U.S.C. § 1331 and 28 U.S.C. § 1367.

21. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). Many of the acts and transactions forming the basis for the claims in this action, including the preparation and dissemination of materially false and misleading statements, and the failure to disclose material information, occurred in substantial part in this District. Additionally, the Company's principal executive offices are in New York, New York, where the day-to-day operations of the Company are (and were during the relevant time) directed and managed.

22. In connection with the acts and omissions alleged in this Complaint, the Defendants, directly and/or indirectly, used the means and instrumentalities of interstate commerce, including, without limitation, interstate telephone communications, the mails, and the facilities of the national securities exchanges.

III. THE PARTIES

A. Lead Plaintiff - The Teachers' Retirement System Of Louisiana

23. Lead Plaintiff, The Teachers' Retirement System of Louisiana ("TRSL"), is a public trust fund founded on August 1, 1936, to provide retirement benefits for its members. TRSL is the largest public retirement system in the State of Louisiana, with 153,000 active and inactive members and more than $12.7 billion in assets. TRSL maintains its principal place of business at 8401 United Plaza Boulevard, Baton Rouge, Louisiana.

24. As detailed in the certification contained on Schedule A to the Consolidated Class Action Complaint filed February 16, 2006 ("CAC"), during the Class Period, Lead Plaintiff TRSL purchased a total of 3,749,368 shares of common stock of Pfizer at an aggregate purchase price of $120,805,969 and suffered losses of approximately $26.4 million in connection with those transactions as the misconduct alleged herein was revealed.

B. Other Named Plaintiffs

25. As detailed in her certification attached as Schedule B to the CAC, plaintiff Christine Fleckles purchased shares of Pfizer common stock during the Class Period, including on dates that were contemporaneous with sales of Pfizer stock by certain Defendants named herein, and suffered losses in connection with those transactions as the misconduct alleged herein was revealed.

26. As set forth in her Certification attached as Exhibit 38 to the Declaration of Mary S. Thomas in Support of Lead Plaintiff's Motion for Class Certification and Appointment of Class Representatives dated March 16, 2011, during the Class Period, plaintiff Julie Perusse purchased shares of common stock of Pfizer, including on dates that were contemporaneous with sales of Pfizer stock by certain Defendants named herein, and suffered losses in connection with those transactions as the misconduct alleged herein was revealed.

27. As set forth in his Certification attached as Exhibit 39 to the Declaration of Mary S. Thomas in Support of Lead Plaintiff's Motion for Class Certification and Appointment of Class Representatives dated March 16, 2011, during the Class Period, plaintiff Alden Chace purchased shares of common stock of Pfizer, including on dates that were contemporaneous with sales of Pfizer stock by certain Defendants named herein, and suffered losses in connection with those transactions as the misconduct alleged herein was revealed.

C. Pfizer Inc.

28. Defendant Pfizer is headquartered in New York, with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is the successor-in-interest of Pharmacia, having acquired Pharmacia, including all of Pharmacia's interest in Celebrex and Bextra, in a transaction valued at $60 billion on or about April 16, 2003. Pfizer is also the successor-in-interest of Searle, which was acquired by Pharmacia in 2000. The Company is a research-based, global pharmaceutical company that develops, manufactures and markets prescription medicines for humans and animals, as well as consumer healthcare products. As of November 4, 2005, the Company had approximately 7.37 billion shares outstanding that traded on the NYSE.

D. The Individual Defendants

i. Henry A. McKinnell

29. Henry A. McKinnell ("McKinnell") was Pfizer's Chief Executive Officer from January 2001 through the end of the Class Period and the Chairman of the Board of Directors from May 2001 through the end of the Class Period. As CEO, McKinnell was Pfizer's Principal Executive Officer. Throughout the Class Period, McKinnell also was a Director and the Chairman of the Board's Executive Committee. In addition, from March 10, 2000 through the end of the Class Period, defendant McKinnell was also a member of Pfizer's Leadership Team (the "PLT"),

the highest ranking committee within Pfizer during the Class Period, which had responsibilities that included, among other things, reviewing and approving COX-2 related press releases. He was President of Pfizer from May 1999 to May 2001, and President, Pfizer Pharmaceuticals Group, the principal operating division of the Company, from January 1997 to April 2001. McKinnell was Chief Operating Officer from May 1999 to December 2000 and Executive Vice President from 1992 to 1999. As discussed below, Searle and Pfizer entered into an agreement to jointly promote Celebrex and Bextra in 1998 and in connection with that co-promotion agreement created a joint Searle/Pfizer committee (known as the "Executive Management Committee" or "EMC") to review information relating to the co-promotion alliance and make decisions relating to the drugs (*i.e.*, Celebrex and Bextra) that were the subject of the alliance. McKinnell was on this EMC throughout the Class Period. Among other information, the cardiovascular safety results of Celebrex and Bextra studies were discussed at meetings of this committee, as set forth more fully below.

30. McKinnell was also a member of Pfizer's Development Planning Committee ("DPC"), which consisted of numerous high-level Pfizer executives, including defendants Katen, LaMattina and Feczko. Similar to the EMC, the cardiovascular safety results of Celebrex and Bextra studies were discussed at meetings of this committee, as discussed more fully below..

31. During the Class Period, defendant McKinnell's compensation was tied directly to the performance of the Company. Defendant McKinnell received millions of dollars in annual salary and bonuses plus millions of dollars in awards of common stock, stock options and other compensation under the Company's various executive compensation incentive award plans, plus other lucrative remuneration and compensation, including the use of the Company's transportation, as well as a handsome severance agreement.

32. Defendant McKinnell signed the following documents that the Company filed with the SEC during the Class Period which concealed materially false and misleading statements and/or omitted to state material facts: the 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).

33. Defendant McKinnell signed the Company's SEC filings, as more fully described herein, and certain of these SEC filings contained certifications signed by him pursuant to § 302 of the Sarbanes-Oxley Act of 2002. Based upon such signed certifications, defendant McKinnell was 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, as detailed herein. Defendant McKinnell is primarily liable for the materially false and misleading representations and omissions of material facts contained within these statements.

34. In addition to Pfizer's public filings that he signed, defendant McKinnell made numerous public statements concerning Celebrex and Bextra during the Class Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Celebrex and Bextra's medical and commercial viability posed by the cardiovascular risks that Celebrex and Bextra presented. These false and misleading statements include those made

personally by defendant 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.

35. During the Class Period, defendant McKinnell sold 809,134 shares of Pfizer stock while it was artificially inflated, recognizing more than $29.7 million in proceeds. As set forth in the Section 20A Count below, certain of these sales were made contemporaneously with purchases by Plaintiffs.

ii. John L. LaMattina

36. John L. LaMattina ("LaMattina") was Senior Vice President and President - Pfizer Global Research and Development from October 2003 through the end of the Class Period. Since 1977, when he joined Pfizer, defendant LaMattina held various positions of increasing responsibility in research and development before becoming Senior Vice President of Worldwide Development in 1999. He was named Vice President of Pfizer Inc.; Executive Vice President - Pfizer Global Research and Development; President - Worldwide Research in April 2001. He was named Vice President of Pfizer Inc.; Executive Vice President - Pfizer Global Research and Development; President - Worldwide Research and Technology Alliances in May 2002. From 2003 through the end of the Class Period, defendant LaMattina was a member of the Pfizer Leadership Team.

37. As discussed below, defendant LaMattina was a member of the DPC, which consisted of numerous high-level Pfizer executives, including defendants McKinnell, Katen and Feczko. The cardiovascular safety results of Celebrex and Bextra studies were discussed at meetings of this committee, as set forth more fully below.

38. In addition, defendant LaMattina, along with defendant Feczko, was also a member of the Global Development Review Committee ("GDRC"), a group that reviewed "late

phase and early marketed products in the pipeline," according to defendant Feczko. The cardiovascular safety results of Celebrex and Bextra studies were also discussed at meetings of this committee, as set forth more fully below.

39. During the Class Period, defendant LaMattina's compensation was tied directly to the performance of the Company, and over the years, including during the Class Period, he received millions of dollars in annual salary and bonuses, restricted stock and stock options and other lucrative compensation under the Company's various executive compensation and incentive plans. During the Class Period, defendant LaMattina sold 67,073 shares of Pfizer stock while it was artificially inflated, recognizing more than $1.8 million in proceeds. As set forth in the Section 20A Count below, certain of these sales were made contemporaneously with purchases by Plaintiffs.

iii. Karen L. Katen

40. Karen L. Katen ("Katen") was appointed Vice Chairman and President – Pfizer Human Health in March 2005 and remained in that position throughout the remainder of the Class Period. As Vice Chairman and a senior executive officer, defendant Katen reported directly to defendant McKinnell. She started with Pfizer in 1974, and moved up the ranks to top senior executive positions. From June 1995 to July 2002, she was President of Pfizer's U.S. Pharmaceuticals Group and from May 1999 to April 2001 she was Senior Vice President of the Company. From April 2001 to March 2005, defendant Katen was Executive Vice President and President of Pfizer Global Pharmaceuticals, the Company's worldwide pharmaceutical organization. During the Class Period, defendant Katen was a member of the Pfizer Executive Committee and a member of the PLT. As head of Human Health — Pfizer's principal operating group — during the Class Period, she led the portion of Pfizer's business responsible for the discovery, development, manufacture, distribution and commercialization of prescription

medicines. From the beginning, defendant Katen was involved in the marketing of Celebrex and Bextra as head of the Celebrex and Bextra brand teams. In that position, defendant Katen was responsible for anything that touched upon the brand's sales force, sales aids, and product promotion (including its prescription label).

41. Katen, along with McKinnell, was a member of the EMC throughout the Class Period. Among other information, the cardiovascular safety results of Celebrex and Bextra studies were discussed at meetings of this committee, as discussed more fully below..

42. During the Class Period, Katen's compensation was tied directly to the performance of the Company. As one of Pfizer's most senior executives during the Class Period, Katen received millions of dollars in annual salary, bonuses, and awards of common stock, stock options and other compensation and lucrative benefits from the Company under the Company's various executive compensation and incentive plans. In this respect, from 2000 through her exit from the Company in 2007, defendant Katen's compensation totaled more than $18 million and she had access to perquesites including, Pfizer's corporate jet and helicopter, company apartments around the world, and chauffeured company cars. In addition, when she left in 2007, Katen also received a severance payment of more than $5.5 million and a pension valued at nearly $40 million.

43. As detailed herein, Katen made numerous public statements concerning Celebrex and Bextra during the Class Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Celebrex and Bextra's medical and commercial viability posed by the cardiovascular risks that Celebrex and Bextra presented. These false and misleading statements include those made personally by Katen, as well as those made in her presence or at her instruction, including those detailed below on 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.

44. During the Class Period, defendant Katen sold 372,536 shares of Pfizer stock while it was artificially inflated, recognizing more than $13.2 million in proceeds. As set forth in the Section 20A Count below, certain of these sales were made contemporaneously with purchases by Plaintiffs.

iv. Joseph M. Feczko

45. Joseph M. Feczko ("Feczko") was, during the Class Period, President of Worldwide Development. He also served as Executive Vice President of Pfizer Global Research and Development and Senior Vice President, Medical & Regulatory Operations of Pfizer Pharmaceuticals Group during the Class Period. Defendant Feczko was a member of the Pfizer Pharmaceuticals Group Leadership Team during 2000. He was named Chief Medical Officer on February 24, 2005 and remained in that position through the end of the Class Period. As President of Worldwide Development and Chief Medical Officer, Feczko reported directly to defendants LaMattina and Katen.

46. As discussed below, defendant Feczko was a member of the DPC, which consisted of numerous high-level Pfizer executives, including defendants McKinnell, Katen and LaMattina. The cardiovascular safety results of Celebrex and Bextra studies were discussed at meetings of this committee, as discussed more fully below. In addition, defendant Feczko, along with defendant LaMattina, was also a member of the GDRC. The cardiovascular safety results of Celebrex and Bextra studies were discussed at meetings of this committee, as discussed more fully below.

47. Defendant Feczko also had responsibilities for Pfizer's policies regarding publication of study results, including Pfizer's policy "commit[ting] to timely communication of meaningful results of controlled clinical trials of marketed or investigational products that are approved for marketing, regardless of outcome," and, indeed, distributed those policies to Pfizer

employees worldwide. As discussed further below, defendant Feczko and Pfizer knowingly violated those policies with respect to studies relating to Celebrex and Bextra.

48. Defendant Feczko, along with defendants McKinnell and Katen, was also a member of the PLT, which had responsibilities that included, among other things, reviewing and approving COX-2 related press releases.

49. As detailed herein, Feczko made numerous public statements concerning Celebrex and Bextra during the Class Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Celebrex and Bextra's medical and commercial viability posed by the cardiovascular risks that Celebrex and Bextra presented. These false and misleading statements include those made personally by Feczko, as well as those made in his presence or at his instruction, including those detailed below on 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.

v. Gail Cawkwell

50. Gail Cawkwell ("Cawkwell") joined Pfizer in December 2000. From December 2000 to February 2001, she was Medical Director, Celebrex, Major Markets. From February 2001 to June 2003, she was Medical Director, valdecoxib. From June 2003 through the end of the Class Period, she was Medical Team Leader and Full Development Team Leader, Celecoxib. Cawkwell indirectly reported to defendant Feczko.

51. As discussed further below, defendant Cawkwell was a member of the "Valdecoxib Joint Product Team," which was comprised of at least 14 Pfizer executives and at least 18 Pharmacia executives. She was also a member of the Bextra Publications Working Group, a joint Pfizer/Pharmacia group comprised of Pfizer and Pharmcia employees from, among others, the marketing, medical, research and development and public relations departments of the respective companies, that made recommendations and decisions concerning when and whether to

publish studies related to Bextra. Defendant Cawkwell also had substantial responsibilities relating to Celebrex as further detailed herein.

52. As detailed herein, Cawkwell made numerous public statements concerning Celebrex and Bextra during the Class Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Celebrex and Bextra's medical and commercial viability posed by the cardiovascular risks that Celebrex and Bextra presented. These false and misleading statements include those made personally by Cawkwell, as well as those made in her presence or at her instruction, including those detailed below on 10/1/04, 10/6/04, 10/19/04, 11/12/04 and 2/1//05.

IV. GROUP PLEADING

53. Defendants McKinnell, LaMattina, Katen, Feczko and Cawkwell will be referred to herein as the "Individual Defendants." As officers, directors, chief scientists, controlling persons and/or spokespersons of a publicly-held company that is registered with the SEC under the federal securities laws and whose common stock trades on the NYSE, and governed by the provisions of the federal securities laws, each of the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to the financial reporting and the publicly-reported quarterly and annual results of operations of Pfizer, so that the market price of the Company's publicly-traded securities, including its common stock, would be based upon truthful, accurate and complete information. In this respect, it was typical that Pfizer's leadership team, which included defendants McKinnell, Katen, LaMattina and Feczko, among others, would receive, review and approve all press releases, public statements and public filings of Pfizer or Pfizer personel with respect to Celebrex or Bextra. Likewise, these same individuals had access to and had the ability to review public statements and filings made by its Co-Promoter with respect to Celebrex and Bextra.

54. The Individual Defendants are liable for the materially false and misleading statements and omissions of material fact in Pfizer's SEC filings and press releases as such statements represent "group-published" information, disseminated to the public as a result of the collective actions of these Defendants. It is appropriate to treat the Individual Defendants as a group and to presume that the false and misleading information conveyed in the public filings, press releases and other publications, as alleged herein, are the collective actions of this narrowly defined group of Defendants. 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 day-to-day operations and were privy to confidential non-public information concerning the operations of Pfizer, as alleged herein. The Individual Defendants were involved in drafting, reviewing and/or disseminating the false and misleading financial statements that were issued by Pfizer, approved or ratified these statements and, therefore, adopted them as their own.

55. Under the rules and regulations promulgated by the SEC under the Exchange Act, specifically Item 303 of Regulation S-K, the Individual Defendants also had a duty to report all trends, demands or uncertainties that were reasonably likely to impact Pfizer's: (1) revenues; (2) expenses; and (3) previously reported financial information, such that it would be indicative of future operating results. As set forth more fully below, the misrepresentations and omissions of the Individual Defendants during the Class Period violated these specific requirements and obligations as well as their duties and obligations pursuant to the Exchange Act.

56. By reason of their positions with the Company, 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 including non-public information concerning Celebrex and Bextra. The Individual Defendants were, therefore, responsible for the

truthfulness and accuracy of the Company's public reports, SEC filings and press releases referred to in this Complaint and knew or recklessly disregarded the falsity of such documents and statements.

57. The Individual Defendants were also responsible for the truthfulness and accuracy of the Company's public statements regarding the safety, efficacy and medical and commercial viability and/or risk profile of both Celebrex and Bextra.

58. The Individual Defendants participated in preparing and/or approving the public reports and other statements and communications described above and discussed more fully herein. 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 and/or would cause the price of Pfizer's common stock to become artificially inflated. Each of the Individual Defendants acted knowingly or in such a reckless manner as to constitute a fraud and deceit upon Plaintiffs.

V. RELEVANT SCIENTIFIC AND REGULATORY PRINCIPLES

A. Statistical Principles That Guide A Drug Safety Inquiry

59. According to the MANUAL ON SCIENTIFIC EVIDENCE, to determine whether a drug is associated with a safety problem, epidemiologists rely on three main types of information: anecdotal evidence, observational studies, and controlled experiments. Of these, controlled experiments, also called randomized trials, or clinical trials, are considered the "gold standard" for assessing causal relationships. This is because the researcher has the ability to control key variables, such as dose and length of exposure that impact the issues being studied.

60. Epidemiologists utilize the concept of relative risk (also called risk ratio - "RR") to quantify the magnitude of risk created by a drug. Relative risk is the probability of a specified outcome in one group (*e.g.*, heart attacks observed in the population exposed to a drug) divided by

the probability of the outcome in another group (*e.g.*, heart attacks observed in population receiving a placebo). If the relative risk equals 1.0, the risk in exposed individuals is the same as the risk in unexposed individuals. There is no association between exposure to the agent and disease or adverse event. In contrast, a relative risk of 4.0 indicates that the risk of disease or adverse event is four times as high as the risk in the unexposed group.

61. When less than an entire population is studied, there is always the possibility that the results that are seen are due to random error. The technique used most often to assess and control for random error is statistical significance. Statistical significance begins with calculation of a "p-value." A p-value represents the probability that a positive association would result from random error if in fact no association were present. An outcome is statistically significant when the observed p-value for the study falls below the pre-selected significance level. The most-frequently utilized p-value is ".05," although other thresholds are sometimes also used to calculate p-values. A p-value of .05 means that the probability is 5% of observing a result (usually an RR) at least as large as that found in the study when, in truth, there is no association. This p-value usually is selected based on convention, and not because it imparts any particular meaning about the importance of a study's findings.

B. The Appropriate Scientific Standard For Assessing Drug Safety

62. To demonstrate safety and efficacy, a pharmaceutical manufacturer is required to conduct preclinical and clinical studies in support of its pre-marketing New Drug Application (or "NDA"). *See* 21 C.F.R. §§ 314.50(d)(2) and (3). These trials are designed and conducted by pharmaceutical manufacturers. *See* 21 C.R.F. § 314.50(e) and 21 C.F.R. § 201.57.

1. Differences Between Safety And Efficacy Studies

63. At the pre-approval phase of drug development, most clinical studies are directed toward establishing effectiveness of treatment. Due to certain limitations inherent in efficacy

study design – primarily the relatively small size of the studies – data gathered from these efficacy studies may not be very informative with respect to drug safety. As Pfizer has acknowledged on its website, "preapproval studies are rarely large enough to detect small differences in the risk of common adverse events or to reliably estimate the risk of rare events."

64. In statistical terms, the ability of a study to detect a "real" effect, if one is present, is often referred to as the "power" of a study, or the probability that the study will lead to the identification of a true effect, as opposed to being the result of chance. Statistical power is influenced by the size of the treatment effect, the number of study participants, and the duration of the study; the power of a study is "low" if the treatment effect is small, few patients are studied and/or the trial duration is short. While efficacy studies, which test an endpoint that occurs with *high frequency in smaller sample sizes,* may potentially reveal safety issues, they are simply not powered to ascertain drug safety, which, because adverse events are rarer, are more likely to be detected by following a larger population over a longer period of time. Relying on studies with low power to detect safety signals can have serious consequences with respect to errors.

65. In statistical analyses, there are two types of errors that must be addressed. A Type I error occurs when researchers conclude that a drug or treatment is better than a control when, in reality, it is not – a false positive. Efficacy studies typically focus on controlling Type I errors, because too high a Type I error can lead to the acceptance of ineffective drugs. A Type II error, on the other hand, occurs when researchers conclude that a treatment effect or difference does not exist when, in reality, it does – a false negative. With respect to drug safety issues, Type II errors are of greater concern, because researchers do not want to claim a drug is safe, *i.e.,* there is no difference in safety between a drug and a comparator, when in fact there is a safety difference. When evaluating drug safety, it is appropriate to focus on studies with high power to

detect adverse events, *i.e.*, trials of longer duration with larger sample sizes, because these studies are more likely to reveal safety problems.

66. During the Class Period (and prior to a change in the law in 2007, discussed below), the FDA would initially approve an NDA and a product's "launch" label. However, after approval, pharmaceutical companies (not the FDA) were responsible for updating a drug's label to include new safety information. A provision in the Code of Federal Regulations provides that "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.57e. It was the duty of the pharmaceutical company, not the FDA, to detect new safety signals associated with the drug's use and report them to the public when a potential danger exists.

2. The Importance Of Detecting And Investigating Signals

67. As problems with a new drug may manifest in only a few adverse events in a clinical trial, the first indication of a harmful drug effect is referred to as a "safety signal." According to the FDA, a safety signal refers to a concern about an excess of adverse events compared to what would be expected to be associated with a product's use. Pfizer's website has acknowledged 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.

Whether a safety signal warrants further investigation (or disclosure) does not hinge on its "statistical significance," *i.e.* probability that the adverse event is due to chance or causal association. To the contrary, according to the book *Drug Truths, Dispelling the Myths About Pharma R&D*, authored by defendant LaMattina: "It is important that, when safety signals are seen with new drugs, these get properly communicated broadly to patients and physicians."

68. The FDA does not require a statistically significant association between a drug and a given effect to warrant a label change such as a precaution or warning. *See* 21 C.F.R. § 201.57(e) ("The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."). Nor does the Agency require a statistically significant association before withdrawing a drug from market.

69. Moreover, to the extent that a safety signal occurs in a clinical trial designed to assess the efficacy of treatment, such as those conducted prior to FDA approval of a drug, it is unlikely that there would be a sufficient number of adverse events to achieve significance at the 95 percent level. Therefore, lack of statistical significance should not be mistaken either for an absence of increased risk of harm or confirmation that a drug is safe.

70. A pharmaceutical company can update a product's label without approval by the FDA. Indeed, during the Class Period, the FDA lacked the authority to require a pharmaceutical company to make a label change (though FDA now has this power derived from legislation enacted in 2007, after the Class Period). In addition, pharmaceutical companies can (and should) inform health care professionals about new safety information relating to a drug using so-called "Dear Health Care Professional" letters that provide the relevant information. Such letters do not require FDA approval.

VI. BACKGROUND ON CELEBREX AND BEXTRA

71. Throughout the Class Period, Pfizer and the Individual Defendants deliberately pursued a fraudulent scheme to make false and misleading statements and to omit disclosing material facts concerning Celebrex and Bextra's safety, and medical and commercial viability. (*See infra* Section IX.). During this time, the Defendants knew or recklessly disregarded statistically significant data, "unfavorable trends" and additional substantial evidence

demonstrating that Celebrex and Bextra posed increased cardiovascular risks. (*See infra* Section VII.). Many of the details of the Defendants' fraud have emerged or were revealed in late 2004 and 2005, following announcements by the Company and others. (*See infra* Sections VII.Q.-VII.V.; XIV.).

A. The Need For An Alternative Painkiller

72. Conditions such as arthritis cause severe and/or chronic pain. Prior to 1999, persons suffering chronic pain and inflammation turned to certain "NSAIDs" (which is an acronym for non-steroidal, anti-inflammatory drugs), such as aspirin, ibuprofen, and naproxen for relief. People taking NSAIDs over a protracted time period, however, often developed stomach ulcers and other gastrointestinal problems. An effective pain reliever that could be taken over a longer period of time without these side effects would presumptively capture a large share of the market.

73. Traditional NSAIDs effectively block two enzymes: Cyclooxygenase 1 ("COX-1"); and Cyclooxygenase 2 ("COX-2"). COX-1 is a protein that acts as an enzyme to catalyze (speed up) the production of prostaglandins (chemical messengers) within the stomach, which promote the production of the natural mucus lining that protects the inner stomach. COX-2 is a protein that acts as an enzyme and specifically catalyzes the production of certain prostaglandins responsible for promoting inflammation. When COX-2 activity is blocked or "inhibited", inflammation is reduced. Because traditional NSAIDs suppress the pain-causing enzyme COX-2, but also suppress the COX-1 enzyme, they tend to cause harmful gastrointestinal side effects. .

B. The Development, Approval And Launch Of Celebrex

74. The development, approval and launch of Celebrex came down to an all-out race to market between Searle and pharmaceutical giant Merck, which began in the 1990s with the discovery of two forms of cyclooxygenase. A story appearing on the *Dow Jones Newswire*, on

May 21, 1999, captured the importance of the discovery to pharmaceutical companies: "The battle for this summer's blockbuster may not occur in movie theaters, but instead in the corner drugstore." The article was referring to the battle between Celebrex and Merck's Vioxx for COX-2 inhibitor supremacy.

75. Capitalizing on the market opportunity created by the discovery of the COX-2 enzyme, Searle, with the assistance of Dr. Philip Needleman (who was head of Research & Development at Searle and, later, Pharmacia) launched an all-out effort to develop a COX-2 selective inhibitor before Merck. Dr. Needleman had left his research laboratory to join Searle to pursue this once-in-a-lifetime opportunity to create the new drug. Deemed Searle's "Manhattan Project," Needleman commandeered one-third of all medicinal chemists at Searle for the project.

76. Financial analysts examining the COX-2 market predicted that the company that won the race to the market would reap rewards of billions. However, there was a big potential downside for Searle. "If [Searle] failed, it would be serious, serious trouble for Searle," Needleman said. "In many ways we bet the company on the drug." With so much at stake, Searle management mapped out what the key players needed to get done each day. Needleman even went back to Searle's parent, Monsanto and Company ("Monsanto"), for an emergency infusion of millions of extra dollars to fund further research of these drugs.

77. Early on, Searle recognized that it incapable of developing and launching Celebrex fast enough to reap the full benefits of the drug's commercial potential. Thus, Searle recruited Pfizer as a marketing partner, who happened to be Merck's most formidable and aggressive rival.

78. On February 18, 1998, Searle and Pfizer jointly announced that they entered into an agreement covering the co-promotion and development of Searle's Celebrex ("Co-Promotion Agreement"). By operation of the Co-Promotion Agreement, Pfizer had the ability to review and

approve all press releases issued by the Co-Promoter regarding Celebrex. By announcing the Co-Promotion Agreement to the investing public, Defendants assured that any subsequent statements made by either Pfizer or Searle related to Celebrex, would knowingly impact the results and expectations for both companies.

79. To facilitate the Co-Promotion Agreement, in 1998, Searle and Pfizer created a joint committee comprised of their top executives, which included defendant McKinnell (who at the time was Executive Vice President of the Pfizer Pharmaceuticals Group and later became Pfizer's CEO), defendant Katen (who at the time was a senior executive with responsibilities for both the international and U.S. pharmaceutical businesses) and John Niblack (another Pfizer Executive Vice President who reported directly to Pfizer's then-CEO) from Pfizer and Phillip Needleman and Richard DeSchutter, the Co-Presidents of Searle's research and development operations. This committee was known as the "Executive Management Committee" or "EMC." McKinnell and Katen remained on the EMC throughout the Class Period and Needleman remained on the EMC through his retirement in 2003 when Pharmacia merged with Pfizer. The members of the EMC were apprised of all high level strategic planning with respect to Celebrex and Bextra.

80. As noted earlier, Pfizer had a separate committee -- the Development Planning Committee or "DPC" -- which was comprised of Pfizer's top-level executives. This committee frequently considered matters relating to Celebrex and Bextra internally at Pfizer. Defendants McKinnell and Katen (who were also EMC committee members), defendants Feczko and LaMattina and numerous other of the most senior executives from Pfizer, were members of the DPC during the relevant time period.

81. The new drug approval application for Celebrex was filed with the FDA on or about June 29, 1998, and received FDA approval on or about December 31, 1998. Celebrex was

the first COX-2 inhibitor to obtain regulatory approval. Merck's Vioxx was not approved by the FDA until almost a year later on May 20, 1999.

82. The FDA approved Celebrex for use by prescription in treating pain and inflammation caused by osteoarthritis ("OA"), a type of arthritis caused by wear and tear on the body's bones and joints, and adult rheumatoid arthritis ("RA"), which is an autoimmune disease that attacks healthy joint tissues, causing inflammation and joint damage. Celebrex was later approved for the treatment of acute pain in adults (such as pain from strains and sprains) or pain after surgery, as well as for the treatment of primary dysmenorrhea (painful menstrual cramps).

83. Celebrex, the first COX-2 inhibitor to hit the market, was launched to the public in January 1999.

84. On December 19, 1999, Monsanto (Searle's parent company) and Pharmacia announced a definitive agreement to merge. Pharmacia acquired the rights to Celebrex (and Bextra) in the merger with Monsanto. Following the merger, Pharmacia succeeded to the rights of Searle in its agreement with Pfizer covering the co-promotion and development of Celebrex (and later Bextra) and, as described herein, Pfizer continued to either jointly participate in or adopt all Pharmacia statements related to Celebrex, as well as review and approve Pharmacia's statements prior to their release.

85. On July 15, 2002, Pfizer and Pharmacia jointly announced that they signed a definitive agreement providing for Pfizer to acquire Pharmacia in a stock-for-stock transaction valued at $60 billion. Pharmacia then spun-off its remaining ownership of Monsanto to its current shareholders, and Pfizer's acquisition of Pharmacia was completed on April 16, 2003. In the acquisition of Pharmacia, Pfizer gained sole control over Celebrex (and Bextra). As defendant McKinnell acknowledged in an internal communication to Pfizer employees dated July 15, 2002, prior to the merger Pfizer and Pharmacia had acted as partners. McKinnell stated: "We know

Pharmacia. We have been partners for the past five years on the COX-2 inhibitors Celebrex and Bextra. Together, we built the first COX-2 family of products…."

86. Unless otherwise stated, Searle, Monsanto, Pharmacia and Pfizer are sometimes hereinafter collectively referred to as "Pfizer."

C. The Development, Approval and Launch Of Bextra

87. Bextra is another COX-2 selective inhibitor discovered by the Searle division of Monsanto in the late 1990s to combat, *inter alia*, the effects of OA and adult RA. Bextra was to be launched and marketed for acute pain (i.e., post-surgery setting) and thus, was expected to be promoted as a stronger, more potent COX-2 inhibitor than Celebrex.

88. Bextra was initially co-promoted and developed by Pfizer and Searle pursuant to the agreement announced by Pfizer and Searle on February 18, 1998. By operation of the Co-Promotion Agreement, Pfizer had the ability to review and approve all press releases issued by the Co-Promoter regarding Bextra. By announcing the Co-Promotion Agreement to the investing public, Defendants assured that any subsequent statements made by either Pfizer or Searle related to Bextra, would knowingly impact the results and expectations for both companies.

89. Parecoxib was the injectible form of Bextra. After injection into the bloodstream, parecoxib quickly metabolizes into valdecoxib (*i.e.*, Bextra). Although Bextra was part of the co-promotion agreement between Searle and Pfizer, parecoxib was not. As detailed below, however, Pharmacia filed a new drug application for parecoxib which was rejected by the FDA due to cardiovascular safety concerns. This rejection was the subject of much discussion within Pfizer, particularly the impact it would have on Bextra.

90. Following the merger between Monsanto and Pharmacia on March 31, 2000, Pharmacia acquired the rights to Bextra. Pharmacia continued Searle's agreement with Pfizer covering the co-promotion and development of Bextra.

91. On or about January 16, 2001, the new drug approval application for Bextra was filed with the FDA.

92. On or about November 16, 2001, the FDA approved Bextra for use by prescription in treating OA, adult RA and primary dysmenorrhea. The FDA denied approval, however, for treatment of acute pain based in part on the results of the CABG-1 Study. The denial of approval for acute pain was highly significant. While Vioxx was approved to treat acute pain, Celebrex (at this time) was not. Indeed, as discussed below, Pfizer's internal documents reveal that the lack of an acute pain indication would significantly reduce anticipated prescriptions for Bextra. (Although, as noted above and discussed further below, Pharmacia and Pfizer, in complete disregard for the FDA's denial of an acute pain indication, knowingly marketed Bextra for acute pain and in so doing made repeated false and misleading claims about Bextra's cardiovascular safety and other safety attributes, which led to the aforementioned guilty plea and record-setting criminal fines and penalties.).

93. Despite the lack of an acute pain indication, Bextra was successfully launched in April 2002. At the time, Bextra was co-promoted and developed by Pfizer and Pharmacia.

94. After Pfizer's acquisition of Pharmacia, which was completed on April 16, 2003, Pfizer gained sole control over the promotion and development of Bextra and was now directly responsible for any false and misleading statements made regarding Bextra by its now current employees, regardless of whether Pfizer implicitly or explicitly adopted such statements as its own, as it had in the past prior to the merger..

D. Pfizer's Financial Dependency On Celebrex And Bextra

95. Pfizer's financial success and future prospects depended on Celebrex and Bextra becoming "blockbuster" drugs. Within the five years after Celebrex and Bextra's expected arrival on the market in 1999-2002, Pfizer faced patent expiration dates for several of its best-selling

drugs and the resulting loss of at least $4.7 billion in annual revenues to generic competition. Profitable Pfizer drugs scheduled to lose patent protection during or shortly after the Class Period included Zithromax, an antibiotic that accounted for over $1.3 billion in sales in 1999, $1.3 billion in 2000, and $1.5 billion in 2001, the patent for which would expire in 2005, and Zoloft, which accounted for over $1.9 billion in sales in 1999, $2.1 billion in 2000, and $2.3 billion in 2001, the patent for which was set to expire in 2006. In comparison, the patent for Celebrex will not expire until 2013. The patent for Bextra will not expire until 2015.

96. Pfizer needed Celebrex and Bextra to make up for these soon-to-be-lost sales from these blockbuster drugs. As a result, Pfizer agreed to co-promote the drugs and then aggressively pursued a merger with Pharmacia to secure continued revenues and earnings past 2010. Dr. Tadeusz J. Szuba's article entitled "Merger Mania" published in the *Journal of the Chamber of Pharmacists* explained that, in order for Pfizer to sustain its revenues and earnings following the expiration of certain patents, it was critical for Pfizer "to go forward with [the] merger with Pharmacia."

97. Pfizer's merger with Pharmacia highlights Pfizer's motive to push sales at any cost. And Peter B. Corr, then the Executive Vice President of Pfizer Global Research and Development, noted in a September 8, 2002 *New York Times* article, in regard to Pfizer's merger with Pharmacia: "you need the power of scale to exploit the science."

E. Success Of Pfizer's COX-2 Launches

98. Pfizer's COX-2 product launches were extremely successful. Celebrex, in fact, is the most successful product launch in the history of the pharmaceutical industry. 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, approximately $2.5 billion in 2003, and $3.3 billion in 2004. Bextra also had a successful debut. Bextra generated revenues of $470 million in 2002, approximately $875 million

in 2003, and over $1.2 billion in 2004. The joint sales of Celebrex and Bextra constituted between 6% and 11% of Pfizer's total sales from 2002 to 2004.

99. Pfizer received a significant portion of the revenue resulting from sales of Celebrex and Bextra until 2003, when Pfizer acquired Pharmacia and its roster of drugs, including Celebrex and Bextra, for $60 billion. After that, all revenue from the sale of Celebrex and Bextra went exclusively to Pfizer. Together, Celebrex and Bextra accounted for approximately 8.7% of Pfizer's revenue in 2004, totaling over $4.5 billion.

100. During the Class Period, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts. Pfizer and its Co-Promoter continuously touted the cardiovascular safety of Celebrex and Bextra, even though the Defendants knew or recklessly disregarded from their own studies that both Celebrex and Bextra presented significant cardiovascular risks. The Defendants further touted the financial performance of both drugs and the importance of such drugs to Pfizer's overall financial results, suggesting that such performance was likely to continue into the future, without disclosing that, had they made publicly available all of the information known to Pfizer from its testing regarding the safety issues raised by these drugs, neither drug would have been such a significant contributor to Pfizer's past and future financial performance.

VII. DEFENDANTS' FRAUDULENT SCHEME

101. As described in detail above and further below, Defendants have known for many years that Celebrex and Bextra increase the risk for cardiovascular adverse events for the users of those drugs. Nonetheless, from the time it first sought approval of Celebrex in 1998, until late 2004 and 2005, Pfizer continuously touted to the public the safety and efficacy of Celebrex and Bextra in order to ensure that the sales of those drugs would provide the level of "blockbuster" revenues that would increase Pfizer's stock price.

102. After Vioxx received FDA approval in mid-1999, the battle for supremacy in the COX-2 market began. Beginning in 2000, negative information was released to the market about the cardiovascular safety profile of Vioxx. Later, after FDA advisory committee hearings in February 2001 (discussed more fully below), a cardiovascular warning was placed on the label for Vioxx (but not Celebrex). Thus, differentiating the cardiovascular safety profile of Celebrex from Vioxx was a key to the Celebrex marketing strategy. Pfizer and its Co-Promoter vehemently denied that cardiovascular risk was a "class effect" of these drugs (*i.e.*, that increased cardiovascular risk was an attribute of all COX-2 drugs) and insisted that Celebrex (and later Bextra) was different from Vioxx.

103. It was not until late in 2004 and 2005, after Vioxx was withdrawn from the market due to cardiovascular dangers, that the truth about Celebrex and Bextra gradually came out in a series of partial disclosures, that were coupled with misinformation and denials from Pfizer and finally, undeniable truths. As a result, Pfizer's revenues from Celebrex and Bextra fell sharply and its share price declined.

A. The June 1998 Finding of Statistical Significance For Heart Attacks in the Elderly

104. Defendants knew as early as June 1998 that elderly patients would be (and ultimately were) one of the largest groups of patients who were likely to use Celebrex. Defendants also knew that increasing age is a risk factor for cardiovascular adverse events and, thus, that elderly patients would typically be at greater risk for cardiovascular adverse events than younger patients.

105. The Integrated Summary of Safety ("ISS") for Celecoxib -- submitted to the FDA in June 1998 in support of the new drug application for celecoxib – analyzes, among other things, the clinical studies that had then been completed relating to Celebrex. Although the ISS was prepared by Searle, Pfizer received a copy of the ISS. Indeed, Dr. Weiner placed the ISS on his

laptop computer for purposes of analyzing the data and the ISS was otherwise accessible to Pfizer's management (as were all clinical studies relating to Celebrex and Bextra). Indeed, at least some of the data underlying the ISS was reviewed by Pfizer during the due diligence review Pfizer conducted in connection with deciding whether to enter into a co-promotion agreement with Searle in the first place.

106. The ISS reveals that Searle and Pfizer knew that there were statistically significant differences between elderly Celecoxib patients and placebo patients on a key element of cardiovascular risk – heart attacks. In a section of the ISS entitled "Cardiovascular Adverse Events in the Elderly," the ISS examined heart attacks in elderly patients (i.e., patients 65 years of age or older), who (as noted above) are generally more susceptible to adverse cardiovascular events due to their age. The ISS states (emphasis added):

> Review of the subgroup analyses of adverse events by age…reveals an apparent **excess of myocardial infarction (MI) in celecoxib-treated elderly patients**. There were 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. Only **the difference between celecoxib and placebo was statistically significant (p=0.046)**.

B. The Fitzgerald Hypothesis

107. Within six months of the submission of the ISS, on December 31, 1998, Celebrex was approved by the FDA. Sales of the drug began in 1999. In early 1999, however, information came to light that threatened to derail the burgeoning success of Celebrex's launch. Doctors associated with the University of Pennsylvania published the results of a study they conducted in January 1999 that theorized that COX-2 inhibitors such as Celebrex may elevate cardiovascular risk. This study would become known as the "Fitzgerald Hypothesis," named for one of the authors of the study, Professor Garrett A. Fitzgerald, M.D.

108. Searle and Pfizer shot back instantly to squelch concerns that the marketplace might have about cardiovascular risk with Celebrex. For example, Searle and Pfizer drafted a

joint statement dated January 15, 1999 in response to the article that states (bolded and italicized emphasis in original):

> The University of Pennsylvania Medical Center distributed a press release on January 14, 1999, which asserts that "Cox-2 inhibitors," including Celebrex, may elevate cardiovascular risk….In fact, Searle commissioned this study from the University, which was completed in May 1996. Furthermore, Searle submitted the data from this study to the…(FDA) in the summer of 1998 for its full evaluation, as part of Celebrex's New Drug Application (NDA). During its extensive review of Celebrex's NDA, the FDA did not voice concerns over these data, nor did it raise them as an issue at the FDA Arthritis Advisory Committee meeting in December. Moreover, FDA's recent approval of Celebrex indicates tha the agency has found this therapy to be safe and effective, when used in accordance with prescribing information. **In Searle's extensive clinical experience, involving thousands of patients, there was *no* incidence of serious cardiovascular events that could be attributed to Celebrex…..**

109. Subsequently, this joint message was communicated to the press via interviews with Searle personnel. Thus, for example, a January 19, 1999 article entitled "New painkiller increases cardiac risk, study shows" in *The Globe and Mail (Canada)* reported that (emphasis added):

> Any suggestion [in the Fitzgerald Hypothesis] that the drug [*i.e.*, Celebrex] could increase cardiac problems is bound to be a significant concern....The drug's primary users are expected to be arthritis sufferers, largely elderly people who, because of their age, already have a higher risk of heart disease. But…Searle, which sponsored the Pennsylvania study [that resulted in the Fitzgerald Hypothesis], presented the findings to the U.S. Food and Drug Administration. And despite the presentation, the FDA fast-tracked approval of Celebrex on Dec. 31, [1998]. Searle spokesperson Scarlett Foster, says the concerns should not be overblown. 'This is only a hypothesis based on tests that were only done invitro, done only in the lab, but *we've done clinical trials with more than 13,000 people' Ms. Foster said in an interview yesterday.* **'The trials showed no elevated heart problems**.'"

110. On January 20, 1999, Dr. Needleman also sent an email to, among others, Steve Geis, who at that time was a senior member of Searle's clinical trial's department and also was a member of joint Pfizer/Searle committees relating to COX-2 inhibitors and/or made medical presentations at meetings of such joint committees commenting on the Fitzgerald Hypothesis. The email from Dr. Needleman to Dr. Geis had the subject line: "U Penn issue – plan of action,"

and was sent to outline the "plan of action" that had been developed to address the issues raised by the Fitzgerald Hypothesis. The email states (emphasis added): "Regarding the Celebrex/CV-risk issue raised by U Penn: Peter Isakson and Scarlett Foster have both had conversations with Garrett Fitzgerald (lead author of the U Penn study, and U Penn central media spokesperson), "**urging him to stop delivering unbalanced information to the press**." The email continues with another part of the plan: "We will also post consumer-friendly Q&As, which we are currently developing to Monsanto's website" and refers to creation of a "task force" from Searle, Pfizer and Chandler-Cicco Agency [, a public relations firm].

111. After the plan had been put in place, Searle and Pfizer went on the attack. As Needleman had stated, a "Q&A" was developed by Searle, Pfizer and the public relations firm for posting on Monsanto's (Searle's parent company) website.

112. On January 25, 1999, an employee at the public relations firm retained by Pfizer and its Co-Promoter faxed to Steve Geis and another Searle employee an email addressed to various Pfizer, Searle and public relations firm personnel. The email has the subject line: "UPenn Media Update, Document and Mon. Conf. Call Info" and states:

> Per our discussions on Friday, the following documents have been developed to be used reactively with reporters who question Celebrex and its effect on cardiovascular risk….These documents will be reviewed and finalized during a Monday morning conference call by the Celebrex PR working group and distributed following the call to the appropriate parties at Searle and Pfizer for final sign-off.

113. The email attached, among othert things, a draft "Q&A regarding Celebrex and Cardiovascular Risk." In response to the question "How many people experienced an adverse cardiovascular event in the clinical trials? What types of events were experienced?," the answer includes (emphasis in original): "There was no difference in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo. **(needs confirmation)."** In response to the question "Does Celebrex labeling have a warning about adverse cardiovascular

events?," the answer includes (emphasis in original): "There was no difference in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo. **(needs confirmation)."**

114. The email also attached draft "Message Points [-] Celebrex and Cardiovascular Risk" one of which states (underlined and bolded emphasis in original):

> There was no evidence of increased risk of cardiovascular events attributed to C elebrex in these trials [*i.e.*, clinical trials]….There was no difference in the incidence of myocardial or vascular events between patients with cardiovascular disease or risk factors taking Celebrex and those taking placebo. **(This is critical information that needs to be confirmed by Searle)**[.] There was no difference in the incidence of myocardial or vascular events between patients taking Celebrex and those taking placebo.

115. Neither the draft "Message Points" or the "Q&A" intended for public consumption disclosed what was set forth in the ISS that had been prepared just six months earlier – that the clinical trial data revealed that there was not just an increase in the incidence of heart attacks in elderly Celecoxib patients versus elderly patients taking placebo, but there was a *statistically significant* increase.

116. Subsequent versions of the "Q&A" and "Message Points" dated March 4, 1999 (that no longer bear the notation "Draft") similarly do not disclose the company-known fact that the clinical trial data revealed that there was a *statistically significant* increase for heart attacks in elderly Celecoxib patients versus elderly patients taking placebo. Rather, public talking points continue to insist that there was no difference in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo in the clinical trial data. Thus, the Q&A's response to the question "How many people experienced an adverse cardiovascular event in the clinical trials? What types of events were experienced?" includes (emphasis added): "There was **no difference** in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo." Similarly, in response to the question "Does Celebrex pose cardiovascular

risk to patients who already have a prior history of cardiovascular disease or risk factors?," the answer states (emphasis added):

> A substantial portion of patients (more than 40 percent) in the Celebrex clinical trials had a history of cardiovascular disease (such as hypertension, angina, myocardial infarction) or risk factors (such as high cholesterol, diabetes). There was **no evidence** of increased risk of cardiovascular events among patients taking Celebrex.

Another question is posed as "What should physicians tell their patients about short and long term cardiovascular risk and Celebrex?" and the answer was (bolded emphasis added; italicized emphasis in original):

> Physicians should tell patients that the incidence of cardiovascular events is not different than that of NSAIDs. The cardiovascular events that are listed in the Celebrex labeling are the types of events you would see with other NSAIDs. It's important to note that there was **no difference in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo**. (*Note to respondents: must say "no difference," not "similar to" placebo.)*….

117. Similarly, the "Messsage Points" also failed to mention the *statistically significant* difference for heart attacks in elderly Celecoxib patients versus elderly patients taking placebo and stated: "There was no evidence of increased risk of cardiovascular events attributed to Celebrex in these trials" and "There was no difference in the incidence of cardiovascular events between patients taking Celebrex, including those with cardiovascular risk factors, and those taking placebo."

118. The joint Searle/Pfizer plan of attack continued in late January 1999. A January 29, 1999 *Reuters* article entitled "Searle defends Celebrex safety" discussed the concerns raised by the Fitzgerald Hyposthesis. Dr. Peter Isakson, Searle's executive director of the COX-2 technology program was interviewed for the article, which states: "In fact, Isakson said the study [*i.e.*, the study underlying the "Fitzgerald Hypothesis"] was included in Searle's data, which it used to gain FDA approval for the drug." In an email just three days earlier, however, a Searle

employee informed Isakson and others that the key data had not been included with the Celebrex new drug application; the employee wrote (emphasis added):

> We have revised the U Penn statement by deleting the following sentence: 'The data were submitted to the FDA in the summer of 1998 for its full evaluation, as part of the New Drug Application (NDA) for Celebrex supporting its COX-1 sparing profile.' The new final statement is attached. Searle did submit to the FDA all the data from the study we had commissed from U Penn. However, Fitzgerald had generated the postacylin data outside of the study protocol—**it is this ad hoc analysis which he uses as the crux of his assertion about CV risk**. Clinical recently discovered that **this additional data was not included in the NDA**….

Isakson replied (emphasis added): "I think this needs to be toned down considerably. We can use it in discussions with investigators, etc. but it's likely to cause an unwanted and unneeded counter reaction from Penn. **Let sleeping dogs lie,**" to which Geis responded: "I agree with Peter. This should be toned down."

119. Sleeping dogs did lie because a few days after this email, Isakson told *Reuters* (as noted above) that the data from the U Penn study "was included in Searle's data, which it used to gain FDA approval for the drug." In that same article, Isakson also said that Searle and the FDA "found **no elevated risk in nearly 10,000 patients studied**" and **"'[n]othing we've seen in our database says it's a concern**.'" (emphasis added) Like the "Q&A's" and the "Message Points," the article does not mention that the clinical trial data revealed that there was a *statistically significant* difference for heart attacks in elderly Celecoxib patients versus elderly patients taking placebo.

120. This misinformation, which was jointly prepared and disseminated by Pfizer and Searle, including the Q&A's and the Message Points, became part of the total mix of information impacting Pfizer's stock price prior to the commencement of the Class Period.

121. After the acquisition of Pharmacia in 2003, Pfizer engaged Geis as a Cox-2 consultant and as an expert witness in the *Carter* and *Grutka* personal injury litigations referenced

above. In an expert report that Geis submitted to the court in that litigation, Geis confirmed the statistically significant finding in elderly celecoxib patients, though he tried to downplay it, when he wrote (emphasis added): "Among the findings noted in the Integrated Summary of Safety Information was a numerical excess of myocardial infarctions or heart attacks in the over-65 population which was of *borderline* statistical significance."

122. After their emphatic denials in early 1999 of having seen any cardiovascular risk with Celebrex, Pfizer's Co-Promoter tasked a cross-functional team in early 1999 to address the cardiovascular issue created by the Fitzgerald Hypothesis. The team was comprised of Dr. Ken Verburg (a doctor in the Searle/Pharmacia clinical department who as discussed below became a Pfizer employee) and Dr. Geis, among others. One of the goals of this team was, as Dr. Verburg stated in a February 19, 1999 e-mail, "to fight future CV fires should they occur." This team eventually became known as the "Cox-2 Inhibitors Clinical Safety Committee" or "CICSC."

C. The July 14, 1999 Cardiovascular Events Analysis

123. In addition to the statistically significant finding for heart attacks in elderly Celebrex patients in the ISS, Pfizer also concealed a July 1999 analysis of ISS data that revealed other statistically significant differences for Celebrex relative to placebo and other arthritis medicines related to cardiovascular safety.

124. Dr. Ken Verburg was a physician in Searle's research and development department. He was one of the Searle doctors who worked on the new drug application for celecoxib that was submitted to the FDA in 1998, and personally had a role in preparation of the ISS. He became an employee of Pharmacia after Pharmacia acquired Searle in early 2000 and became an employee of Pfizer when Pfizer acquired Pharmacia in April 2003 and at all relevant times thereafter.

125. Dr. Verburg prepared a memorandum dated July 14, 1999 that stated: "Attached is a summary of Celecoxib ISS Data Concerning Cardiovascular Adverse Events prepared by Bob Makuch." Bob Makuch was a biostatistician at Yale University that had been retained as a consultant by Searle and participated in CICSC meetings. The memo was sent to, among others, certain executives at Searle and a biostatistician at Pfizer and was also received by Dr. Leland Loose at Pfizer.

126. The summary attached to Dr. Verburg's memo states: "The following data 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. Whereas the ISS tables document the observed adverse events in every body system, 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." The summary also lists the study protocol numbers of the various arthritis studies that had already been completed as of the date of Dr. Verburg's memo. The summary further states:

> 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. While the Integrated Summary of Safety for Celecoxib concluded that 'cardiovascular serious adverse events…were unremarkable and did not indicate any pattern of drug association,' McAdam et al. [*i.e.*, the authors of the Fitzgerald Hypothesis] have suggested that further larger trials are necessary to establish the cardiovascular consequences of inhibiting prostacyclin biosynthesis. They find that COX-2 inhibitors do not affect platelet aggregation, but may impair renal function or increase the incidence of thrombosis.

127. For the studies in North America at Celecoxib 100 and 200 mg (which were approved dosages to treat arthritis), the summary attached to Dr. Verburg's memo reveals that: (a) there were 178 cardiovascular adverse events in the Celecoxib group and 55 in the placebo

group and that the increase was "statistically significant" at p=0.001; (b) for "Heart Rate and Rhythm Disorders," there were 24 such adverse events for study participants taking Celecoxib versus 5 for study participants taking placebo and the increase was "statistically significant" at p=0.10; and (c) for "Myo Endo Pericardial and Valve Disorders," there were 22 such adverse events for study participants taking Celecoxib versus 7 for study participants taking active control (*i.e.*, traditional arthritis medicines) and that the increase was "statistically significant" at p=0.10.

128. For the studies in North America at Celecoxib 100 and 200 mg (approved dosages to treat arthritis), the summary attached to Dr. Verburg's memo also contains a "Subgroup Evaluation" for just rheumatoid arthritis patients. This subgroup analaysis reveals that: (a) for "Heart Rate and Rhythm Disorders," there were 9 such adverse events for study participants taking Celecoxib versus 0 for study participants taking placebo and the increase was "statistically significant" at p=0.05; and (b) for Myo Endo Pericardial and Valve Disorders, there were 6 such adverse events for study participants taking Celecoxib versus 0 for study participants taking active control and the increase was "statistically significant" at p=0.10.

129. Analysis of the "International Arthritis Trials" also showed statistically significant increases. For "Heart Rate and Rhythm Disorders," the summary attached to Dr. Verburg's memo indicates that there were 10 such adverse events for Celecoxib versus 2 for active control and that the increase was "statistically significant" at p=0.05.

130. The summary attached to Dr. Verburg's July 14, 1999 memorandum was never published in a manuscript or otherwise made available to the public. It was not provided to the FDA or any foreign drug regulatory authorities. It was only accessible to the Defendants.

D. The Alzheimer's 001 Study

131. As noted earlier, Searle and Pfizer entered into an agreement to jointly promote Celebrex and Bextra in 1998. To facilitate the joint promotion arrangement, Searle and Pfizer

created a joint committee comprised of their top executives. This committee was known as the "Executive Management Committee" or "EMC." In 1998, the members of this committee were: (a) from Pfizer, defendant McKinnell (who at the time was Executive Vice President of the Pfizer Pharmaceuticals Group and later became Pfizer's CEO), defendant Katen (who at the time was a senior executive with responsibilities for both the international and U.S. pharmaceutical businesses) and John Niblack (another Pfizer Executive Vice President who reported directly to Pfizer's then-CEO); (b) and from Searle, Dr. Needleman and Richard DeSchutter, the Co-Presidents of Searle's research and development operations, and one other senior executive. (McKinnell and Katen remained on the EMC from 1998 through the end of the Class Period; Dr. Needleman remained on the EMC from 1998 until his retirement in 2003.)

132. A clinical study examining the effects of celecoxib on the progression of Alzheimer's disease (the Alzheimer's 001 Study) had begun on July 1, 1997 and was completed on June 24, 1999 – just a few weeks before Dr. Verburg's July 14, 1999 memo discussed above. (The results from the Alzheimer's 001 Study were not, however, available for inclusion in the summary attached to Dr. Verburg's memo, as noted below.) The study results revealed that there were at least 27 adverse cardiovascular events among patients taking 200 mg BID of Celebrex versus just 1 adverse cardiovascular events among patients taking placebo.

133. The Alzheimer's 001 Study was a very important study because it was the Company's longest-term (having lasted fifty-two weeks), placebo-controlled study relating to Celebrex. Thus, as the DSMB would later state in its December 24, 2004 letter to Pfizer, since the study was "the only medically ill-elderly population [Pfizer] ha[d] in a placebo controlled trial of celecoxib, [the study] might **reveal information otherwise unobserveable in medically healthier or younger samples.**" (Emphasis added)

134. A slide presentation for a July 16, 1999 meeting of the EMC (as discussed earlier, a top-level, joint Pfizer/Searle committee created specifically to consider and make decisions on matters relating to the co-promotion of Celebrex and Bextra): (a) stated that "[a] preliminary estimate of peak revenue resulting from an indication for Treatment of Alzheimer's Disease is $465 million;" (b) indicated that Merck & Co. Inc. ("Merck"), which marketed Vioxx (a competing COX-2 inhibitor), was also pursuing an Alzheimer's indication; and (c) stated that the results of the Alzheimer's 001 Study would be available in September 1999, and at that time, a recommendation would be made to the EMC by Searle and Pfizer's "joint" Alzheimer's 001 Study Team.

135. Pfizer directly received the Alzheimer's 001 Study results by no later than August 20, 1999 and, as part of the Joint Searle/Pfizer Alzheimer's Project Team, performed "extensive analyses of [this] data." In addition, the Joint Searle/Pfizer Alzheimer's team also met with the companies' external advisors on August 31, 1999 to review the study results. Slides from this August 31, 1999 meeting, which according to an internal e-mail "include[ed] Pfizer representatives," contain certain adverse cardiovascular results for this study.

136. The results of the Alzheimer's 001 Study were discussed at a "Cox-2 Inhibitors Clinical Safety Committee" meeting held on September 16 and 17, 1999 at the O'Hare Hilton Hotel in Chicago. This committee (which had reformulated after the publication of the Fitzgerald Hypothesis) was comprised of, among others, numerous senior Searle research and development personnel. At this meeting, the medical monitor for the Alzheimer's 001 Study (a Searle employee named Dr. Stephen Sainati) reported having seen safety "signals" in the Alzheimer's 001 Study results. Drs. Geis and Verburg, among numerous others, were present for and/or received minutes of the meeting.

137. Another committee at Searle that considered matters relating to Celebrex was the "Senior Management Board." This committee was comprised of senior Searle research and development executives, including Dr. Needleman. The Senior Management Board played a central role in determining not to continue developing Celebrex for the treatment of Alzheimer's disease – and indication that the joint Pfizer/Searle Executive Management Committee estimated potentially to be worth a very lucrative $465 million. This decision was made in or around November 1999.

138. A November 2, 1999 Senior Management Board slide presentation entitled "Celebrex (Celecoxib) Alzheimer's Disease" (bearing the logos of both Searle and Pfizer) explains the cardiovascular safety results of the Alzheimer's 001 Study. The presentation, which lists Dr. Sainati as one of the presenters of the study results, reflects that the "Overall Incidence" of certain cardiovascular adverse events in the Alzheimer's 001 study -- specifically "Cerebrovascular Disorder," "Cardiac Failure," "Atrial Fibrillation," "Angina Pectoris" and "Myocardial Infarction" - was 2.9% in the placebo group versus 9.8% in the celecoxib 200 mg BID group and that the difference was statistically significant. In other words, the incidence of these cardiovascular adverse events in the long-term Alzheimer's 001 Study was more than three times as great for patients taking Celebrex than for patients taking placebo. The presentation further reflects that Celebrex was not efficacious for treatment of Alzheimer's disease.

139. Neither Searle nor Pfizer published the cardiovascular safety results of the Alzheimer's 001 Study at any time before or during the Class Period, until, as described above, in January 2005, after the DSMB had "reminded" Pfizer in late December 2004 that these results had never been published.

140. On January 24, 2000, a Pfizer employee sent an email to defendant Joe Feczko, who at that time was a senior Pfizer executive in Pfizer's global research & development and

medical departments and subsequently became the Company's Chief Medical Officer. The email stated: "Joe: Below are the message points that Searle is using in response to requests for information on Celebrex/Alzheimer's Disease. In addition, the attached document includes the message points that are/or have been used for the investment community and media." The message points say nothing about the statistically significant difference for certain cardiovascular adverse events depicted in the earlier Senior Management Board presentation dated November 2, 1999. Indeed, despite the fact that a safety analysis was one of the primary objectives of the Alzheimer's 001 Study, the message points say nothing at all about the safety results from the study.

141. Quite the opposite from revealing the cardiovascular safety results from the Alzheimer's 001 Study, in or about April 2000, Searle employees responsible for the Alzheimer's 001 Study co-authored an abstract entitled "Results of a Double-Blind, Randomized, Placebo-Controlled Study of Celecoxib in the Treatment of Progression of Alzheimer's Disease" for use at a medical conference held in Stockholm, Sweden. Those Searle/Pharmacia employees included Dr. Geis, Dr. Sainati (the medical monitor for the Alzheimer's 001 Study) and a Searle statistician.

142. The abstract does not reveal the statistically significant differences for certain cardiovascular adverse events that were depicted in the November 2, 1999 Senior Management Board presentation nor does it make any mention at all concerning the differences in cardiovascular effects between Celebrex and placebo that were observed in the study. Instead, with respect to the safety results in the trial, the abstract falsely states (emphasis added): "The safety profile ***was similar*** in the two treatment groups" and falsely concludes "Celecoxib 200 mg BID was safe and well tolerated in this elderly population."

143. Unsurprisingly, a news story that reported on the presentation that Dr. Sainati made in Stockholm in April 2000 (for which Dr. Sainati and his co-authors had submitted the abstract) discusses the efficacy results from the study (and contains quotes from Dr. Sainati), but does not contain any mention whatsoever of the statistically significant differences for cardiovascular events seen in the study or the cardiovascular safety results more generally, or, indeed, any safety information at all.

144. Meanwhile, shortly after the misleading abstract regarding the Alzheimer's 001 Study was published, yet another committee of senior executives at Pfizer met and discussed the Alzheimer's 001 Study and the fact that Pfizer and Searle were abandoning their pursuit of this $465 million-a-year potential. As noted above, the DPC was comprised of many of the most senior Pfizer executives including: defendants McKinnell, Katen, LaMattina, Feczko and other senior Pfizer executives. Minutes of a May 17, 2000 DPC meeting reflect that McKinnell, Katen, LaMattina and Feczko, among other senior executives, were present at a meeting at which a senior marketing executive "reviewed the key changes in the Celebrex development program including dropping Alzheimer's Disease."

145. In February 2001, the FDA Advisory Committee hearings were held to consider, among other things, the cardiovascular safety of Celebrex and Vioxx at the Holiday Inn Gaithersburg, Gaithersburg, Maryland. Searle prepared a submission dated February 7, 2001 regarding the cardiovascular safety of Celebrex for the February 2001 advisory committee hearings. The Co-Promoter made no mention of the Alzheimer's 001 Study or the 10 to 1 difference in heart attacks in the SUCCESS Study, although it did discuss other aspects of the SUCCESS trial. As discussed above, the SUCCESS trial had been completed in April 2000 more than nine months prior to the hearings. In addition, none of the cardiovascular data relating to Bextra (discussed above and further below) was made in the submission. Transcripts of the

Feburary 2001 advisory committee hearings, at which both Philip Needleman and Steve Geis spoke, also reveal that no discussion of the Alzheimer's 001 Study or the SUCCESS Study was held or even mentioned. This advisory committee panel decided after the hearings that Vioxx, but not Celebrex, should carry a warning about its cardiovascular risks.

146. The difference in cardiovascular warnings for Celebrex versus Vioxx gave Celebrex a valuable marketing advantage over Vioxx. The competiton between COX-2 inhibitors was so intense that the Searle/Pharmacia/Pfizer co-venture resorted to making false or misleading claims about the comparative safety of Celebrex relative to Vioxx during their co-promotion efforts. Indeed, the FDA sent letters dated October 6, 1999 and April 6, 2000 to Pfizer's Co-Promoter concluding that promotional materials used to sell Celebrex -- in which it was claimed that Celebrex had a "superior" safety profile compared to Vioxx -- were false and misleading because such claims had never been proven to be true. More specifically, the October 6, 1999 letter from the FDA states that the false or misleading Celebrex promotion included "suggest[ions] [that] Celebrex has a 'superior safety' profile when compared to Vioxx, when such has not been demonstrated by substantial evidence" and that the FDA "considers this unsubstantiated comparative claim to be false or misleading."

147. Despite the FDA's warnings, the false or misleading statements related to the co-promotion of Celebrex continued. A February 5, 2001 internal Pfizer memorandum (received by defendants McKinnell, Katen and Feczko, among several other senior Pfizer managers (i.e., *just one-day prior to the advisory committee hearings*) details the contents of (and attaches) another FDA "WARNING LETTER" dated February 1, 2001 and addressed to Pharmacia's then-CEO. The "WARNING LETTER" explains that despite the FDA's previous communications and written assurances in response thereto that the misleading promotion of Celebrex would stop, the

false or misleading promotion of Celebrex nevertheless continued. The "WARNING LETTER" states (emphasis added):

> Your promotional activities described above raise significant health and safety concerns in that they minimize crucial risk information and promote Celebrex for unapproved new uses. 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 and other risks, contained unsubstantiated comparative claims, and lacked fair balance. Based upon your written assurances that this violative promotion of Celebrex had been stopped, we considered these matters closed. **Despite our prior written notification, and notwithstanding your assurances, Pharmacia has continued to engage in false or misleading promotion of Celebrex**.

148. Despite Pfizer's awareness of the false or misleading claims that were being made by its Co-Promoter about Celebrex's safety, the cardiovascular safety results of the Alzheimer's 001 Study (and the SUCCESS Study) were not discussed at the February 2001 FDA Advisory Committee hearings. Indeed, with the valuable marketing advantage over Vioxx that resulted from the February 2001 Advisory Committee hearings secured, Pfizer continued to remain silent about the Alzheimer's 001 Study cardiovascular safety results well into the Class Period.

149. After Pfizer had concluded its merger with Pharmacia on April 25, 2003 and was solely responsible for marketing Celebrex and Bextra and the sole recipient of the revenue generated from the drugs, Pfizer made and/or repeated misleading claims about the cardiovascular safety of Celebrex while fraudulently suppressing, among other things, its knowledge of the cardiovascular safety results from the Alzheimer's 001 Study, as well as the additional knowledge possessed by the former Searle and Pharmacia senior level employees who were now Pfizer employees such as Dr. Verburg.

150. For example, 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. This press release states:

"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 . . ."

151. Unbeknownst to investors, however, the 2003 meta-analysis excluded the statistically significant cardiovascular safety results from the Alzheimer's 001 Study. Pfizer knew that this material information had been excluded. Indeed, a Pfizer employee received an advance copy of the meta-analysis which stated that the Alzheimer's study results were being excluded and then distributed to numerous Pfizer employees in a May 22, 2003 internal Pfizer email. Pfizer also knew that the Alzheimer's 001 Study, unlike Pfizer's short-term arthritis studies that were the subject of the 2003 meta-analysis, was a one-year study (one of the longest Celebrex studies) and, thus, had the benefit of observing Celebrex's longer-term effects.

152. In July 2003, at about the same time Pfizer began to trumpet the 2003 meta-analysis, defendant Cawkwell received the cardiovascular safety results from the Alzheimer's 001 Study in response to an email she sent to Dr. Verburg requesting the results. The email received by defendant Cawkwell contained cardiovascular adverse event information reflecting that there were 11 adverse events for Celecoxib 200 mg BID for cardiovascular disorders, general versus 0 for placebo, 14 adverse events for Celecoxib 200 mg BID for Heart Rate and Rhythm Disorders versus 1 for placebo and 10 adverse events for Celecoxib 200 mg BID for Myo Endo Pericardial & Valve Disorders versus 0 for placebo and that each of these differences were statistically significant.

153. Moreover, the statement that the latest meta-analysis was "independent" was itself misleading. In an April 7, 2003 email from Dr. Gandelman, a senior doctor in Pfizer's medical group, to the principal author of the meta-analysis, Dr. Gandelman wrote: "In your Celebrex CV

meta-analysis did you ever look at the data from high risk CV patients and compare to NSAIDs or placebo?" to which the "independent" meta-analysis author replied (emphasis added): "**I will talk to you about this issue on the phone** – it is not very promising – I can tell you that."

154. It is not until the "independent" analysis was published in *The American Journal of Cardiology* in or about August 15, 2003, that the public would learn that "studies of Alzheimer's disease" were excluded from the latest meta-analysis. However, even this information was meaningless because no mention whatsoever is made of the fact that statistically significant cardiovascular differences were seen in the Alzheimer's 001 Study.

155. In an email to a Pfizer employee sent June 10, 2004 relating to the Alzheimer's 001 Study, a Merck employee (Larry Hirsch) wrote:

> 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 assertations aside, we are judged by our actions.

On the same day, the Pfizer employee responded to the Merck employee and copied defendant Cawkwell and Michael Parini, a lawyer in Pfizer's legal department, and wrote:

> Michael, 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.

156. The "PhRMA Clinical Trial Code" was a reference to certain principles on the Conduct of Clinical Trials and Communication of Clinical Trial Results that Pfizer had in place. Earlier, defendant Feczko distributed the principles to Pfizer employees firm-wide in a January 10, 2003 memorandum that stated:

> Attached for your information are the recently released PhRMA Principles of Conduct of Clinical Trials. Pfizer played an integral part in their development and has fully endorsed them as of October 1st, 2002. It is worth noting that current practices and SOPs at Pfizer are already consistent with these PhRMA principles.

The memorandum further stated:

> Since we at Pfizer have already established high standards of business and clinical practice, the inclusion of these voluntary principles into Pfizer's SOPs and policies will not require significant changes.

The Principles attached to the memo state under the heading "Communication of Study Results":

> "Clinical trials may involve already marketed products and/or investigational products. We commit to timely communication of meaningful results of controlled clinical trials of marketed products or investigational products that are approved for marketing, regardless of outcome. Communication includes publication of a paper in a peer-reviewed medical journal, abstract submission with a poster or oral presentation at a scientific meeting, or making results public by some other means.

The Principles further state (emphasis added):

> **In all cases,** the study results should be reported in an **objective, accurate, balanced and complete manner**, with a discussion of the strengths and limitations of the study.

157. Despite the fact that Pfizer's main COX-2 competitor provided Pfizer with a "gentle reminder" that the Alzheimer's 001 cardiovascular safety results were not published, no changes were made to the earlier abstract regarding the Alzheimer's 001 Study, which, as discussed above, stated: "The safety profile *was similar* in the two treatment groups" and concluded "Celecoxib 200 mg BID was safe and well tolerated in this elderly population."

158. In stark contrast to the information available to the public which proclaimed a "similar" safety profile, Pfizer's Pain and Arthritis Medical Group Leader, Dr. Claire Wohlhuter, in a January 12, 2005 email wrote:

> With regard to Alzheimer 001, Patients treated with 200 mg BID were **at greater risk of serious CV thromboembolic adverse events** vs. placebo.

E. Pfizer's False Or Misleading Statements Regarding The Cardiovascular Safety Of Celebrex Versus Vioxx In Marketing Materials

159. As discussed above, defendants McKinnell, Katen and Feczko (as well as other senior Pfizer executives) received a memo dated February 5, 2001 that attached a "**WARNING LETTER**" to Fred Hassan, the CEO of Pharmacia, from the FDA.

160. This February 5, 2001 WARNING LETTER was preceded by to prior letters from the FDA to Searle/Pharmacia dated October 6, 1999 and April 6, 2000 in which the FDA objected to the dissemination of Celebrex marketing materials that misrepresented Celebrex's cardiovascular safety profile. Searle/Pharmacia provided written assurances to the FDA that these misrepresentations would stop. But they did not stop.

161. In no uncertain terms, the February 5, 2001 "**WARNING LETTER**" from the FDA makes this abundantly clear and states (emphasis added):

> "[Pharmacia's] promotional activities…raise[d] significant health and safety concerns in that they minimize crucial risk information and promote Celebrex for unapproved new uses. 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 and other risks, **contained unsubstantiated comparative claims**, and lacked fair balance. Based upon your written assurances that this violative promotion of Celebrex had been stopped, we considered these matters closed. Despite our prior written notification, and notwithstanding your assurances, **Pharmacia has continued to engage in false or misleading promotion of Celebrex**."

162. Among the "Unsubstantiated Comparative Claims" cited by the FDA was (emphasis added):

> **Your suggestion that Celebrex is safer, or has fewer side effects than Vioxx is false or misleading because such conclusions have not been demonstrated by substantial evidence.** Celebrex has not been compared to Vioxx in trials prospectively designed to assess these endpoints.

F. The SUCCESS Study

163. In addition to 1998 elderly patient information, the summary attached to Dr. Verburg's July 1999 memo, the Alzheimer's 001 Study and the other information discussed above, Pfizer also concealed the cardiovascular safety results from another study.

164. A clinical study known as the SUCCESS Study began in December 1998 and concluded on April 18, 2000. It was a safety study designed to compare Celebrex and two traditional arthritis medicines -- diclofenac and naproxen -- in the treatment of osteoarthritis of the knee and hip. As noted earlier, the study revealed a 10 to 1 increase in heart attacks for Celebrex versus the traditional arthritis medicines diclofenac and naproxen combined. Adjusting for the differences in the enrollment of Celebrex takers versus traditional arthritis medicines (there were approximately twice as many study patients taking Celebrex as were taking traditional medicines), there was a five-fold increase in heart attacks in the study for Celebrex versus the traditional arthritis medicines.

165. As noted above, although the SUCCESS Study results were known to Pfizer and Searle and Pharmacia at the time of the February 2001 FDA Advisory Committtee hearings, no mention was made of the SUCCESS Study results in the submission made in advance of the hearings or at the hearings themselves. Nor were the SUCCESS Study results published in a manuscript at any time from 2000 through 2005.

166. Pfizer (specifically Dr. Gandleman, among others) was in possession of the SUCCESS Study results no later than early December, 2000, prior to the February 2001 Advisory Committee hearings. On January 26, 2001, also prior to the February 2001 hearings, the medical monitor for the SUCCESS Study emailed his colleagues at Pharmacia regarding the SUCCESS Study results and stated: "The rates of myocardial infarction are worrisome."

167. Not long thereafter, on March 30, 2001, Dr. Geis sent an email pertaining to the SUCCESS study to, among others, Dr. Verburg and several senior officers of Pharmacia – including Dr. Needleman (a member of the Senior Management Board and the joint Searle/Pfizer EMC) and Goran Ando (a senior Searle executive who was added as a member of the EMC in or about July 2002) attaching a document entitled: "Analysis of SUCCESS For Potential Regulatory Submission To Support CLASS sNDA." The CLASS sNDA was the supplemental new drug application that Searle had submitted to the FDA to obtain changes to the label for Celecoxib based on the results of the CLASS Study. The document attached to Dr. Geis's email, under the heading "General Safety Data" states (emphasis added):

> In terms of cardiovascular safety, the data show an excess of myocardial infarctions comparing celecoxib to NSAIDs (10 vs. 1) but not combined thromboembolic events. While the MI data are not statistically significant, not supported by the sum totality of thromboembolic data, and possibly due to unbalanced randomization, **the trend contrasts with the NDA and CLASS databases**.

In the "Summary" section at the end, the document states (emphasis added): "Finally, a **possible trend towards an increase in myocardial infarctions may raise additional regulatory concerns** even though the trend is not substantiated by an analysis of all thromboembolic complications. The potential **negative impact of this aspect of the data may outweigh any potential advantages** when put forth in a regulatory context."

168. As noted earlier, the SUCCESS Study results were not included in the submission made for the February 2001 advisory committee hearings, and the final SUCCESS Study report was not submitted to the FDA until July 2001, although the study had been completed well over a year earlier (in April 2000).

169. In August 2001, an article was published in the August 22/29 issue of the Journal of the American Medical Asssociation ("JAMA") which questioned the cardiovascular safety of COX-2 inhibitors. In response to the JAMA article, the Pfizer/Pharmacia "Review Council," a

committee comprised of senior executives from both Pfizer (including Dr. Gandleman) and Pharmacia (the "RC"), met to discuss a response. The initial draft responsive press release contained the following quotation:

> 'All Celebrex studies have consistently shown no increased risk for heart attack and stroke, compared to traditional NSAIDs studied…'

170. Indeed, the significance of the inclusion of the word "All" in the press release was emphasized in an August 15, 2001 email from a Pfizer employee, Ken Bahrt, to Dr. Gandleman which stated (capitalized emhasis in original):

> Mitch, Here was the PR piece with the ALL language

171. Reflecting Dr. Gandleman's knowledge of the existence of study results which contradicted their public stance (*e.g.*, SUCCESS and ALZ 001), the RC revised the draft press release to delete the word "All" from the quotation. Pfizer then issued the press release on August 21, 2001 which stated "Celebrex studies have consistently shown no increased risk for heart attack or stroke compared to traditional NSAIDs studied." The press release further stated that "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."

172. In addition to the foregoing, in or about June 2002, the Malyasian health authority had reclassified celecoxib from an "over-the-counter" medicine to a prescription medicine mainly due to concerns over cardiovascular safety issues raised in the August 22/29 issue of the Journal of the American Medical Asssociation ("JAMA") which questioned the cardiovascular safety of COX-2 inhibitors, an article which, as detailed below, Pfizer responded to with staunch denials.

173. Pharmacia decided to appeal the decision and sent an October 10, 2002 letter to the Malyasian health authority. The letter purports to, among other things, "address the

cardiovascular safety of celecoxib (CELEBREX)" and discusses, among other things, the CLASS Study and the SUCCESS Study. The letter claims that the CLASS Study demonstrated that "there was no difference in the incidence of serious cardiovascular (CV) thromboembolic events, including myocardial infaction (MI) and stroke, in celecoxib (CELEBREX)-treated patients as compared to ibuprofen- and diclofenac-treated patients." With respect to the SUCCESS Study, the letter states:

> [O]ther controlled studies including SUCCESS 1 study involving over 13,000 patients comparing celecoxib (CELEBREX) with naproxen and diclofenac showed that there was no increased CV thrombotic events with celecoxib (CELEBREX) **(Appendix F)**."

174. This was false given that a heart attack is a "CV thrombotic event" and, as discussed earlier, the SUCCESS Study revealed a 10 to 1 increase in heart attacks for Celebrex versus the other NSAIDs studies (*i.e.*, naproxen and diclofenac). Moreover, the "Appendix F" to which the letter refers to support this false assertion about the SUCCESS Study contains no reference to the 10 to 1 difference in MIs in the SUCCESS Study.

175. Pfizer was also well aware that the SUCCESS Study results had not been published. Both defendants Feczko and LaMattina were members of yet another committee that considered matters relating to Celebrex and Bextra – the Global Development Review Committee or "GDRC." Minutes of a GDRC meeting held April 15, 2003, at which Feczko and LaMattina were present, state: (a) "Because of ongoing medical community and health authority questions on the GI and CV profiles of our brands, our portfolio's future growth is at risk"; (b) "The question of the safety of COX-2s in [coronary artery disorder] patients has remained an issue and the ability to differentiate Celebrex and Bextra from other COX-2s is key to expanding their market share"; (c) "As part of the discussion, 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."; (d) "Pfizer has been urging Pharmacia to proceed with this publication; Pharmacia has

been concerned about maintaining the authors' independence."; and (e) "Pfizer has stated that as the sponsor of the study Pharmacia has an obligation to make the results of the study available **in a timely manner**" (Emphasis added.)

176. Still, no publication of the SUCCESS Study results was made prior to 2005.

177. Pfizer acknowledged (internally) the reason for the lack of publication of the SUCCESSS Study results in a draft "Cox-2 Strategic Operation Plan" slide deck presentation dated June 5, 2003 that was sent to defendant Cawkwell and others. The presentation states (emphasis added):

SUCCESS I Publication **May Raise Questions**

Underneath that heading the presentation states (emphasis added):

5 X Increase in MIs (p=ns), With Majority in 200 mg qd.

Indeed, by early 2004, even Pfizer's own employees were internally questioning the lack of publication of the SUCCESS Study results. For example, in an e-mail dated April 22, 2003, Pfizer physician Elizabeth Kitsis urged the company to publish the SUCCESS study results "in a timely manner because they could be useful to the medical community." In a February 6, 2004 email from a Pfizer employee in Japan to defendant Cawkwell, the Pfizer Japan employee wrote (emphasis added):

> Gail-san: 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?

178. These internal questions were entirely justified. Earlier, on July 9, 2003, Pfizer had submitted the SUCCESS Study for publication to the New England Journal of Medicine (the "NEJM"). But the NEJM rejected the publication in part because Pfizer attempted to hide the 10 to 1 difference in heart attacks in the study. The draft manuscript submitted to the NEJM, which was co-authored by several Pharmacia employees, under the heading "Cardiovascular Safety"

stated: "The risk of acute myocardial infarction was low, and statistically similar among the different groups." In a letter dated September 4, 2003, which was received by defendant Cawkwell on October 23, 2003, the NEJM rejected the manuscript. The NEJM's letter states (emphasis added):

> (a) "It is unacceptable to state that the MI rates were statistically similar – 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**"; and
>
> (b) "The fact the 10 myocardial infarctions occurred in the combined celecoxib groups compared to 1 in the combined NSAID groups may not be statistically significant, but **it looks like such data are being hidden.**"

179. Indeed, the NEJM explained that the SUCCESS Study results raise a potential signal for heart attacks. The rejection letter states (emphasis added):

> 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.**

No press release was issued by Pfizer stating the reasons for the rejection of the SUCCESS manuscript by NEJM and no manuscript with the SUCCESS Study results was published prior to 2005. When ultimately posting these results to an industry website in 2005, Pfizer physicians and other personnel, including Dr. Gandelman, commented that the publication of the SUCCESS results was likely to "invite questions."

G. The CLASS Study

180. In addition to the fraudulent concealment of the Alzheimer's 001 Study, SUCCESS Study and other data and information discussed earlier herein, Pfizer also misrepresented the results of the CLASS Study.

181. The Celecoxib Long-Term Arthritis Safety Study (or, as defined earlier, the "CLASS Study") was designed to compare the incidence of clinically significant upper GI events associated with celecoxib with those in ibuprofen or diclofenac in both OA and RA patients. In fact, CLASS was a combination of two trials; one comparing Celebrex to ibuprofen, and another comparing Celebrex to diclofenac. A total of 8,059 patients were randomized: 4,031 to the celebrex 400 mg BID group, 2,019 to the diclofenac 75 mg BID group, and 2,009 to the ibuprofen 800 mg TID group. The CLASS Study's two trials were scheduled to be 12 and 16 months in length, respectively.

182. On April 17, 2000, more than a month before the CLASS Study Final Study Report was completed, Pfizer and Pharmacia issued a press release (the "April 17, 2000 Press Release") which stated:

> In a landmark study to assess the overall long-term safety of the COX-2 specific inhibitor Celebrex (celecoxib capsules), arthritis patients taking four times the recommended osteoarthritis (OA) does of the drug 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 (NSAIDs) drugs***.

(Emphasis added)

183. The April 17, 2000 Press Release left the clear – but false – impression that the CLASS Study demonstrated a statistically significant advantage for GI ulcers versus the comparator NSAIDs. The purported results of the CLASS Study were published on September 13, 2000, to much fanfare by Pfizer, in an article entitled "Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis" in the *Journal of the American Medical Association* (the "CLASS JAMA Article"). The CLASS JAMA Article, like the April 17, 2000 Press Release, falsely claimed that Celebrex caused fewer symptomatic ulcers and ulcer complications than did diclofenac or ibuprofen at ***6 months*** of follow-up. The CLASS JAMA Article further claimed that the overall incidence of cardiovascular

events, and the incidences of myocardial infarctions ("MIs") in particular, were similar between the treatment groups.

184. On April 28, 2000, Pharmacia issued another press release (the "April 28, 2000 Press Release") entitled "New Study Validates Safety of Pharmacia Corporation's Celebrex on Stroke, Heart Attack Issues," which discussed the results of the CLASS Study and stated in part:

> 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.
>
> ***
>
> ***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.***

(Emphasis added)

185. Incredibly, the CLASS JAMA Article, the April 17, 2000 Press Release and the April 28, 2000 Press Release failed to mention that the actual CLASS Study trials encompassed ***12-16 month periods***, respectively, and that when the full trial results were analyzed, the purported GI advantage for Celebrex entirely evaporated. The CLASS JAMA Article also failed to disclose that the study's 16 authors were either employees of Pharmacia, or paid consultants to Pharmacia.

186. Ultimately, the FDA convened an Arthritis Advisory Committee in February 2001 (the "2001 Advisory Committee") to analyze the GI and cardiovascular effects of COX-2 drugs, including Celebrex. According to the FDA CLASS analysis prepared for the 2001 Advisory Committee, when the full GI results of the Class Study were analyzed, they contradicted the

published CLASS JAMA Article. In fact, the FDA found that "[f]or upper GI safety, and also for global safety, ***there does not appear to be any meaningful advantage for Celebrex***." .

187. In addition, both the CLASS JAMA Article's and the April 28, 2000 Press Release's claims regarding the positive cardiovascular results of CLASS were patently false at the time they were made, as explained in an August 2001 JAMA article by Drs. Debabrata Mukherjee, Steven E. Nissen and Eric J. Topol entitled "Risk of Cardiovascular Events Associated With Selective COX-2 Inhibitors" (the "Nissen Article"). The Nissen Article concluded that "the annualized myocardial infarction rates for Cox-2 inhibitors in both VIGOR [a clinical trial of Merck's COX-2 drug, Vioxx, in RA patients] and CLASS were ***significantly higher*** than that in the placebo group of a recent meta-analysis of 23,407 patients in primary prevention trials (0.52%): 0.74% with rofecoxib (p=.04 compared with the placebo group of the meta-analysis) and 0.80% with celecoxib (p=0.2 compared with the placebo group of the meta-analysis)" and that "the available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors."

188. Moreover, and unbeknownst to Pfizer's investors, when the CLASS Study's CV results were subjected to subgroup analysis, the results were worse than even the Nissen Article reported. In fact, and as Pfizer was fully aware at least seven months prior to the 2001 FDA Advisory Committee, Celebrex demonstrated a much higher rate of MI versus NSAIDs in the CLASS Study within the RA patient subgroup.

189. Specifically, on June 8, 2000, in the course of an email discussion regarding the appropriate presentation of the CLASS Study CV results versus the VIGOR Study CV results, Pfizer physician Dr. Mona Wahba stated that "the fair presentation should be comparing apples to apples, what I mean is to compare RA patients on CLASS versus VIGOR. Dr. Wahba further stated that within the RA subgroup, the incidence of MIs for RA patients on CLASS was 0.3%

for Celebrex versus 0.1% for NSAIDS" and that the result "could be statistically significant." In fact, the CLASS Study RA results versus diclofenac were highly statistically significant: there were 10 MIs in the Celebrex treatment group versus zero MIs in the diclofenac treatment group.

190. The troubling CLASS Study CV results were widely discussed. A February 19, 2001 email from Pharmacia physician Dr. Steven Geis to Drs. James Lefkowith and Ken 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**.

(Emphasis added). Yet at no time did Pfizer correct its false statements regarding the CV results of CLASS. Nor did Pfizer ever formally publish the complete results of the CLASS Study, as the BMJ and JAMA demanded

191. Ultimately, both the *British Medical Journal* ("BMJ") and JAMA publicly endorsed the FDA's conclusions, and criticized Pfizer for its deceitful conduct. In a November 21, 2001 editorial, JAMA stated that the full results of the CLASS Study "draws the opposite conclusion" from the published CLASS JAMA article, and that, as a result, physicians could be misled. Similarly, in a June 2002 article entitled "Are Selective Cox 2 Inhibitors Superior To Traditional Non Steroidal Anti-Inflammatory Drugs? Adequate Analysis of the CLASS Trial Indicates That This May Not Be The Case," the BMJ stated that the full CLASS Study results "clearly contradict the published conclusions." Thus, both BMJ and JAMA demanded that the full results of the CLASS Study be formally published. They never were.

H. The "Serious Signal" Letter from the World Health Organization

192. The World Health Organization ("WHO") maintains a database containing summaries of case reports of suspected adverse drug reactions. On September 20, 2001, a representative of the Uppsala Montoring Centre ("UMC"), which monitors safety signals with

drugs using the WHO database, sent Pharmacia an email with a "signal draft on Celecoxib & Myocardial infarction" that the UMC was planning on publishing in the WHO's next "signals" publication. The conclusion in the "signal draft" stated (emphasis added):

> 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.**

193. The email was forwarded to, among others, Drs. Geis and Verburg at Pharmacia and Dr. Mitch Gandleman, a senior medical officer at Pfizer who reported indirectly to defendant Feckzo.

194. Neither Pfizer nor Pharmacia disclosed their receipt of this communication from the WHO. No publication of the "signal draft" occurred.

I. The February 17, 2003 "Rapporteur's" Preliminary Assessment Report and Related Meta-Analyses

195. In addition to the United States, Celebrex was approved for sale in certain European Union countries.

196. In July, 2002, according to an internal email, one of the European Union countries (France) "called for…[a] safety review of the entire class of COX-2 inhibitors, raising questions about the role of these products as a more expensive successor to standard NSAIDs." As was explained in the email, "there were reports that the national agency, AFSSAPS, had raised questions about the risk of cardiovascular side-effects when the products were used to treat pain." Thereafter, a cardiovascular safety review of Celebrex and other COX-2 inhibitors was undertaken. During this process, the European Union member countries that approved Celebrex for sale are represented by so-called "Rapporteurs" (i.e., doctors who review safety and make assessments that are reported to the European Union member).

197. Pharmacia had knowledge that an "assessor" of the German Rapporteur had completed his own meta-analysis that showed an increased cardiovascular risk for Celebrex

relative to the traditional arthritis medicine diclofenac. More specifically, on January 22, 2003, a Pharmacia employee emailed Dr. Verburg, among others, and wrote: "As a heads-up, at…[a] meeting today a comment was made by Dr. Koch from Germany (statistician) that they have done their own meta-analysis across the arthritis studies and have determined a Relative Risk of 2.3 for cele v. diclofenac for thromboembolic events." The "Relative Risk" here indicates that it was 2.3 times more likely that, in the arthritis studies analyzed, Celebrex would result in a thromboembolic event than would diclofenac. The email was forwarded to, among others, Dr. Geis and senior regulatory personnel at Pharmacia. No disclosure of either the conclusions or of this meta-analysis was ever made.

198. In a February 17, 2003 email to numerous Pharmacia and Pfizer employees, a Pharmacia regulatory employee distributed, among other things, the German Rapporteur's preliminary assessment report relating to Celebrex. The report was sent to Dr. Gandleman at Pfizer on February 18, 2003.

199. Under the heading "Biostatistical Comments for cardiovascular safety *(Koch)*," the preliminary assessment report states (emphasis added): "[T]he company [*i.e.*, a Pharmacia affiliate in Europe that owned the rights to sell celecoxib] states that 'the incidence of serious CV thrombotic events in patients treated with celecoxib is similar to that seen with non-selective NSAIDs.' **This view is, however, not supported due to reasons outlined in the following sections**." Among the reasons outlined thereafter were (emphasis added):

> (a) "[T]here is still a **clear signal for an increased risk of myocardial infarctions** with celecoxib in comparison to (some) non-selective NSAIDs";
>
> (b) "The company [*i.e.*, the Pharmacia affiliate in Europe] states that the borderline significant finding from the SUCCESS study with respect to an increase in myocardial infarctions (MI) as compared to diclofenac was an isolated finding and that the clinical significance of this finding was difficult to assess. 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;

> (c) "A meta-analysis for the endpoint MI including also the…controlled arthritis trials (CAT) and comparing celecoxib-results to un-specfied NSAIDs likewise **shows an increased risk for celecoxib with respect to the endpoint MI**…."; and
>
> (d) the submitted data of the…Controlled Arthritis Trials, the CLASS- and the SUCCESS-studies show that **celecoxib was associated with an [sic] dose-dependent increased frequency of myocardial infarction** in the celecoxib groups compared to convestional NSAIDs."

200. In a September 15, 2003 email from a Pharmacia regulatory official to, among others, a Pharmacia statistician, the regulatory official wrote:

> [An official in Pharmacia's regulatory department] asked that I get in touch with you to see if you knew where the relative risk numbers vs. diclo came from (see red text below), our analysis or Germany before you discuss with Dr. Koch….
>
> The analysis showed that the incidence of myocardial infarction was numerically increased in the celecoxib group as compared to the diclofenac group, (relative risk 2.25, 95% CI 0.60-7.25). The relative risk in relation to ibubrofen was similar 1.11, 95% CI 0.45-2.72). The overall risk from pooled CAT [i.e., clinical arthritis trials], CLASS and SUCCESS data for celecoxib (200-800 mg/day) in comparison to diclofenac (100-150 mg/day) was 3.36 (95% CI 1.14-9.90). The subgroup analysis of patients of low-dose ASA-use showed an overall risk of 4.37 (95% CI 1.06-18.05).

201. In a September 16, 2003 reply email from another Pharmacia statistician to Pharmacia regulatory personnel and the Pharmacia statician who received the September 15, 2003 email, among others, the Pharmacia statistician wrote with respect to the meta-analysis that had been conducted by the Rapporteur's representative (bolded and underlined emphasis in original):

> The numbers in the red text are from Germany. When we use our meta-analysis package, we come up with the numbers in BLACK below for MI.
>
> The overall risk from pooled CAT [i.e., clinical arthritis trials, CLASS and SUCCESS data for celecoxib (200-800 mg/day) in comparison to diclofenac (100-150 ,g/day) was **2.88** (95% CI **1.03-8.06 p-value=0.0445)**. The subgroup analysis of patients of low-dose ASA-use showed an overall risk of **3.17** (95% CI **0.89-11.31 p-value =0.0757**)….

J. Internal Communications Discussing Bextra's "Vioxx-like" Safety Profile

202. The new drug application for valdecoxib (later known by the tradename Bextra) had been submitted to the FDA in January 2001. The application sought approval for the treatment of several indications, including arthritis, menstrual cramping and acute pain. Prior to the filing of the Bextra new drug application, Pfizer and Searle/Pharmacia conducted several studies relating to the drug that were reported to Pfizer's and Searle/Pharmacia's senior management.

203. On September 18 and 19, 2000, a "Pharmacia/Pfizer Valdecoxib Strategic Summit" was held at the Millennium Broadway hotel in downtown Manhattan. The agenda for the "Summit" lists fifty-two employees from Pfizer and Pharmacia that attended, many of whom were senior executives of the respective companies; members of the clinical, regulatory, medical and marketing areas of each firm were in attendance at the Strategic Summit.

204. The Pfizer attendees included defendants Feczko and LaMattina and other senior executives, including John Niblack (President of Pfizer global research & development department), Peter Corr (Executive Vice President of Pfizer's global research & development department), Craig Saxton (Executive Vice President of Central Research), Steven Ryder (Senior Vice President in Pfizer's worldwide clinical department and Ethan Weiner (a senior physician in in Pfizer's worldwide clinical department). The Pharmacia attendees included Dr. Needleman (co-President of the reseach & development area), Goran Ando (Executive Vice President of reseach & development for arthritis and inflammation), Peter Isakson (a senior research & development executive), Dr. Geis (discussed above) and Richard Spivey (head of Pharmacia Regulatory).

205. The goals of the Strategic Summit were: (a) for the two companies and their executives to "[g]ain a common level of understanding" regarding valdecoxib; (b) to review the

"Target product profile" and "Clinical Development Plan" and the progress to date; and (c) to review the "regulatory environment." At this Strategic Summit, the safety results from several studies were discussed, including certain pivotal arthritis studies relating to valdecoxib known as the "047 Study" and the "060 and 061" studies (as well as the CABG-1 Study, discussed further below).

206. The "047 Study" was a large, six-month safety study of valdecoxib taken by patients at high dosages and compared valdecoxib to naproxen (a traditional arthritis medicine). The study began on August 25, 1999 and was completed on August 31, 2000, shortly before the Strategic Summit. The 047 Study results revealed "safety signals" but were never published in a peer-reviewed manuscript. Indeed, a draft publication relating to the 047 Study results was "embargoed" because it would have damaged the product, as discussed further below.

207. In an October 17, 2000 email from Dr. Needleman to Drs. Geis and Verburg after the Strategic Summit, Dr. Needleman received an analysis of the 047 Study results and wrote (emphasis added): "Thanks for the detailed analysis. **To me it looks like a small but annoying signal is present.**"

208. Similarly, from Pfizer, Dr. Weiner emailed his boss, Dr. Ryder, on October 3, 2000 and wrote (emphasis added): "047 is the big 6 month safety study of high dose valdecoxib. **The safety profile looks very Vioxx-like** in my opinion"

209. The "060 and 061 Studies" also revealed "signals." Both studies began in September 1999 and were completed on May 31, 2000 and July 4, 2000, respectively. These studies were the two pivotal valdecoxib studies in rheumatoid arthritis patients and compared valdecoxib versus naproxen (a traditional arthritis medicine) and placebo.

210. The Strategic Summit presentation revealed that there were statistically significant differences observed in the valdecoxib arthritis trials for hypertension and peripheral

edema. Indeed, prior to the Strategic Summit, in an August 28, 2000 email exchange between Dr. Needleman, Dr. Verburg and Dr. Geis regarding the "Valdecoxib 061 Results," Dr. Verburg wrote: "In contrast, 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 events appeared to be dose-related. We saw a similar pattern in the 060 trial." Dr. Needleman replied and stated: "**It does look like we're seeing a [sic] dose dependent cardiovascular effects.** What's the gestalt in comparison to the safety profile compared to celebrex and vioxx? I'm obviously framing the business opportunity in my mind."

211. Similarly, prior to the Strategic Summit, a Pfizer employee, Dr. Eliot Forster (who also attended the Strategic Summit) wrote in a August 15, 2000 email to Ethan Weiner, Peter Corr, Steven Ryder, and Craig Saxton pertaining to the 060 Study (emphasis added):

> Of note, there were two MIs in the valdecoxib groups and an increased incidence of edema, hypertension and rash. **There is clearly an increased incidence of MI with valdecoxib compared to placebo and NSAIDs at this point in the data-base**. This data-base is yet to be Qced so the actual numbers may move slightly).

212. In response to the email from Dr. Forster, Dr. Saxton (via an email sent by his assistant) replied to the group on August 17, 2000 and wrote (emphasis in original):

> "Given the small numbers for the numerator, I don't see how you can state - 'There is already an increased incidence of M.I. with Valdecoxib.' Obviously the incidence needs monitoring but I hardly think we're able to draw the conclusion you reach**.** I suggest we discuss this further by telephone."

Unlike the paper trail created by emails, which Pfizer was required to preserve, Pfizer had no system in place to record employees' telephone conversations.

213. Dr. Weiner then forwarded Dr. Saxton's email to Dr. Leland Loose, Executive Director in Pfizer's Global research & development unit and a member of Pfizer's COX-2 team. Dr. Loose replied on August 18, 2000 stating (emphasis added):

> I spoke with Eliot [Forster] after he had spoken to Craig [Saxton]. **In essence Craig wants the visibility decreased as you can understand**.

214. Regarding the CABG-1 Study, the Strategic Summit presentation clearly showed a statistically significant difference in "cardiovascular events," which it defined as the composite of myocardial infarction or severe ischemia, cerebrovascular accident, deep vein thrombosis, and pulmonary embolism events.

K. The "Embargo" On Publication Of Study 047 That Would Damage Bextra

215. The "Bextra Publications Working Group" was a joint Pfizer/Pharmacia group comprised of Pfizer and Pharmcia employees from, among others, the marketing, medical, research and development and public relations departments of the respective companies. Defendant Cawkwell was a member of the "Bextra Publications Working Group." This group made recommendations and decisions concerning when and whether to publish studies related to Bextra.

216. On March 19, 2002, Cawkwell received an email attaching minutes from a February 5 and 6, 2002 Bextra Publications Working Group meeting held at the Old Mill Inn in Basking Ridge, New Jersey. The minutes contain a heading for the "047 manuscript." (The 047 Study, as noted earlier, was a large, 6-month safety study of high dose valdecoxib about which Dr. Weiner remarked: "[t]he safety profile looks very Vioxx-like in my opinion.") The minutes state (emphasis added): "Post-meeting note: The decision to go ahead with this publication, at the face-to-face meeting, was over turned at a subsequent telecom (March 5, 2002). Originally the group had decided that these data should be published as an issue of crediability [sic] 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**."

217. Nothing in the PhRMA Principles (discussed earlier) allowed for the embargoing of a study publication because it "would be damaging to the product." The embargo lasted throughout 2003, 2004 and 2005.

L. The Findings From The "016 Study"

218. Study 016 began on December 17, 1997 and ended on June 25, 1998. It was a six week double-blind, randomized, placebo-controlled, multicenter, parallel group, dose-ranging study designed to determine the efficacy of valdecoxib in rheumatoid arthritis patients. In addition, the safety of Bextra in rheumatoid arthritis patients was also assessesed versus naproxen and placebo.

219. In a June 12, 2000 email from a Pfizer employee in the Clinical Research Department to Dr. Mona Wahba, a medical director on Pfizer's COX-2 team regarding the "016 Study Report," the Pfizer employee wrote: "Mona: Not very pleasant reading this weekend!" and listed "Key points" relating to the study. With respect to safety, the employee wrote (emphasis added) "I'm also **worried about the safety data**" and further wrote (emphasis added):

> **CV: 6 MIs on valde vs. 0 on placebo or naproxen**. 4 of 6 within 14 days of starting valde…Also, 1 vasculitis on 0.5 BID (in an RA population, that's expected and less disconcerting than the 6 MIs). Also there is a small rise in systolic BP [*i.e.*, blood pressure] on the highest valde doses, not seen on naproxen."

220. Two days later, Dr. Wahba sent an email to other Pfizer employees on the Cox-2 team with the subject line: "016 major concerns." The email begins: "Dear all, i'll address only major concerns about 016 in this message…." Under "Safety" the email largely repeats the "worrisome" and "disconcerting" information from the email Dr. Wahba had received two days earlier and states: "CVS: 6 MI's on Valde, none on Pbo 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!"

221. The results in this study were not published in a manuscript prior to 2005.

M. The "040 Cancer Pain Study"

222. The 040 Cancer Pain Study began on July 13, 2000 and ended on January 25, 2002. It was a twelve week, double-blind, randomized, placebo-controlled study designed to determine the efficacy of valdecoxib as compared to placebo in the treatment of patients with chronic pain related to cancer or a result of prior cancer pain therapy and to assess safety of Bextra in this patient population.

223. The study showed that there was a statistically significant difference for peripheral edema in patients taking valdecoxib versus patients taking placebo. In addition, Bextra was associated with a statistically significantly increase in deaths versus placebo. Twenty-six out of 118 patients receiving valdecoxib died; by comparison, 12 out of 117 patients in the placebo group died.

224. Pfizer physicians, including defendant Cawkwell, and Drs. Gandelman and Weiner, became aware of the 040 Study results by no later than April 2002. However, they were urged to "not discuss more widely at th[at] time." Despite recommendations from Pfizer physician, Dr. Elizabeth Kitsis, the 040 Study results went unpublished. In an e-mail dated April 23, 2003, which copied defendant Cawkwell, Dr. Kitsis again recommended publication of the 040 Study. In an April 24, 2003 email, Dr. Mitch Gandleman also wrote to defendant Cawkwell that "special committees" need to be set up to address publication of the CABG-1 Study, the SUCCESS Study and "the cancer pain trials with valde." Defendant Cawkwell replied, among other things (emphasis added): "Pfizer publication policy doesn't necessitate that we publish every study, and **we have embargoed a number of celebrex and bextra studies**. Perhaps we should review/discuss our criteria for what gets published, what not, and why, and review the list of not published studies and reconsider. This might be a separate committee instead of a cancer pain pubs committee." An e-mail sent to defendant Cawkwell dated April 25, 2003 confirmed

that Pfizer "currently ha[d] no pub plans" for the 040 Study, as well as a host of others (including valdecoxib Study 047 and Study 061).

225. The 040 Cancer Pain Study was not published during the remainder of the Class Period.

N. The CABG-1 Cardiovascular Safety Signal

226. The CABG-1 Study began on January 12, 2000 and was completed on June 16, 2000. It was a safety study that compared the administration of parecoxib (the injectible form of valdecoxib) together with valdecoxib versus placebo in patients that had undergone coronary artery bypass graft (i.e., "CABG") surgery. The study results revealed statistically significant increases in adverse events (including cardiovascular adverse events) for patients taking parecoxib followed by valdecoxib versus patients taking placebo.

227. Pharmacia and Pfizer first became aware of the CABG-1 results after the results were "unblinded" in July 2000. The results of the CABG-1 Study were discussed at the Valdecoxib Summit held in September 2000 at which more than 50 Pfizer and Pharmacia executives were scheduled to and/or did attend, including defendants Feczko and LaMattina.

228. With all the results from the 060 and 061 Studies, the 047 Study and the CABG-1 Study in hand no later than October 2000 and, thus, knowledge of valdecoxib's "Vioxx-like" profile, Pfizer made its intentions of concealing this information from the marketplace quite explicit in internal communications at the Company.

229. In a February 19, 2001 email from Ethan Weiner to several Pfizer employees, Dr. Weiner commented on the "Q and A book for the shareholder's meeting." The prior year's "Q&A" contained the question "What can you tell us about the next generation Cox-2 inhibitors in the pipeline?" And the answer from the prior year was: "Valdecoxib, the second generation COX-2 inhibitor being co-developed by Pfizer and Searle is currently in late stage clinical trials.

Based on the data we have so far, the clinical profile of this compound appears to be strong." In the February 19, 2001 email, Dr. Weiner updated the prior year's Q&A answer with (emphasis added):

Do you have cardiovascular problems like Vioxx? – **ans[wer]: do not disclose[.]**

230. Pfizer subsequently acted in accordance with Dr. Weiner's email. For example, in an April 18, 2001 Pfizer press release containing a "Q&A," the following question is posed: "Q: What is the status of valdecoxib?" The answer was: "A: Valdecoxib is a rapidly acting, highly potent selective Cox-2 inhibitor for rheumatoid arthritis, osteoarthritis, and pain that Pfizer is co-developing and will co-promote with the product's discoverer, Pharmacia. The product was filed for these indications with the FDA in the first quarter." Nothing regarding valdecoxib's "Vioxx-like" qualities or the 047 Study or CABG-1 Study was disclosed in the press release.

231. The FDA denied approval for parecoxib based on the CABG-1 Study and then later, in November 2001, the FDA denied approval of an indication for acute pain for valdecoxib also based in part on the CABG-1 Study.

232. In connection with the new drug application that Pharmacia had filed for parecoxib, the FDA told Pharmacia that that there was a safety signal revealed by the CABG-1 Study (and the 047 Study). For example, a June 11, 2001 "FDA Contact Report" regarding the subject "CABG study conclusions" was prepared by Pharmacia and reported a telephone conference held with FDA on June 11, 2001. The FDA Contact Report states: "[An FDA physician] telephoned today to explain that he felt that there was an issue with the results of the CABG study (I93-035) that he did not want to misrepresent. He commented that we had interpreted the data to say that, yes, there was a concern, but that it was strictly limited to the CABG population." The entry continues (emphasis added): "He [*i.e.*, the FDA physician] has also reviewed the cardiorenal safety data from the valdecoxib high dose safety study (047) and

feels there are **signal events in both studies** that suggest a worry in a broader patient population." Similarly, minutes of an August 3, 2001 meeting between Pharmacia and FDA, in which Drs. Needleman, Geis and Verburg participated, reflect that (emphasis added): "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."

233. Pfizer was informed of the FDA's concerns about parecoxib. Indeed, the rejection of the parecoxib NDA based on the CABG-1 Study was important to Pfizer because, as Defendants were well aware, the CABG-1 Study involved valdecoxib. Upon hearing the news that the FDA rejected the parecoxib new drug application based on safety and efficacy issues, the immediate reaction of Pfizer personnel is particularly telling. In this respect, Pfizer employee Steven Ryder emailed Dr. Ethan Weiner on July 15, 2001 and wrote: "Ominous. Do you think it is the cardiovascular safety issue?" Weiner replied (emphasis added): "I suspect (based on no evidence yet) that the safety issue is cardiovascular and the efficacy issue is problems with the post-surgical pain models. **In that case, the valdecoxib dossier is in big trouble as well**." Thus, with nothing more to go on than a "safety" rejection, two Pfizer employees intimately involved in Bextra, immediately concluded that the safety issue must be related to cardiovascular issues and that such issues would have an impact on Bextra sales levels. Later, Dr. Weiner's suspicions were confirmed as the FDA's concerns about the evidence of cardiovascular safety issues in the CABG-1 Study were made abundantly clear to Pfizer senior management.

234. After the rejection of the parecoxib NDA by the FDA, a series of emails among Pfizer employees in mid-July 2001 indicate that there was a need "to put together a concise update for Karen Katen regarding the pare situation" and that "Steve Ryder and [defendant] John LaMattina have demanded the same."

235. Thus, a Pfizer doctor sent an email dated July 16, 2001 to defendant LaMattina, Peter Corr, Steven Ryder, Ethan Weiner (and others) that states: "We wanted to provide you with a brief and 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 attached a document entitled "non approval impact.doc" which discussed the potential impact for the then-pending new drug application for valdecoxib and states (emphasis added):

> **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**.

By August 2001, it was common knowledge within Pfizer that there were cardiovascular safety signals in the CABG-1 Study and 047 Study. For example, in a August 8, 2001 email sent by a Pfizer regulatory executive to [defendant] Cawkwell and several other Pfizer employees, the regulatory executive wrote (emphasis added):

> All, We know that the **safety signals for valdecoxib/parecoxib are thromboembolic events (CABG) and hypertension (high dose 047).**

236. In an August 9, 2001 email, a Pfizer employee prepared "talking points" for Hank McKinnell regarding the situation with parecoxib and its effect on valdecoxib. The "talking points" were for defendant McKinnell's use in connection with negotiating over the "milestone" payments due under Pfizer's COX-2 co-promotion agreement with Pharmacia. In short, the more commercially valuable valdecoxib was anticipated to be, the greater the "milestone" payment Pfizer would have to make to Pharmacia under the Co-Promotion Agreement. After having been refined by Pfizer's Global Clincial Leader for the COX-2 Alliance between Pfizer and Pharmacia, the "talking points" conclude that "the milestone is inflated" and specifies the rationale. Thus, the

"talking points" summarize 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 parecoxib NDA and their 'not approvable' letter;" and state (emphasis added):

> (a) "the 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**);"
>
> (b) "[t]he AP [*i.e.*, acute pain] dose, when given over time, is one at which the **cardio-renal side effects became an issue**. Furthermore, arthritis is a disease category where patients stay on medications chronically, hence off-label usage at higher than recommended dosages (so called 'dose creep') may result in cario-renal side effects.";
>
> (c) "[a]n extrapolation of data from the NDA database, comparing the cardio-renal safety profile of valdecoxib to both Celebrex and Vioxx via normalization to naproxen, **shows a rate of clinically significant hypertension amongst valdecoxib users**;" and
>
> (d) "not only does the rejection of the parecoxib data [in the parecoxib NDA] raise concerns as to valdecoxib's safety, but also it raises concerns about the approval of the AP [*i.e.*, acute pain] label, since the safety issues arose in an AP [i.e., acute pain] study. **It is likely that the AP [*i.e.*, acute pain] indication will not be approved [by the FDA] at launch**, or that the label will be restricted."

237. Thereafter, it became even clearer that the CABG-1 Study was going to create problems with the acute pain indication sought in the valdecoxib new drug application. For example, in a teleconference between Pharmacia and Pfizer representatives and the FDA held October 22, 2001, minutes of the meeting reflect that "The problem with the acute pain indication [sought in the valdecoxib new drug application] was the safety signal from the CABG trial." A separate summary of the same October 22, 2001 teleconference with the FDA, that was emailed to defendant Cawkwell and others on October 22, 2001, states (emphasis added): "[The] CABG study revealed **a signal that seems (for FDA) to cast doubt on the safety data from all the other surgical and arthritis studies**."

238. On or about October 31, 2001, the DPC met and the CABG-1 Study results were reviewed. Indeed, an email dated November 1, 2001 from Ethan Weiner (who presented at the

meeting) to another Pfizer employee indicates that at the DPC meeting there was "[m]uch criticism of Pharmacia for doing the CABG trial in the first place – Hank [McKinnell] wanted to see the data again, which [a Pfizer doctor familiar with the study] presented." In addition to Dr. McKinnell, draft minutes of the meeting indicate that defendants Feczko, LaMattina, Katen and thirteen other senior Pfizer executives were also present for the meeting.

239. A slide presentation that was prepared for the DPC meeting, which had been reviewed by defendant Feczko and Ethan Weiner in advance, states under the heading "CABG Surgery (High Risk) Patients" that "[t]he incidence of thrombo-embolic events with 2x the recommended daily dose of parecoxib/valdecoxib for acute pain was higher than placebo." The slide presentation also reflects that with respect to valdecoxib there was a "[d]ose dependent increase in HTN [*i.e.*, hypertension]/edema most apparent at 80 mg."

240. The negative financial impact of the CABG-1 Study on valdecoxib was also discussed explicitly at the DPC meeting. In a slide entitled "Market Impact," the slide presentation further indicates that (emphasis added): "Valdecoxib **CABG data adds credence to Cox-2 CV class effect**" and "Valdecoxib label with CABG warning loss 25%."

241. On November 5, 2001, the "Valdecoxib Joint Product Team," which was comprised of at least 14 Pfizer executives, including defendant Cawkwell, and at least 18 Pharmacia executives, had a meeting at the Short Hills Hilton hotel in Short Hills, New Jersey. The team discussed the anticipated launch of valdecoxib after FDA approval. According to minutes of the meeting, which defendant Cawkwell attended, the matters discussed included (emphasis added): "CABG data will affect managed care perceptions of the portfolio, possibly raising safety concerns about Celebrex" and "**Merck might use CABG as ammo**."

242. Shortly thereafter, on November 9, 2001, Cawkwell emailed to her Pfizer colleagues the Pfizer valdecoxib team's "Launch Recommendations" and stated that "Karen

Katen will be going over this I believe in preparation for her meeting with Carrie Cox [a senior Pharmacia executive] this AM." The "Launch Recommendations" noted that the "Pharmacia/Pfizer Cox-2 Alliance received the draft U.S. valdecoxib label from the FDA on 11/07" and that: "There was no undesireable CABG wording [in the label]."

243. About a week later, on November 16, 2001, the FDA granted approval for Bextra for treatment of arthritis and menstrual cramping, but denied approval for acute pain in part due to the CABG-1 Study. More specifically, the FDA approval letter states that one of the "deficiencies" relating to the acute pain indication was: "The 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)." The reason for the denial of the acute pain indication [i.e, the CABG-1 Study], among other things, was redacted from the version of the approval letter that ultimately became available to the public.

244. Shortly before the November 16, 2001 rejection of the acute pain indication for Bextra, as noted earlier, the "JAMA Article" was published questioning the cardiovascular safety of COX-2 inhibitors and in response Pfizer and Pharmacia emphatically denied that there was any signal at all suggesting there could be a cardiovascular risk with Celebrex. In the wake of *valdecoxib's* approval, an article was published in the *Wall Street Journal* on November 19, 2001, which again raised the issues from the JAMA Article and quotes Dr. Geis regarding Bextra. The article states (emphasis added):

> [S]ales growth for [COX-2 inhibitors] has slowed recently amid concerns that they could increase the risk for heart attacks and strokes. An August article in the Journal of American Medical Association highlighted the risks.
>
> 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.

On November 19, 2001, Dr. Ryder forwarded this *Wall Street Journal* article to Dr. Weiner and others at Pfizer. In a reply email sent on November 20, 2001, Dr. Weiner highlighted Dr. Geis's statement in the article (i.e. the text emphasized above) and wrote (emphasis added):

> "Please see highlighted text. After all the trouble with JAMA, they **just don't learn**."

Despite Dr. Weiner's and Dr. Ryder's knowledge of the falsity of Dr. Geis's statement, Pfizer did nothing to correct the statement by the Co-Promoter of the product. Instead, Pfizer continued to perpetuate the false and misleading impression of the cardiovascular safety of Bextra that had been created.

245. Pfizer had a Wall Street analysts meeting scheduled for December 18, 2001. In preparation for the meeting, in a November 16, 2001 email, a Pfizer employee asked numerous other Pfizer employees, including defendant Cawkwell, for a "Q&A on hot issues" that might come up at the meeting. In response, defendant Cawkwell wrote (emhasis added): "I would think the 'hot questions' are: **Why no acute pain approval**? What is the CV and renal safety profile of Bextra? **What are the safety issues in the CABG trial**?...." Thus, Defendants clearly understood the falsity of their statements, as well as the material nature of the misrepresentations and omissions.

246. In further preparation for the meeting, Pfizer and Pharmacia employees, including Steve Geis, received an email on December 4, 2001 with a "Final EMC Rehearsal Schedule" for the upcoming analysts meeting. As stated earlier, the EMC was a top level committee that consisted of the highest level executive officers at Pfizer and Pharmacia. At this time, the Committee included both defendants McKinnell and Katen from Pfizer and also Needleman, Fred Hassan (Pharmacia's CEO) and Carrie Cox (a senior executive that headed Pharmcia's global prescription business and reported directly to Hassan) from Pharmacia. The rehearsal schedule included a forty-five minute time period allotted for a discussion of valdecoxib.

In a subsequent email sent on December 6, 2001, a Pharmacia employee wrote: "please find, for your eyes only, the (maybe not final) final presentations for the emc meeting next week Monday 10th [sic]. That day Henk [sic], Karen, Carrie and fred will meet after the EMC, after 5 pm, to finalize the launch date…." Attached to the email was a document entitled "EMC Presentation" which referenced, among other things, the CABG-1 Study.

247. Despite anticipating the "hot questions" that would likely be raised in preparation for the December 18, 2001 meeting with analysts, a slide deck presented by defendant Katen at the December 18th analyst meeting does not mention that the reason for the denial of the acute pain indication for valdecoxib was in part the CABG-1 Study. Indeed, the presentation does not mention the CABG-1 Study at all, nor does it mention any of the information seen in other studies where Bextra looked "Vioxx-like." With respect to Bextra, the presentation slides state only:

EXCEPTIONAL SAFETY OF A COX-2.

248. In September 2002, Pharmacia and Pfizer had drafted a joint press relase relating to the publication of the results of the 060 Study (discussed earlier) in a medical journal. In commenting on the draft press release in a September 3, 2002 email to Pfizer and Pharmacia personnel, a Pharmacia employee stated (emphasis added):

> Attached are my comments. I'm not a big fan of this release. I'm not sure what it gets us – particularly if we talk about a statistically significant increase in hypertension at 40 mg. Remember that this was our proposed dose for acute pain and this **release is likely to draw suspicion that the lack of the acute pain indication was related to safety issues**.

Defendant Cawkwell responded: "Agree would not use as is, but with changes could be fine," suggested changes to the release and remarked "that by changing the wording slightly we can make it less negative sounding…."

249. As discussed below, despite hiding from investors that the CABG-1 Study was one of the reasons for the FDA's denial of an acute pain indication for valdecoxib and that the

FDA had stated that the CABG-1 Study cast doubt on the safety of the drug in other patient populations, Pharmacia and Pfizer nevertheless went ahead and knowingly marketed the drug for acute pain. Indeed, internal documents at the Company indicate prescriptions for Bextra were substantially higher for pain than for the FDA-approved arthritis and menstrual cramping indications.

250. For example, an undated slide presentation entitled "So Much Power" (bearing both Pfizer's and Pharmacia's logos) indicated that in August 2002 (less than one year ***after*** the FDA's denial of the acute pain indication for valdecoxib), that only 15% of the prescriptions in the United States for Bextra were written for arthritis and menstrual cramping (the approved indications) while 30% of U.S. prescriptions for Bextra were being written for acute pain, 12% for back pain, 23% for other chronic pain and the remaining 21% for "all other" categories.

251. Ultimately, as a result of, among other things, the off-label marketing of Bextra for acute pain, a Pfizer subsidiary pled guilty in 2009 to a criminal felony violation of the law and Pfizer paid a fine in excess of one billion dollars, as discussed further below.

O. The CABG-1 Study Is Not Published Until June 2003

252. Although the study results were known since mid-2000, publication of these results were delayed and manipulated for several years. .

253. Rougly seven months after the study completed, in March 2001, Pharmacia prepared a draft manuscript relating to the CABG-1 Study and sent that draft to Pfizer for review and approval, as required under the co-promote agreement. A Pfizer doctor commented on the draft manuscript in a March 26, 2001 email to Ethan Weiner and other Pfizer employees. The Pfizer doctor wrote:

> 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.

254. Not surprisingly, JAMA, to whom the CABG-1 Study manuscript was submitted for publication, rejected the paper stating "it was not good science." This rejection, however, was viewed internally by some Pfizer personnel as "a good thing." The manuscript was not published until June 2003, over 18 months after the FDA denied approval for Bextra for acute pain based in part on the safety concerns in the CABG-1 Study. But even then, the manuscript omitted certain adverse events that were meaningful to provide a complete understanding of the safety implications of the results. Specifically, it omitted the two events of pulmonary embolism that were recognized as far back as the Strategic Summit in September 2000, as contributing to a statistically significant difference in the incidence of cardiovascular adverse events in the parecoxib/valdecoxib arm of the CABG-1 Study compared to placebo. Notably, these statistically significant results, including the two events of pulmonary embolism, were ultimately included in an amended prescribing label for Bextra in late 2004.

P. The CABG-2 Cardiovascular Safety Signal

255. In late October or early November, 2001, Pfizer and Pharmacia began to consider the design of a second study of valdecoxib (and parecoxib) in coronary artery bypass graft patients – the CABG-2 Study. In a November 2, 2001 email to numerous Pfizer employees, including defendant Cawkwell, regarding potential study designs for the CABG-2 Study, Dr. Weiner wrote (emphasis added):

> "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"]"

256. Not that Defendants needed any further confirmation regarding the cardiovascular risks of Bextra given what they had seen from, among other things, Studies 047, 060, 061, 016,

040 and the various meetings and e-mail traffic related to those studies (as well as parecoxib's rejection), but the signal in the CABG-1 Study (which Pfizer repeatedly and falsely denied ever having seen in the first place in its public statements) was further confirmed by the CABG-2 Study.

257. The CABG-2 Study began on January 28, 2003 and ended January 23, 2004. The study was designed to evaluate safety (including cardiovascular safety) and had two active treatment groups – a placebo/valdecoxib treatment arm and a parecoxib/valdecoxib treatment arm, which were each compared to a placebo/placebo treatment arm.

258. The so-called "Top-Line" results from the CABG-2 Study were summarized in a March 2, 2004 memo sent to 32 Pfizer employees, including defendant Cawkwell, Dr. Ethan Weiner, Dr. Mitch Gandleman, Dr. Claire Wohlhuter and Ed Harrigan (the global head of Pfizer's regulatory group who reported to defendant Feczko). The memo states that a "blinded review committee comprised of external experts reviewed and adjudicated" the study results and further states (emphasis added):

> The primary analysis for this study (all "CRAE's" [i.e., clinically relevant adverse events] 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.**

The memo continued: "The results indicate that there may be safety signal [sic] that need to be evaluated especially in light of the results from the earlier CABG surgery study (Study -035) which was conducted at higher doses."

259. The memo with the Top-Line results of the CABG-2 Study was forwarded to defendant Feczko and two other members of the DPC on March 4, 2004.

260. On July 23, 2004, a Pfizer employee emailed defendants McKinnell, Katen, LaMattina and several other Pfizer senior executives (including Pfizer's General Counsel) a draft of Pfizer's Form 10-Q for the quarter ended June 27, 2004. The draft contained a section for Bextra which 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.

261. Nothing regarding the statistically significant cardiovascular results in the CABG-2 Study was added to this disclosure. Instead, Pfizer subsequently issued its Form 10-Q for the quarter ended June 27, 2004 with the following disclosure regarding Bextra:

> 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 the second quarter of 2004.

262. Pfizer made no disclosure of the statistically significant cardiovascular findings from the CABG-2 Study in August 2004, despite concerns having been raised about increased cardiovascular risk seen for Bextra's competing COX-2 inhibitor Vioxx.

263. On July 23, 2004, a Pfizer regulatory employee in Europe sent an email to Harrigan (Pfizer's global regulatory chief who reported to defendant Feczko) regarding the CABG-2 Study and meetings Pfizer had with European regulators. The email listed "possible outcomes" and stated with respect to the Bextra label in Europe: "Stronger Wording to current text: Either around CABG OR even perhaps broader risk (CV - general or High Risk patients)." The same day, Harrigan forwarded the email to defendants Feczko and LaMattina and wrote (emphasis added):

> "fyi, **could be the next thing to hit the fan.**"

264. In an email on August 26, 2004, Harrigan emailed Feczko and wrote, among other things: "You probably saw this – Merck is down $1.12" and then Harrigan excerpted a August 25, 2004 *Reuters* article entitled: "FDA study finds Vioxx increases heart attack risk." Feckzo replied on the same day and wrote (emphasis added):

> "Ed thanks. I was aware of the vioxx study from the press. **The Bextra implications are concerning**…."

265. On September 30, 2004, Merck announced to the marketplace that it was withdrawing Vioxx from the market due to cardiovascular safety concerns with Vioxx. Rather than come clean about the substantial, undisclosed evidence of cardiovascular risks with Celebrex and Bextra, at defendant McKinnell's urging, Pfizer attempted to seize upon the withdrawal of Vioxx as a marketing opportunity.

Q. After Vioxx's Withdrawal, CEO McKinnell Directs That Pfizer Issue A Statement Denying Cardiovascular Risk To Avoid Collateral Damage And To Seize Upon A Marketing Opportunity

266. 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 (emphasis added):

> 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….

267. The next day, on October 1, 2004, Pfizer issued a press release (which, as typically was the case, was reviewed and approved by defendants McKinnell, Katen, Feczko and LaMattina as well as other members of Pfizer's senior management) stating (emphasis added):

> 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.

268. With the blessing of senior management, defendant Cawkwell echoed this statement in the press release in a spree of interviews with the press. For example, an October 1, 2004 article in *The Boston Globe* states (emphasis added):

> 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.

269. Throughout this time period, defendants McKinnell, Katen, Feczko and LaMattina as well as other members of Pfizer's senior management, were given updates on defendant Cawkwell's (and defendant Feczko's) statements in the media

270. Pfizer also ran advertisements in the media touting the supposedly "strong cardiovascular safety" of Celebrex. For example, Pfizer ran an ad in *The New York Times* on October 7, 2004 that states (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."

271. In addition, Pfizer sent letters directly to healthcare providers that misrepresented the evidence Pfizer possessed about cardiovascular risks associated with Celebrex. For example, a letter sent to healthcare providers shortly after Vioxx's withdrawal from the market on September 30, 2004 and signed by defendant Cawkwell and another Pfizer employee states: "[t]he cardiovascular safety of CELEBREX (celecoxib) is well established in long-term studies" and "[p]atients treated in clinical studies for up to 4 years showed no increased CV safety concerns."

272. As reflected in a Pfizer "Health Authority Contact," the Swedish Medical Products Agency ("MPA"), the Swedish equivalent of the FDA, "requested a long-term cardiovascular (CV) safety data for Celebrex" on September 30, 2004, after Vioxx was withdrawn. In response, on or about October 1, 2004, Pfizer submitted to the Swedish MPA, which acted as a representative for various other regulators in the European Union, a "Celecoxib Cardiovascular Safety Summary." The Health Authority Contact containing the "Celecoxib Cardiovascular Safety Summary" was sent directly to at least 168 Pfizer employees, including defendants Feczko and LaMattina and Ed Harrigan, Mitch Gandleman, Ethan Weiner, Ken Verburg

273. The "Celecoxib Cardiovascular Safety Summary" was prepared primarily by the medical group within Pfizer, which was run by defendant Feczko and included defendant Cawkwell. In the Introduction, the "Celecoxib Cardiovascular Safety Summary" acknowledges that Vioxx was withdrawn from the market "directly as a result of a long-term study evaluating the effects of this agent compared to placebo in subjects at risk of developing recurrent colonic polyps" and further acknowledges that this Vioxx study was "halted because of an increased risk of serious cardiovascular events…." Thus, Pfizer was well aware that Vioxx was withdrawn from the market based on cardiovascular risks seen in a *long-term*, *placebo-controlled* study in *non-arthritis patients*. The Alzheimer's 001 Study (completed in 1999) was also a *long-term, placebo-controlled* study in *non-arthritis* patients; yet Pfizer continued to conceal adverse cardiovascular results from this trial.

274. Nevertheless, with the "Celecoxib Cardiovascular Safety Summary" states (emphasis added):

> [T]here is **no evidence for concerns** regarding an increased risk for CV adverse events with celecoxib.

275. To back up Pfizer's assertion that there was "no evidence for concerns," the "Celecoxib Cardiovascular Safety Summary" addresses the Alzheimer's 001 Study. That section begins: "Pfizer has conducted 1 clinical trial in Alzheimer's disease that is pertinent to the current concerns regarding long term CV safety of celecoxib."

276. With respect to safety in the Alzheimer's 001 Study, the entirety of the submission was as follows (emphasis added):

> In summary only 2 MI events occurred in this trial in the celecoxib treatment group with too few events to draw conclusions. Five AEs (3.5%) occurred under the cerebrovascular category in the placebo group and 8 (2.7%) occurred in the celecoxib group. Hence, **these data do not suggest any cardiovascular risks in an Alzheimer's population.**

277. To achieve this desired result, Pfizer excluded numerous cardiovascular adverse events that occurred in the Alzheimer's 001 Study. Indeed, the statement made here in the response to the Swedish MPA's request was radically different from the statement made in the Senior Management Board presentation in 1999 (discussed earlier) which reflected that the "Overall Incidence" of the following adverse events "Cerebrovascular Disorder," "Cardiac Failure," "Atrial Fibrillation," "Angina Pectoris" and "Myocardial Infarction" - was 2.9% in the placebo group versus 9.8% in the celecoxib 200 mg BID group and that the difference was statistically significant.

278. As discussed in greater detail below, the "Celecoxib Cardiovascular Safety Summary" fails to even mention that there were adverse cardiovascular events in the trial for cardiac failure, atrial fibrillation and angina pectoris and otherwise omits significant information regarding cardiovascular adverse events in the Alzheimer's 001 Study. Moreover, the summary failed to mention that there were 17 deaths in the Alzheimer's 001 Study, some of which were cardiovascular-related.

279. The "Celecoxib Cardiovascular Safety Summary" submitted to MPA was also very different than the information contained in the July 2003 email defendant Cawkwell had personally received (discussed earlier) which clearly reflected statistically significant differences for cardiovascular events in the Alzheimer's 001 Study.

280. Lastly, the "Celecoxib Cardiovascular Safety Summary's" misleadingly innocuous conclusion is a far cry from (and indeed the direct opposite of) the January 12, 2005 statement of Dr. Claire Wohlhuter, Pfizer's Pain and Arthritis Medical Group Leader to her supervisor (referenced earlier herein) that:

> With regard to Alzheimer 001, Patients treated with 200 mg BID were **at greater risk of serious CV thromboembolic adverse events vs. placebo.**

R. The Truth Begins To Emerge And Pfizer's Stock Price Declines

281. Approximately one week after Vioxx was pulled from the market, according to *Reuters News*, "an editorial published in *The New England Journal of Medicine* late on Wednesday [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."

282. Whereas the market had consistently ignored such general comparisons in the past, this was no longer the case once Vioxx was withdrawn and Pfizer's stock fell 6% on October 7, 2004 as a result of this disclosure.

283. As pressure continued to mount from the announcement of Vioxx's withdrawal, Pfizer could no longer deny the "interesting problem" related to Bextra that defendant McKinnell had cited in his September 30, 2004 email which was sent directly to the majority of the remaining Individual Defendants. On October 15, 2004, Pfizer finally disclosed the results of the CABG-2 Study in a so-called "Dear Healthcare Provider Letter" sent to physicians, which was discussed in an accompanying press release. The letter was signed by Dr. Claire Wohlhuter and had been

reviewed by defendant Cawkwell, who (as noted above) had first received the CABG-2 Study results on March 2, 2004 – more than *seven months* earlier.

284. Even with the CABG-2 Study results in the marketplace, however, Pfizer continued to lie to the public – this time concerning the *timing* of when they knew about the CABG-2 Study results. The press release accompanying the "Dear Healthcare Provider Letter" stated that the CABG-2 Study "was just recently completed." This was untrue; as discussed earlier, the study was completed in January 2004 and Pfizer knew that the cardiovascular safety signal seen in the CABG-1 study was confirmed by the results of the CABG-2 Study no later than March 2, 2004, when the "Top-Line" results were distributed internally at Pfizer along with an analysis that stated:

> 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. . . . The results indicate that there may be safety signal [sic] that need to be evaluated especially in light of the results from the earlier CABG surgery study (Study -035) which was conducted at higher doses.

285. In response to this partial disclosure, the downward pressure on Pfizer's stock price continued as, according to analysts at CIBC World Markets, "concern regarding adverse events in CABG . . . has knocked 4% off the shares today."

286. Subsequent to the initial press release, however, defendant Cawkwell elaborated on the "just recently completed" lie in the press release, as evidenced by an interview she gave for an October 19, 2004 *New York Times* article entitled: "A New Trial of Celebrex, and Questions on Its Timing" by Andrew Pollack. The article explains (emphasis added):

> "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.**"

287. This too was false. Though it was apparently unknown to *The New York Times*, Dr. Cawkwell had the CABG-2 Study results in her hand (as did in excess of 30 other Pfizer employees) by March 2, 2004, more than 7 months (not 2 months) prior to the October 15, 2005 "Dear Healthcare Provider Letter." Defendant Feczko had the results no later than March 4, 2004.

288. Although the market had learned some of the truth relating to Bextra, Pfizer continued to deny that there was ***any*** study that showed increased risk with Celebrex. Then 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% according to *Reuters News*. However, in the story carried in DowJones that same day, Dr. Patice Roy, Pfizer Canada's director of scientific affairs, while acknowledging that the Health Canada adverse reaction information was important, affirmatively represented that "you 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." In fact, Roy was reported as saying that Pfizer has recently announced a major program to investigate the ***cardio-protective potential*** of the drug.

289. Once again, the marketplace credited Pfizer's denials of the existence of ***any*** study that showed increased risk, including placebo-controlled studies as reflected in a November 4, 2004 Merrill Lynch "FlashNote" wherein the analyst discussed the reason why Pfizer still rated a "buy":

> 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)….

290. These positive analyst reports regarding Celebrex had the impact of stabilizing Pfizer's stock price for the time being. Bextra, however, continued to be a struggle for Pfizer. In this respect, on November 10, 2004, *The New York Times* published an article linking Bextra to Vioxx based upon the presentation of results by Dr. Fitzgerald at an American Heart Association conference held in New Orleans the preceding day, wherein FitzGerald described the magnitude of the signal with Bextra being even higher than what was seen in Vioxx and referring to it as "a time bomb waiting to go off." Pfizer was able to blunt some of the impact of this statement by suggesting, in the same article that the increase was due to the high risk setting of heart surgery in which Bextra was given was the cause of the results and further proclaimed that other studies of Bextra involving 8,000 patients with arthritis who were followed for 6 to 52 weeks found no heart problems. As a result of this give and take, Pfizer's shares fell 2.1%.

291. It was not until December 17, 2004 that Pfizer could no longer contain the truth regarding Celebrex's safety profile. On that date, the National Cancer Institute (not Pfizer) announced the premature cessation of a *long-term*, *placebo-controlled* trial of Celebrex in *non-arthritis* (i.e., cancer) patients (known as the "APC Study") because of a dramatic increase in cardiovascular death and stroke among the participants in the trial.

292. On December 17, 2004, as a result of the disclosure by the National Cancer Institute, Pfizer's stock price dropped by 12%.

293. The bad news continued on Monday, December 20, 2004 as Pfizer announced that it was suspending all advertising on Celebrex temporarily at the FDA's request, causing a further drop of 5.7%.

294. Pfizer was able to stem the negative tide on December 22, 2004, when *The Wall Street Journal* reported on the prior day's trading, stating: "Pfizer climbed 68 cents, or 2.8%, to

$24.97 [on December 21, 2004]. New data from a government study that implicated naproxen, an older painkiller, as harmful to the heart may help take the negative spotlight off of Pfizer's Celebrex. The study found that Celebrex didn't lead to a higher risk of cardiovascular problems than a dummy pill." In addition, *Reuters News* reported on December 22, 2004 that the Company's stock price rose again to "$25.82 - adding to gains on Tuesday [December 21, 2004], which came after a study of Alzheimer's patients eased investors' fears that U.S. regulators will force Pfizer to withdraw its arthritis drug Celebrex."

295. These activities were entirely consistent with Pfizer's past actions. For example, after the withdrawal of Vioxx and prior to the release of the APC Study results, Pfizer attempted to deflect increasing concerns about the cardiovascular safety of Celebrex by claiming that Celebrex might be proven to decrease cardiovascular risk. More specifically, Pfizer (through Dr. Gandleman who acted as a Pfizer spokesman) touted publicly that it was setting out to prove that Celebrex was "cardioprotective" (*i.e.*, like aspirin, Celebrex could decrease the risk of heart attacks or other adverse cardiovascular events). After hearing of Pfizer's plans to attempt to prove Celebrex is cardioprotective, Pharmacia's former Chief Safety Officer, who worked extensively with Dr. Gandleman on matters relating to the cardiovascular safety of Celebrex and Bextra, sent an email to a Pfizer employee stating:

> 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] 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.

296. Also on December 22, 2004, the European Medicines Authority ("EMEA") issued a press release stating that it had received summary data from the initial testing of Celebrex – the APC Study and another set of tests known as the "PreSAP" clinical trials. The EMEA's preliminary assessment found a significantly increased risk of serious cardiovascular events in the

APC Study. The EMEA then decided to accelerate its review of COX-2 inhibitors. As a part of this review, Pfizer was asked to submit data in January 2005, and then present the information at the January 17-20, 2005 meeting of the EMEA's Committee on Medicinal Products for Human Use.

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

297. Behind the scenes, Pfizer was also working to secretly *change* the conclusion that had been reported to the FDA in 2001 regarding the Alzheimer's 001 Study.

298. In October 2004, Pfizer had begun to address inquiries from the FDA regarding the Alzheimer's 001 Study. As reflected in a "Health Authority Contact" dated October 25, 2004 sent to, among many others, defendant Cawkwell and Dr. Claire Wohlhuter, the FDA requested additional information from Pfizer relating to patients who suffered "cerebrovascular disorders" in the study. Pfizer also secretly initiated a process which would ultimately lead to (i) significant changes to the clinical study report that had been submitted to the FDA in June 2001 regarding the Alzheimer's 001 Study and (ii) correcting the false and misleading impression created by the April 2000 abstract.

299. The original Alzheimer's 001 Study final study report submitted to the FDA stated: "In conclusion, the results of this study ***demonstrate***" that "Oral doses of celecoxib 200 mg BID were generally safe and well tolerated in this elderly, debilitated population." In addition, the written text of the 83-page study report failed to state that there were statistically significant increases observed for cardiovascular events between Alzheimer's patients taking Celebrex versus patients taking placebo, although the tables annexed to the remainder of the 2,890 page report did contain information on the statistical differences for cardiovascular adverse events in the study.

300. On December 17, 2004, the Commmittee on Energy and Commerce of the U.S. House of Representatives commenced an investigation and requested information relating to the

cardiovascular safety of Celebrex in response to which the Company's lawyers would later provide documents relating to the Alzheimer's 001 Study.

301. On December 23, 2004, the FDA issued a public health advisory recommending the limited use of all COX-2 inhibitors (Celebrex, Bextra and Vioxx) following recently released data showing that the COX-2 inhibitors may be associated with an increased risk of cardiovascular events especially when they are used for long periods of time or in very high risk settings such as immediately after CABG surgery.

302. Meanwhile, also on December 23, 2004, but unbeknownst to the market, two members of the Data Safety Monitoring Board ("DSMB") for the Alzheimer's 001 Study had a telephone conversation with defendant Cawkwell and another Pfizer employee regarding the Alzheimer's 001 Study. In that telephone call, as evidenced by a December 23, 2004 email from defendant Cawkwell to two Pfizer in-house attorneys (including Michael Parini discussed earlier) and others summarizing the conversation, Cawkwell:

> reassured the DSMB that…[Pfizer] recognize[s] that **this is a study that had shown *unfavorable imbalances* of specific CV events**.

(Emphasis added)

303. In addition, on December 27, 2004, also unbeknownst to the market, Pfizer received a letter from the DSMB dated December 24, 2004 following up on the December 23rd telephone conversation. The letter, initially received by defendant Cawkwell, and subsequently forwarded to defendant Feczko, Pfizer's in-house counsel (including Michael Parini), and numerous other Pfizer employees states (emphasis added):

> Towards the end of the trial [*i.e.*, the Alzheimer's 001 Study] we observed an accrual of adverse events, mainly the expected gastrointestinal events. However, review of final data in August 1999 and later showed that there was an indication of **excess cardiovascular-related and other risk**, although not to an extent that would be nominally statistically significant.

The letter further states (emphasis added):

> (a) "It [*i.e.*, the Alzheimer's 001 Study] needs to be formally analyzed separately as well as in your integrated safety summaries and meta-analyses, yet **it can't be "merely" lumped into a comprehensive metaanalytic model**. In fact this database may be the only medically ill-elderly population you have in a placebo controlled trial of celecoxib, and thus might **reveal information otherwise unobserveable in medically healthier or younger samples**;" and
>
> (b) "It [*i.e.*, the Alzheimer's 001 Study] **should have been fully published in 2000**, and perhaps if it had been some attention might have been drawn to potential safety issues."

304. On January 5, 2005, unbeknownst to the market, Pfizer changed the conclusion it had released to the public since at least the April 2000 abstract. Pfizer submitted to the FDA a supplemental report to the original Alzheimer's 001 Study report that had been submitted in June 2001. Unlike in the original report submitted in June 2001, the supplemental report states in the text that (emphasis added):

> 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). These differences were primarily driven by the individual terms cardiac failure, fibrillation atrial, and angina pectoris.

The supplemental report also changes the conclusion that was in the original report -- which was, "In conclusion, the results of this study demonstrate" that "Oral doses of celecoxib 200 mg BID were generally safe and well tolerated in this elderly, debilitated population." The new conclusion was (emphasis added):

> The safety and tolerability of celecoxib 200 mg BID, compared to placebo, in this elderly, debilitated population **cannot be decisively concluded** from this study.

305. Pfizer did not disclose the existence of this supplemental Alzheimer's 001 Study report to investors.

306. Although the supplemental Alzheimer's 001 Study report changed the conclusion in the final FDA study report, no changes were made to the abstract from the Alzheimer's 001 Study, which remained in the public domain. Like the original Alzheimer's 001 Study report

submitted to the FDA, the abstract (emphasis added): (a) contained the conclusion that "Celecoxib 200 mg BID was safe and well tolerated in this elderly population" and (b) failed to state 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)." Indeed, as alluded to earlier herein, the abstract went a step further than the original FDA final study report in that it affirmatively (but falsely) stated (emphasis added): "The safety profile ***was similar*** in the two treatment groups." Still, no disclosure was made to correct the abstract or otherwise inform the marketplace about the truth concerning the Alzheimer's 001 Study at this time.

307. Also unbeknownst to the market, Pfizer changed the misleading information regarding the Alzheimer's 001 Study in the "Celecoxib Cardiovascular Safety Summary" it had earlier submitted on or about October 1, 2004 to the Swedish MPA after Vioxx was withdrawn.

308. On or about January 8, 2005, Pfizer made a submission to the Swedish MPA and other European regulators. As reflected in the January 8, 2005 submission, in or about November 2004, "[t]he European Commission…[initiated a process] in order to assess **all aspects** of cardiovascular safety of COX-2 inhibitors (celecoxib, etroicoxib, lumiracoxib), *including* thrombotic events (e.g., cardiac and cerbrovascular) **and cardio-renal events**." One of the questions posed to Pfizer in the procees was to "Analyze the risk of **cardiorenal reactions** (hypertension, oedema, cardiac failure) **versus placebo** and active controls." Nevertheless, Pfizer limited its "revised" discussion of the Alzheimer's 001 Study to cardiovascular thromboembolic events, a more narrow subset of cardiovascular events generally.

309. Under the heading for the Alzheimer's 001 Study, the January 8, 2005 submission states:

> Regarding cardiovascular safety, patients treated with celecoxib 200 mg BID had greater incidence of serious cardiovascular thromboembolic adverse events compared to patients treated with placebo (Table 15).

The table, which is entitled "Serious Cardiovascular Thromboembolic Adverse Events," reflects that:

> (a) 1 patient in the Celecoxib 200 mg BID group had a cardiac arrest versus 0 patients in the placebo group;
>
> (b) 2 patients in the Celecoxib 200 mg BID group had a myocardial infarction versus 0 patients in the placebo group;
>
> (c) 1 patient in the Celecoxib 200 mg BID group suffered "Tachycardia ventricular" versus 0 patients in the placebo group;
>
> (d) 1 patient in the Celecoxib 200 mg BID group had a cerebral hemorrhage versus 0 patients in the placebo group;
>
> (e) 6 patients in the Celecoxib 200 mg BID group had a cerebrovascular disorder versus 3 patients in the placebo group; and
>
> (f) 1 patient in the Celecoxib 200 mg group had a pulmonary embolism versus 0 in the placebo group.

The submission also states that there were 17 deaths during the study, 13 of which were in the celecoxib group versus only four of which were in the placebo group.

310. By contrast, as noted earlier, the submission made to the Swedish MPA after the withdrawal of Vioxx (more than three months earlier) stated only (emphasis added):

> In summary only 2 MI events occurred in this trial in the celecoxib treatment group with too few events to draw conclusions. Five AEs (3.5%) occurred under the cerebrovascular category in the placebo group and 8 (2.7%) occurred in the celecoxib group. Hence, **these data do not suggest any cardiovascular risks in an Alzheimer's population.**

The statement that "these data do not suggest any cardiovascular risks in an Alzheimer's population" was not included in the January 8, 2005 submission.

311. A December 7, 2004 email from a Pfizer employee to defendant Cawkwell, among others, explains the strategy behind Pfizer's submission to the MPA regarding the Alzheimer's 001 Study after Vioxx's withdrawal. The email states (emphasis added):

> 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 synchronise in EU with the US AC [*i.e.*, FDA advisory committee].

312. While privately "deferring" inclusion of cardiovascular data in submissions to regulators, publicly Pfizer was still telling the market that ***no evidence*** of cardiovascular risk had been seen in the clinical trial data for Celebrex. For example, in a January 4, 2005 interview with Ron Insana that was published in *USA Today*, defendant McKinnell was quoted as follows (emphasis added):

> 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***….

313. On January 24, 2005 -- about twenty days after submitting the supplemental clinical study report to the FDA that changed, among other things, the "safe and well tolerated" conclusion of the Alzheimer's 001 Study and more than four years after the abstract regarding the Alzheimer's 001 Study -- Pfizer quietly posted on the Internet a "Clinical Study Synopsis" of the Alzheimer's 001 Study, along with numerous other studies.

314. Similar to the undisclosed Senior Management Board presentation from November, 1999 (more than five years earlier), the synopsis revealed that:

> A **statistically significant difference** favoring placebo in AEs [i.e., adverse events] was observed [in the Alzheimer's 001 Study] for certain CV-related body system terms (CV Disorders, General; Heart Rate and Rhythm Disorders; Myo,

> Endo, Pericardial & Valve Disorders). These differences were primarily driven by the individual terms cardiac failure, fibrillation atrial, and angina pectoris.

315. In stark contrast to the August 2000 abstract and the submission made to the Swedish MPA after the withdrawal of Vioxx, the synopsis revealed that the following "Serious Adverse Events" occurred in the Alzheimer's 001 Study:

> (a) 5 serious adverse events involving cardiac failure in the Celecoxib 200 mg BID group versus none in the placebo group;
>
> (b) 4 serious adverse events involving angina pectoris in the Celecoxib 200 mg BID group versus none in the placebo group;
>
> (c) 4 serious adverse events involving atrial fibrillation in the Celecoxib 200 mg BID group versus none in the placebo group;
>
> (d) 2 serious adverse events involving myocardial infarction in the Celecoxib 200 mg BID group versus none in the placebo group; and
>
> (e) 2 adverse events involving pulmonary edema in the Celecoxib 200 mg BID group versus none in the placebo group.

The synopsis further revealed that there were 17 deaths in the study, 13 of which were in Celebrex patients and only 4 of which were in placebo patients.

316. Of course, the synopsis that Pfizer quietly posted on the Internet does not state (as did the earlier abstract) that the safety profile in the two groups was similar. Indeed, like the supplemental Alzheimer's report that had been quietly submitted to the FDA in January 2005, the synopsis now concluded that the safety and tolerability of celecoxib in Alzheimer's patients "cannot be decisively concluded."

317. Still, despite the non-public changes to the Alzheimer's 001 Study report, Pfizer continued to lie in the synopsis about the true significance of the Alzheimer's 001 Study. While the synopsis does reflect that there were statistically significant differences, the synopsis does **not** state (as Dr. Claire Wohlhuter, Pfizer's Pain and Arthritis Medical Group Leader stated in her

January 12, 2005 email to her superiors (which was sent about two weeks prior to the synoposis being posted on the Internet)) that (emphasis added):

> With regard to Alzheimer 001**, Patients treated with 200 mg BID were at greater risk of serious CV thromboembolic adverse events vs. placebo.**

318. Pfizer's stealthy posting of the Alzheimer's 001 Study synopsis on the Internet did not work, as it was discovered and publicized in a February 1, 2005 article appearing in *The New York Times*. The article explained that Sidney M. Wolfe, a director Public Citizen, a consumer advocacy group, found the synopsis at the end of January 2005 and states: "Dr. Wolfe publicized the 1999 study [*i.e.*, 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."

319. Dr. Wolfe, who was present for and spoke at the February 7, 2001 Advisory Committee hearings (discussed earlier) where neither the Alzheimer's 001 Study or the SUCCESS Study results were disclosed, is further quoted in the *Times* article as follows (emphasis added):

> **'It's a clear signal that I would have loved to have known about four years ago.**'

320. Similarly, the *Times* article also states 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." As noted earlier, that panel decided in 2001 that Vioxx, but not Celebrex, should carry a warning about its cardiovascular risks.

321. *The Times* article also states:

> Dr. Cawkwell said yesterday that the 1999 study that showed Celebrex was ineffective in treating Alzheimer's disease had been presented at a conference in Sweden in 2000. But she said she did not know whether the study's safety data had been presented.

Defendant Cawkwell did know, however, that an article that reported on the presentation that was made in Sweden in 2000 regarding the Alzheimer's 001 Study did not contain any information whatsoever regarding the safety results of the study. Indeed, that article had been sent to defendant Cawkwell (and in-house counsel for Pfizer) more than a month earlier in a December 29, 2004 email from a Pfizer employee.

322. Following a joint meeting of the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees held from February 16-18, 2005 regarding the safety of COX-2 inhibitors it was reported on February 18, 2005, by the *Associated Press* that the FDA Advisory Panel "voted 31-1 that Celebrex should remain on the market and 17-13 in favor of Bextra with two abstaining."

323. Given the landslide vote in favor of Celebrex remaining on the market and the relative tie in the vote with respect to Bextra, the writing was on the wall that in contrast to past predictions following APC, Celebrex was likely to remain on the market with continued strong sales, while Bextra's sales were unlikely to ever return to prior levels. As reported by the *Associated Press*, this news sent shares of Pfizer rising 6.9%, or $1.74 per share.

T. The FDA Requires A "Black Box" Warning Label On Celebrex

324. The FDA has specific requirements on the content and format of labeling of human prescription drugs. One requirement concerns product label warnings. In general, the FDA has three levels of such warnings, including, in order of the least to most serious: (a) contraindications; (b) cautionary statements; and (c) black box warnings.

325. A contraindication describes situations in which the prescription drug should not be used because the risk of use clearly outweighs the benefits. Contraindications instruct patients not to take a particular medicine if they are taking another medication or suffering from a pre-

existing condition that would cause the patient to have a particular hypersensitivity to use of the drug. For example, many medicines should not be used by women during pregnancy.

326. A cautionary statement describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and the steps that should be taken should they occur, in connection with the use of the prescription drug. Celebrex and Bextra, for example, were both required to contain, since their approval by the FDA, the same cautionary statements all NSAIDs are required to carry concerning gastrointestinal risks.

327. The black box warning is the most serious warning placed in the labeling of prescription medication. Black box warnings are used by the FDA 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 warning in the FDA's arsenal, 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.

328. On April 7, 2005, upon urging from the FDA, Pfizer agreed to insert a black box warning in Celebrex's label. 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**).

329. By the end of the Class Period, it became clear that Celebrex sales had been negatively impacted by the inclusion of the above black box warning.

330. The FDA requested that Pfizer change the Celebrex label after considering the presentations, discussions and recommendations from the 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 [gastrointestinal] 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.***" (Emphasis added).

331. 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."*** (Emphasis added).

U. Pfizer Removes Bextra From The Market

332. On April 7, 2005, in the same press release in which it announced the "black box" label for Celebrex, Pfizer announced that it had been told by the FDA to remove Bextra from the market. Pfizer stated that:

> Pfizer respectfully disagrees with FDA's position regarding the overall risk/benefit profile of Bextra. However, in deference to the agency's views, the company has agreed to suspend sales of the medicine pending further discussions with the FDA. Pfizer said it will explore options with the agency under which the company might be permitted to resume making Bextra available to physicians and patients. For now, patients should stop taking Bextra and contact their physicians about appropriate treatment options..

V. Pfizer Reports The Financial Impact Of Its Prior False Statements

333. On April 19, 2005, Pfizer filed a Form 8-K with the SEC attaching a press release (the "April 19, 2005 Form 8-K") discussing Pfizer's financial results for the first quarter of 2005. The April 19, 2005 Form 8-K disclosed the financial impact of Pfizer's April 7, 2005 decision to suspend Bextra sales, thereby underscoring Pfizer's reason for concealing Bextra's cardiovascular risks in the first place:

> On April 18, 2005, the Company determined that certain intangible assets relating to Bextra, one of our selective Cox-2 inhibitor pain relievers, have become impaired due to our decision, announced on April 7, 2005, to suspend the sales of Bextra. The Company recorded certain charges totaling $1.213 billion ($766 million, net of tax) in the first quarter of 2005.

334. Finally, on October 20, 2005, in the early morning before the market opened, Pfizer announced: "The regulatory actions relating to Celebrex and the suspension of sales of Bextra have contributed to an additional decline in third-quarter 2005 selective COX-2 inhibitor worldwide revenues of $754 million (down 67 percent) and year-to-date selective COX-2 inhibitor worldwide revenues of $2.0 billion (down 62 percent) in comparison to the same periods in the prior year."

335. The stock market has responded to the negative disclosures about Bextra and Celebrex with a massive sell-off of Pfizer stock. During the Class Period, from October 31, 2000 through and including October 19, 2005, Pfizer rose to a high of $47.44 per share before falling to $21.90 upon Pfizer's October 20, 2005 disclosure of Celebrex's low sales. As the partial disclosures commenced in October of 2004, Pfizer's stock fell from $31.18 per share to $21.90, a drop of approximately $ 68.4 billion in market capitalization.

VIII. GOVERNMENTAL ACTIONS RELATED TO CELEBREX AND BEXTRA

A. A DOJ Investigation Results In A Guilty Plea And Pfizer's Payment Of The Largest Ever Criminal Fine In History

336. Almost immediately after Merck made its September 30, 2004 announcement withdrawing Vioxx from the market, regulatory authorities commenced investigations into Pfizer's conduct concerning the sale and marketing of Celebrex and Bextra. The primary objective of the investigations was to determine Pfizer's knowledge of the dangers that Celebrex and Bextra posed before and after the FDA approved the drug for prescription use.

337. In the fall of 2004, in response to the announcements by Merck and Pfizer regarding safety issues with COX-2 drugs, the U.S. Department of Justice ("DOJ") and a group of state attorneys general requested internal Pfizer documents about the marketing and safety of both Celebrex and Bextra.

338. Although the Company did not disclose the scope of the DOJ's investigation, industry experts believed the DOJ would examine, among other things, whether the Defendants misled regulators and/or manipulated federal health programs such as Medicare and Medicaid into paying for prescriptions of Celebrex and Bextra even when its use was not warranted.

339. The DOJ also investigated Pfizer's aggressive marketing practices. On March 10, 2004, the *Associated Press* reported that the DOJ was investigating Pfizer's Bextra marketing and sales practices:

> Pfizer Inc. said in a regulatory filing on Wednesday that the Justice Department was investigating its sales and marketing practices for two drugs, along with certain management care payments.
>
> Pfizer said the drugs under investigation were human growth hormone Genotropin and arthritis medication Bextra. Pfizer wouldn't comment beyond its 10K filing with the Securities and Exchange Commission. The Justice Department also declined to comment.

340. The DOJ investigation culminated in a guilty plea agreement dated August 31, 2009 between Pharmacia & Upjohn Company, Inc., a Pfizer subsidiary, pursuant to which Pharmacia & Upjohn Company, Inc. pled guilty to a felony violation of the Food, Drug and Cosmetic Act, Title 21, U.S.C. Sections 331(a), 333(a)(2) and 352(f)(1), relating to, among other things, false and misleading safety claims relating to Bextra and paid a criminal fine in the amount of $1,195,000,000 and forfeiture of $105,000,000.

341. In a related deferred prosecution agreement between Pfizer and the DOJ dated August 31, 2009 and approved by Pfizer's board of directors, Pfizer agreed to settle numerous lawsuits that had been filed against it under the federal False Claims Act and other civil liability for a total amount of $1,000,000,000, including payment to government and state Medicaid fraud control units of $503,000,000 with respect to the unlawful promotion of Bextra.

342. The deferred prosecution agreement further states: "Pfizer Inc. acknowledges that [the Pfizer subsidiary] expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information and is in fact guilty of that offense. Pfizer Inc. agrees that it will not make statements inconsistent with this explicit admission of guilt by [the Pfizer subsidiary] to the crime charged in the Information."

343. In a related Sentencing Memorandum dated October 9, 2009 in *United States of America v. Pharmacia & Upjohn Company, Inc.*, Criminal No. 09 CR 10258-DPW, U.S.D.C. for

the District of Massachusetts, the DOJ wrote in relevant part: "The United States submits that should this case have gone to trial, the evidence would prove the following;"

> (a) "Pharmacia's sales managers instructed their sales teams to promote Bextra for acute pain, including the pain of surgery, even though they knew that Bextra was not approved for these uses. Moreover, the sales force failed to disclose to physicians, customers and others that the FDA specifically declined to approve Bextra for those uses and doses, and that the FDA's refusal was due in part to a safety concern about potential serious adverse events, including cardiovascular events, in some surgeries based upon the results of the CABG-1 study.";
>
> (b) "Another way Pharmacia sales representatives promoted Bextra was to request physicians to replace Vioxx with Bextra event though Vioxx had an FDA-approved acute pain indication and Bextra did not. They also told physicians that Bextra was safer and more effective than Vioxx, despite the fact that Pharmacia knew there were no head-to-head studies of Bextra and Vioxx for the approved uses of Bextra that showed that Bextra was safer or more effective;
>
> (c) "Pharmacia sales representatives promoted Bextra 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."; and
>
> (d) "In the Medical Letters [sent to physicians who were known to prescribe Vioxx and designed to convince them to switch to Bextra], Pharmacia did not disclose the FDA's safety concern with the use of Bextra for unapproved uses. Nor did Pharmacia disclose that the FDA raised a concern about the use of Bextra in surgery based upon the CABG I study and the excess of serious cardiovascular thromboembolic events in the Bextra (after parecoxib) arm of the study."

344. The Sentencing Memorandum also states that: "During the period of criminal conduct, Pharmacia's net gain from the sales of Bextra was determined to be one billion, seven hundred ninety-one million dollars ($1,791,000,000)….57% of the net gain, or one billion, twenty-one million dollars ($1,021,000,000), is attributable to off-label sales."

345. The Sentencing Memorandum also states that (emphasis added):

> **[T]he evidence showed that tolerance of illegal conduct by substantial authority personnel was pervasive throughout the organization. Indeed,…, the conduct was not just tolerated by the snior marketing members within [the Pfizer subsidiary's] headquarters, but also urged by them….**

* * *

> **[T]he illegal conduct was pervasive throughout the company and stemmed from messages created by high levels within the national marketing team**. The corporate culture contributed to causing the conduct and allowing it to continue. **Sales employees explained that off-label promotion was tolerated and no big deal, even though they knew it was illegal**. **The goal was to avoid getting caught.** Employees, including district managers, explained that they did not questions their supervisors about the illegal conduct that they were being instructed to carry out, because to do so would be considered a "CLM" or "Career Limiting Move." A CLM meant that an employee took an action that possibly ended his/her promotion potential or led to being disfavored by management and, ultimately, fired.

B. FDA Action

346. In addition to the DOJ investigation commenced in the fall of 2004, on or about January 10, 2005, the FDA issued to Pfizer yet another Warning Letter about Celebrex ("January 10, 2005 Warning Letter"). The January 10, 2005 Warning Letter described a number of problems with five separate Celebrex advertisements: (1) a 15-second direct-to-consumer ("DTC") television ad, featuring a guitar; (2) a 30-second television DTC advertisement entitled "Celebrex Presents Arthritis Tips;" (3) a print advertisement directed to health care providers entitled "Strength They Can Stay With;" (4) a direct mail patient brochure for Bextra; and (5) a 27-minute television DTC infomercial entitled "On the Road to Joint Pain Relief."

347. The January 10, 2005 Warning Letter stated:

> These five promotional pieces variously: omit material facts, including the indication and risk information; fail to make adequate provision for the dissemination of the FDA-approved product labeling; and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims. They are, therefore, in violation of the Federal Food, Drug and Cosmetic Act (Act) and FDA implementing regulations.

IX. CLASS PERIOD EVENTS AND THE DEFENDANTS' FALSE AND MISLEADING STATEMENTS

A. Pre-Class Period Events And False And Misleading Statements

348. On February 1, 1999, Dr. Needleman gave an interview to the Philadelphia Inquirer in which he stated that "There has been no evidence of extra heart problems in the approximately 9,000 people who have taken Celebrex in trials…" Dr. Peter Isakson followed up by stating that "In fact we'll keep track of all safety around the patients taking the drug,'" and assured the investing public that "We'll monitor cardiovascular just like we monitor all the safety around Celebrex."

349. Thus, Pfizer's Co-Promoter, on behalf of itself and Pfizer, assured the market that they would be monitoring the cardiovascular risks associated with Celebrex.

350. On February 15, 2000, Pfizer issued a press release entitled "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"). In the February 15, 2000 Press Release, Pfizer 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***." (Emphasis added).

351. On February 22, 2000, Pfizer issued a press release (the "February 22, 2000 Press Release") entitled "Celebrex Sets Industry Records in First Year Generating 19 Million Prescriptions: An Estimated Seven Million Patients." The February 22, 2000 Press Release stated, in part:

> Marking the one-year anniversary of the record-setting COX-2 specific inhibitor, Searle and Pfizer Inc. reported today that . . . Celebrex [was] . . . the most successful pharmaceutical launch in U.S. history.
>
> * * *
>
> "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."***

(Emphasis added).

352. On February 29, 2000, Pfizer issued a press release (the "February 29, 2000 Press Release") entitled "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 stated, in part:

> Driven by a motivated patient population seeking ***an effective, well tolerated anti-arthritic medication***, Searle and Pfizer Inc. reported today that Celebrex® (celecoxib capsules) in its first year generated an unprecedented 19 million prescriptions, a volume unrivaled by any other prescription drug in its first year.

(Emphasis added).

353. On April 6, 2000, Pfizer issued a press release (the "April 6, 2000 Press Release") entitled "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." (Emphasis added).

354. On April 17, 2000, Pfizer issued a press release (the "April 17, 2000 Press Release") entitled "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 stated:

> In a landmark study to assess the overall long-term safety of the COX-2 specific inhibitor Celebrex® (celecoxib capsules), arthritis patients taking four times the recommended osteoarthritis (OA) dose of the drug 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 (NSAIDs) . . . . ***Importantly, Celebrex showed no increase in thromboembolic or other cardiovascular-related events, even among non-aspirin users***.
>
> * * *
>
> ***Furthermore, Celebrex showed no increases in thromboembolic events (such as myocardial infarctions and stroke) or other cardiovascular adverse events compared with the traditional NSAID comparators.*** This is an important finding in light of the fact that 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.

(Emphasis added).

355. On April 18, 2000, Pfizer issued its financial results for the first quarter of 2000, ended April 2, 2000, in a press release (the "April 18, 2000 Press Release"). The April 18, 2000 Press Release stated that "***Celebrex showed no increase in thromboembolic or other cardiovascular-related events, even among non-aspirin users***." (Emphasis added).

356. On April 28, 2000, Pharmacia issued a press release (the "April 28, 2000 Press Release") entitled "New Study Validates Safety of Pharmacia Corporation's Celebrex on Stroke, Heart Attack Issues." The April 28, 2000 Press Release discussed the results of the CLASS Study. It stated:

> 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.
>
> * * *
>
> 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.

(Emphasis added).

357. On May 23, 2000, Pfizer issued a press release (the "May 23, 2000 Press Release") entitled "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 contained the following materially false and misleading statements and/or omissions of material fact:

> New data from the Celebrex® (celecoxib capsules) long-term safety study presented during Digestive Disease Week (DDW) 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. Further, study 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. No such increase was observed with patients taking Celebrex, regardless of H. pylori status.
>
> * * *
>
> Cardiovascular Findings
>
> ***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 of non-aspirin users had cardiovascular risk factors such as hypertension, high cholesterol, tobacco use and a history of heart attacks.

(Emphasis added).

358. On June 22, 2000, Pfizer issued a press release (the "June 22, 2000 Press Release") entitled "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 contained, *inter alia*, the following materially false and misleading statements and/or omissions of material fact:

> New data derived from the first-ever head-to-head safety study presented that compares Pharmacia's COX-2 inhibitor Celebrex® (celecoxib capsules) with Merck's Vioxx® (rofecoxib) show that hypertensive osteoarthritis (OA) patients taking Vioxx experienced statistically significantly more increases in edema (1) and systolic blood pressure compared with those taking Celebrex . . . .
>
> Specifically, Vioxx-treated patients experienced a two-fold increase in clinically significant edema compared to the Celebrex-treated patients. 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.

359. The foregoing pre-class period statements, which all became part of the total mix of information impacting Pfizer's stock price at the onset of the Class Period, failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex. At the time these statements were made, high level Pfizer personnel, including without limitation the Individual Defendants knew or recklessly disregarded, among other things, the following information with respect to Celebrex:

a. the finding of statistically significant increases of heart attacks for elderly Celebrex patients versus patients taking placebo in the June 1998 ISS;

b. the potential for increased cardiovascular risk for COX-2 inhibitors as embodied in the January 1999 FitzGerald Hypothesis and analysis;

c. the findings of statistical significance for all cardiovascular events for Celebrex versus placebo as set forth in the July 14,1999 Verburg memo;

d. the findings of statistical significance for cardiovascular adverse events for Celebrex versus placebo in the November 1999 Senior Management Board presentation; and

e. the March 2000 CLASS Study cardiovascular results, with respect to which Pfizer and its Co-Promoter published only half the data.

360. At the time these statements were made, high level Pfizer personnel, including without limitation the Individual Defendants knew or recklessly disregarded, among other things, the following information with respect to Bextra:

a. the study results from the 016 Study, for which a study report was completed in August 2000; and

b. the "Vioxx-like" cardiovascular safety results and safety signals in the 047 Study, 060 and 061 Studies and CABG-1 Study, which were presented at a September 18-19th 2000 summit attended by numerous Pharmacia and Pfizer senior executives (including Defendants Feczko and LaMattina).

361. Thus, by the beginning of the Class Period, Defendants had substantial information at their disposal that reflected that statements regarding the cardiovascular risks associated with the use of Celebrex and Bextra would have to be, at a minimum, tempered, in order for them not to be materially false and misleading. Instead, as also reflected below, Defendants consistently and blatantly misrepresented the safety profile of Celebrex and Bextra by

omitting material information from their public statements and filings and/or flat out lying about cardiovascular safety.

B. Beginning Of The Class Period

362. On October 31, 2000, Pfizer issued a press release (the "October 31, 2000 Press Release") entitled "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 contained the following materially false and misleading statements and/or omissions of material fact:

> 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."

363. On November 1, 2000, Pharmacia filed a Form 8-K with the SEC (the "November 1, 2000 8-K") which stated, in part (Emphasis added):

> 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.***

364. As demonstrated by Pfizer's internal documents, Pfizer knew its statements of comparative safety over Vioxx were false and misleading. Moreover, by virtue of its silence, adopted the false and misleading statements of its Co-Promoter as its own, knowing that such

statements would impact the total mix of information for Celebrex and as a result, Pfizer's own stock price.

365. On May 2, 2000, Deutsche Bank issued a report on Pfizer embracing Pfizer's false and misleading statements. The Deutsche Bank report rates the Company a "Strong Buy." It further 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."

366. For the reasons set forth above in paragraphs 359 and 260, Defendants knew or recklessly disregarded that the emphasized portions of these statements were each materially false and misleading when made as they all failed to disclose material adverse information concerning the cardiovascular risks associated with Celebrex by falsely claiming that Celebrex showed no increase in thromboembolic or cardiovascular-related events.

C. 2001 Events And False And Misleading Statements

367. During the time period from January 1, 2001 through December 31, 2001, the Defendants made and/or caused to be issued numerous 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) and made false advertisements to the general public. During this time frame, Pfizer's Co-Promoter also made and/or caused to be issued numerous 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).

368. For example, 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.

(Emphasis added).

369. 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, *inter alia*, 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.***

(Emphasis added).

370. On August 21, 2001, Pharmacia and Pfizer issued a joint press release which states (emphasis added):

> 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,". . .**

371. The next day, on August 22, 2001, Pfizer and Pharmacia followed up with a joint press release stating the following (emphasis added):

> 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. . .

372. Pfizer's and Pharmacia's "strong support" for the supposed cardiovascular safety profile of Celebrex was followed up with the following media statements:

> (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 Admininstration … 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 (emphasis added): "'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 (emphasis added): "'**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 (emphasis added): "'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**.'"
>
> (e) a September 16, 2001 article in *The Gleaner* which states that (emphasis added) "Pharmacia and Pfizer have reiterated their confidence in the efficacy and safety of Celebrex . . . for patients with osteoarthritis and adult rheumatoid arthritis… . Celebrex has a well-documented gastrointestinal and **cardiorenal safety profile"**; and

(f) 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.

373. No contradictory statements or corrective disclosures were made by Pfizer related to the false and misleading statements made by Pharmacia, its Co-Promoter, and thus, Pfizer adopted these statements as its own, with knowledge that they were impacting the total mix of information related to Celebrex and by extension, Pfizer's own stock price.

374. 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.

(Emphasis added).

375. During Pfizer's October 17, 2001 earnings conference call, defendant Katen stated: "We have not seen any problems with cardiovascular safety with Celebrex."

376. During Pfizer's October 17, 2001 earnings conference call, defendant McKinnell made the following statement: "There's never been a cardiovascular issue raised around Celebrex other than by inference, which we think is faulty science and analysis."

377. On November 13, 2001 Pfizer issued a press release (the "November 13, 2001 Press Release") entitled "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.***

(Emphasis added).

378. 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.

(Emphasis added).

379. 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.

(Emphasis added).

380. Similarly, a December 18, 2001 press release issued by Pfizer reports on the Wall Street analysts meeting (which was attended by defendants McKinnell and Katen, among other senior Pfizer executives, including Dr. John Niblack and Dr. Peter Corr) and states (emphasis added): (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."

381. On October 18, 2001, Bear Stearns issued a report on Pfizer in which it embraced Pfizer's false and misleading statements. Bear Stearns rated Pfizer "Attractive," with a target price of $45-48. It further stated 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."

382. The foregoing 2001 statements, which all became part of the total mix of information impacting Pfizer's stock price during the Class Period, failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and/or Bextra. At the time these statements were made, high level Pfizer personnel, including without limitation the Individual Defendants, knew or recklessly disregarded, in addition to all of the adverse, non-public information summarized above at paragraphs 359 and 360 above and described in greater detail herein, the following information:

a. March 26, 2001 – the comments of a Pfizer doctor on the hidden safety issue in a CABG-1 Study draft manuscript prepared by Pharmacia which states that ultimately "the real data will have to be shown";

b. March 30, 2001 – an e-mail from Geis to Needleman and Verburg which describes the 10 to 1 increased in heart attacks for Celecoxib patients in the SUCCESS Study and characterizes is as a trend;

c. July 15, 2001 – Pfizer commentary on the implications of the FDA's rejection of Pharmacia's new drug application for parecoxib, including Weiner's immediate

suspicion that it must be due to the cardiovascular safety issue and that Bextra's "dossier" is in big trouble as well;

d. August 8, 2001 – an e-mail circulated among high level Pfizer personell stating that "All, We know that the safety signals for valdecoxib/parecoxib are thromboembolic evetns (CABG) and hypertension (high dose 047");

e. August 9, 2001 – "talking points" prepared for defendant McKinnell in which the increased cardiovascular risk of Bextra is openly discussed and used as leverage for Pfizer to negotiate better terms under its co-promote agreement with Pharmacia;

f. August 22, 2001 - revisions by the joint Pfizer/Pharmacia "Review Council" of the press release removing the reference to "all Celebrex studies have shown" and replacing it with more benign (but misleading) "Celebrex studies have shown….";

g. September 20, 2001 – a letter from UMC stating that a "serious signal" exists for heart attacks for Celebrex patients in the World Health Organization database;

h. October 22, 2001 – an FDA communication to Pfizer and Pharmacia that the CABG-1 Study results cast doubt on the safety data for all studies;

i. October 31, 2001 – a DPC meeting where: (a) the CABG -1 Study results were discussed. including the conclusion that "Safety in [the] CABG [-1] trial [was] unacceptable due to thromboemobolic events, GI events and renal dysfunction" and that the "Valdecoxib CABG data adds credence to [the] Cox-2 CV Class Effect," (b) Pharmacia is criticized for even doing the trial in the first place; and (c) the ultimate financial impact on Bextra is discussed in terms of a potential loss of 25%.

383. For these reasons, Defendants knew or recklessly disregarded that the emphasized portions of these statements were each materially false and misleading when made as they all 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 that comparisons to Vioxx, NSAIDs or other traditional arthritis medications were inherently misleading without including this material information.

D. 2002 Events And False And Misleading Statements

384. During the time period from January 1, 2002 through December 31, 2002, the Defendants made, caused to be issued and/or adopted numerous 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) and made false advertisements to the general public. During this time frame, Pfizer's Co-Promoter also made and/or caused to be issued numerous 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).

385. 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 contained, *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.

(Emphasis added).

386. On March 25, 2002, Dr. Geis of Pharmacia is quoted in *The Wall Street Journal* as stating that a study in the *American Journal of Cardiology* in February did not identify, "'any differences 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.'"

387. No contradictory statements or corrective disclosures were made by Pfizer related to the false and misleading statements made by Pharmacia, its Co-Promoter, and thus, Pfizer adopted these statements as its own, with knowledge that they were impacting the total mix of information related to Celebrex and by extension, Pfizer's own stock price.

388. On June 7, 2002, Pfizer issued a press release (the "June 7, 2002 Press Release") entitled "FDA Approves New CELEBREX™ (Celecoxib) 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.***

(Emphasis added).

389. On June 8, 2002, *The New York Times* wrote in an article based on an interview with Steve Geis of Pharmacia (emphasis added): "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**."

390. Also on June 8, 2002, *The Record* quoted Geis as follows (emphasis added): "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."

391. No contradictory statements or corrective disclosures were made by Pfizer related to the false and misleading statements made by Pharmacia, its Co-Promoter, and thus, Pfizer

adopted these statements as its own, with knowledge that they were impacting the total mix of information related to Celebrex and by extension, Pfizer's own stock price.

392. On July 15, 2002, the *Associated Press* reported Pfizer's plans to purchase Pharmacia for $60 billion in an all-stock deal.

393. In addition, on July 15, 2002, Pfizer announced its financial results for the second quarter of 2002, which it filed as a Form 425 with the SEC on the same day (the "Second Quarter 2002 Press Release"). The Second Quarter 2002 Press Release entitled "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.

(Emphasis added).

394. 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 (emphasis added):

> [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."**

395. On July 29, 2002, defendant McKinnell stated in an interview with *The Pink Sheets* (emphasis added): "'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."

396. On August 13, 2002, Pfizer filed with the SEC its Form 10-Q for the second quarter of 2002 (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.

(Emphasis added).

397. On October 16, 2002, Pfizer filed with the SEC as a Form 425 its press release announcing its second quarter 2002 results (the "October 16, 2002 Form 425"). The October 16, 2002 Form 425 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.

(Emphasis added).

398. On October 28, 2002, Pfizer issued a press release entitled "Data Confirm Gastrointestinal Safety Profile of COX-2 Specific Inhibitor BEXTRA® versus Non-Specific

Comparator NSAIDs in Arthritis Patients." The October 28, 2002 Press Release contained the following materially false and misleading statements and/or omissions of material fact (emphasis added):

> 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."

399. On November 13, 2002, Pfizer filed with the SEC its Form 10-Q for the third quarter of 2002 (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 (emphasis added):

> 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.***

400. Analysts embraced Pfizer's false and misleading statements. On April 12, 2002, Bear Stearns issued a report on Pfizer. It stated that "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. It rated Pfizer a "Strong Buy." It further stated that "PHA's [*i.e.*, Pharmacia's] Celebrex/Bextra COX-2 franchise is in a fierce, but winning, marketing battle with Merck's

Vioxx. In 2Q02, label changes were made to both Celebrex and MRK's Vioxx to reflect the results of the CLASS and VIGOR studies. The Celebrex label change is more positive in our view - i.e., perhaps less favorable on GI safety, but more favorable on CV risks. Recent developments in this therapeutic category, on the whole, have tipped the balance in favor of the PHA/PFE COX-2 franchise, given the general perception that all COX-2 products are roughly equivalent in terms of efficacy and GI safety, the nagging concerns around CV safety that focus primarily on Vioxx, and the delay for MRK's Arcoxia. This is reflected in the COX-2 total Rx share that now stands at approximately 59% for the PHA/PFE franchise vs. 41% for MRK (after reaching roughly 50/50 share just before publication of the JAMA article last August)."

401. The foregoing 2002 statements, which all became part of the total mix of information impacting Pfizer's stock price during the Class Period, failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and/or Bextra. At the time these statements were made, high level Pfizer personnel, including without limitation the Individual Defendants knew or recklessly disregarded, all of the adverse, non-public information summarized above at paragraphs 359 and 360 and 382 and in addition (a) on March 19, 2002, the Bextra Publications Working Group (of which defendant Cawkwell was member decided to "embargo" publication of Study 047 because "publication of these data would be damaging to the product"; (b) in September 2002, defendant Cawkwell discussed with her Pfizer colleagues how publication of the 060 Study results was "likely to draw suspicion that the lack of the acute pain indication [for valdecoxib] was related to safety issues [seen in the CABG-1 Study]"; and (c) in October 2002, Pharmacia misrepresented the cardiovascular safety results in the SUCCESS Study in a letter to a foreign regulatory agency (Malyasia).

402. For these reasons, Defendants knew or recklessly disregarded that the emphasized portions of the 2002 statements were each materially false and misleading when made as they all 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 that comparisons to Vioxx, NSAIDS or other traditional arthritis medications were inherently misleading without including this material information.

E. 2003 Events And False And Misleading Statements

403. During the time period from January 1, 2003 through December 31, 2003, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts (i) related to the safety of Celebrex and Bextra (including studies of COX-2 inhibitors); and (ii) made false advertisements to the general public.

404. On January 22, 2003, Pfizer filed with the SEC as an exhibit to a Form 8-K a 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."

405. On April 22, 2003, Pfizer filed with the SEC as an exhibit to a Form 8-K a press release announcing its first quarter 2003 press release (the "First Quarter 2003 Press Release"). The First Quarter 2003 Press Release contained the following materially false and misleading statements and/or omissions of material fact (emphasis added):

> 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**.

406. On June 18, 2003, the *Waymaker* published an article entitled "Pfizer Sees Strong Prospects Based on Rapid Integration of Pharmacia and Expanded Product and R&D Opportunities." The article describes the success already achieved by Celebrex and Bextra, predicted considerable growth and states as follows:

> 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.

(Emphasis added).

407. On July 25, 2003, Pfizer filed with the SEC as an exhibit to its Form 8-K a 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.

(Emphasis added).

408. 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"). Among other Pfizer executives, defendants McKinnell and Katen participated in the Second Quarter 2003 Conference Call, which contained 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***.

(Emphasis added).

409. On October 22, 2003, Pfizer filed with the SEC as an exhibit to a Form 8-K a press release (the "Third Quarter 2003 Press Release"). The Third Quarter 2003 Press Release

contained the following materially false and misleading statements and/or omissions of material fact (emphasis added):

> 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**.

410. Analysts embraced Pfizer's false and misleading statements. On June 18, 2003, following a Pfizer conference call with analysts, Deutsche Bank issued a report on Pfizer. It rated Pfizer a "Buy." It further stated that "[f]or 2003, we expect sales of $3.75 billion for PFE's oral COX-2 agents, an increase of 6%. The franchise is winning the marketing battle with Merck's *Vioxx/Arcoxia* franchise …"

411. The foregoing 2003 statements, which all became part of the total mix of information impacting Pfizer's stock price during the Class Period, failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the

cardiovascular risks associated with Celebrex and/or Bextra. At the time these statements were made, high level Pfizer personnel, including without limitation the Individual Defendants knew or recklessly disregarded, in addition to all of the adverse, non-public information summarized above at paragraphs 359 and 360, 382 and 401 and described in greater detail herein, the following information:

a. January 22, 2003 – an email to Verburg indicates that the German Rapporteur conducted its own meta-analysis across arthritis studies and determined a relative risk of 2.3 for Celebrex versus diclofenac for thromboembolic events;

b. February 17, 2003 – a German rapporteur's report states:

(a) "[T]here is still a **clear signal for an increased risk of myocardial infarctions** with celecoxib in comparison to (some) non-selective NSAIDs";

(b) "The company [*i.e.*, the Pharmacia affiliate in Europe] states that the borderline significant finding from the SUCCESS study with respect to an increase in myocardial infarctions (MI) as compared to diclofenac was an isolated finding and that the clinical significance of this finding was difficult to assess. 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;

(c) "A meta-analysis for the endpoint MI including also the…controlled arthritis trials (CAT) and comparing celecoxib-results to un-specfied NSAIDs likewise **shows an increased risk for celecoxib with respect to the endpoint MI**…."; and

(d) the submitted data of the…Controlled Arthritis Trials, the CLASS- and the SUCCESS-studies show that **celecoxib was associated with an [sic] dose-dependent increased frequency of myocardial infarction** in the celecoxib groups compared to convestional NSAIDs."

c. April 15, 2003 – the GDRC (including defendants LaMattina and Feczko) meets to discuss the SUCCESS Study results (containing the 10 to 1 increase in heart attacks for Celebrex versus two traditional arthritis medicines) and expressly

acknowledges that the SUCCESS Study results were not published (despite the fact that the study had been completed three years earlier);

d. April 23, 2003 – a decision is made to embargo publication of the Study 040 (cancer pain study) results;

e. April 25, 2003 – the Pfizer/Pharmacia merger is completed and Verburg becomes a Pfizer employee (in addition to other Pharmacia employees who worked on matters relating to Celebrex and/or Bextra) and Geis becomes a Pfizer consultant; thus, to the extent they had knowledge that was not previously possessed or accessible to Pfizer, Pfizer now has access to all such information;

f. June 5, 2003 – a slide deck in defendant Cawkwell's files is prepared in connection with the "Cox-2 Strategic Operation Plan" which acknowledges that there was a "5X increase in MIs" in the SUCCESS Study and states "Publication [of the SUCCESS Study results] May Raise Questions.";

g. July 2003 – Verburg, at the request of defendant Cawkwell, forwards to defendant Cawkwell the cardiovascular safety results of the Alzheimer's 001 Study which clearly show there were statistically significant increases for Celebrex versus placebo; and

h. September 4, 2003 – the *New England Journal of Medicine* rejects publication of the SUCCESS Study results due to Pfizer's inappropriate safety conclusions and attempts to hide the data relating to the 10 to 1 increase in heart attacks in the study.

412. For these reasons, Defendants knew or recklessly disregarded that the emphasized portions of these statements were each materially false and misleading when made as they all 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 that comparisons to Vioxx, NSAIDs or other traditional arthritis medications were inherently misleading without including this material information.

F. 2004 Events And False And Misleading Statements

413. During the time period from January 1, 2004 though December 31, 2004, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts (i) related to the safety of Celebrex and Bextra (including studies of COX-2 inhibitors); and (ii) made false advertisements to the general public.

414. On January 22, 2004, Pfizer filed with the SEC as an exhibit to its Form 8-K 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 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**.

(Emphasis added).

415. On April 20, 2004, Pfizer filed with the SEC as an exhibit to a Form 8-K a press release announcing its first quarter 2004 financial results (the "First Quarter 2004 Press Release"). The First Quarter 2004 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 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.

(Emphasis added).

416. On May 7, 2004, Pfizer filed with the SEC its Form 10-Q for the first quarter of 2004 (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.

(Emphasis added).

417. On June 12, 2004, Pfizer issued a press release (the "June 12, 2004 Press Release") entitled "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 12, 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.

(Emphasis added).

418. 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.

(Emphasis added).

419. 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.***

(Emphasis added).

420. The foregoing statements made in the first 9 months of 2004, which all became part of the total mix of information impacting Pfizer's stock price during the Class Period, failed to disclose material adverse information then known by or recklessly disregarded by the

Defendants concerning the cardiovascular risks associated with Celebrex and/or Bextra. At the time these statements were made, high level Pfizer personnel, including without limitation certain of the Individual Defendants knew or recklessly disregarded, in addition to all of the adverse, non-public information summarized above at paragraphs 359-360, 382, 401, 411 and described in greater detail herein, the following information:

a. February, 6, 2004 – an e-mail from a Pfizer employee to defendant Cawkwell asking why SUCCESS has never been published and citing safety rumors about "serious…CV risks of celecoxib";

b. March 2, 2004 – the CABG-2 "top-line" results are reported to defendant Cawkwell, Weiner, Harrigan and more than 30 other Pfizer employees with an analysis showing that the study revealed "a significantly higher incidence of CV thromboembolic CRAEs (i.e., clinically relevant adverse events)" for parecoxib/valdecoxib patients versus placebo patients;

c. March 4, 2004 – the CABG-2 results are sent to defendant Feczko and two others on Pfizer's DPC;

d. June 10, 2004 – an e-mail from Merck gently reminding Pfizer that the Alzheimer's 001 Study results were never published; and

e. July 23, 2004 – Harrigan's email to defendants Feczko and LaMattina about the potential effect of CABG-2 on Bextra in Europe which stated: "fyi, could be the next thing to hit the fan."

421. For these reasons, Defendants knew or recklessly disregarded that the emphasized portions of the 2004 statements set forth above were each materially false and misleading when made as they all 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 that comparisons to Vioxx, NSAIDs or other traditional arthritis medications were inherently misleading without including this material information.

422. On August 25, 2004, the FDA announced the results of a major safety study of patients taking Vioxx that was conducted by David Graham, MD, an FDA epidemiologist. The FDA study 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.

423. On August 26, 2004, *The Wall Street Journal* reported that in response to news of a 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."

424. 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 served as a complete wake-up call for Pfizer that its own cardiovascular risks that had been concealed over the years should have been disclosed. However, at the insistence of defendant McKinnell, Pfizer's CEO at the time, Pfizer viewed this as the opportunity of a lifetime to market its COX-2 drugs with virtually no competition.

425. In this respect, Pfizer falsely asserted the cardiovascular safety of both Celebrex and Bextra in a press release (the "September 30, 2004 Press Release"), 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**.

The September 30, 2004 Press Release and the August 26 2004 statement made by defendant Feczko were materially false and misleading statements regarding the cardiovascular safety of Celebrex and Bextra in that they failed to disclose material adverse information then known by or recklessly disregarded by the 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 misleading in their comparison with the safety issues linked to Merck's Vioxx.

426. The *St. Louis Post-Dispatch* also published an article on October 1, 2004 entitled "Pfizer's Celebrex may get boost from Merck's decision to pull Vioxx." In that 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.

427. Also on October 1, 2004, Pfizer issued a press release, once 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."

(Emphasis added).

428. On October 1, 2004, the *Boston Globe* published an article attributing the following statements to defendant Cawkwell (emphasis added): "[T]he company knows of **no study** that shows an increased heart risk with Celebrex. . ."

429. The October 1, 2004 Press Release and the other statements set forth above from that same date were each materially false and misleading for the same reasons as the September 30, 2004 Press Release.

430. On October 4, 2004, *The Wall Street Journal* reported defendant Feczko made the following statement:

> "We're even more confident today because the studies have consistently not demonstrated any increased cardiovascular risk with Celebrex."

431. The foregoing statement by defendant Feczko was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that Pfizer studies have consistently not demonstrated any increased cardiovascular risk with Celebrex.

432. 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."

433. The foregoing statement by defendant Cawkwell was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that

there was no evidence of increased risk or heart problems among the 75 million Americans who have taken Celebrex.

434. Pfizer ran an advertisement in *The New York Times* on October 7, 2004 that states (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 up to 4 years show no increased cardiovascular safety concerns."

435. The foregoing statement by Pfizer was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that there were no studies showing increased cardiovascular safety concerns.

436. 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®).

(Emphasis added). The October 12, 2004 Statement made false and misleading statements regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting 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.

437. On October 15, 2004, Pfizer filed as an exhibit to a Form 8-K a press release (the "October 15, 2004 Press Release"). The October 15, 2004 Press Release announced plans to conduct further Bextra cardiovascular safety studies, and 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.***

(Emphasis added). The October 15, 2004 Press Release made false and misleading statements regarding the cardiovascular safety of Bextra in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Bextra, demonstrated by the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, by falsely claiming that available clinical information showed no increased risk of cardiovascular thromboembolic events in patients taking Bextra.

438. On October 18, 2004, Pfizer issued a press release entitled "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.

(Emphasis added). The October 18, 2004 Press Release made false and misleading statements regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by deceptively reaffirming the long term safety of Celebrex.

439. In an October 19, 2004 *New York Times* article entitled: "A New Trial of Celebrex, and Questions on Its Timing" by Andrew Pollack (the "October 19, 2004 *New York Times* Article"), the article states (emphasis added):

> 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.**

440. The October 19, 2004 *New York Times* Article made false and misleading statements regarding the cardiovascular safety of Bextra in that it failed to disclose material

adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Bextra, demonstrated by the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, and also because defendant Cawkwell falsely claimed that Pfizer knew the results of the CABG-2 Study two months before the article when in reality Pfizer (and defendant Cawkwell) knew the results on March 2, 2004, more than seven months earlier.

441. 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"). Among other Pfizer executives, Defendants McKinnell, Katen and Feczko participated in the call. The Third Quarter 2004 Conference Call 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.

(Emphasis added). The emphasized statements made during the Third Quarter 2004 Conference Call regarding the cardiovascular safety of Celebrex were materially false and misleading statements when made in that Defendants failed to disclose material adverse information then known by or recklessly disregarded concerning the cardiovascular risks associated with Celebrex, as demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein. Further, the statements that Celebrex has an outstanding long term safety profile were also false and misleading when made. The emphasized statements made regarding the cardiovascular safety of Bextra were also materially false and misleading when made in that Defendants failed to disclose material adverse information then known by or recklessly disregarded concerning the cardiovascular and thrombotic risks associated with Bextra, as demonstrated by the CABG-1 Study, the CABG-2 Study and the other studies alleged

earlier herein. Defendants also falsely claimed that available clinical evidence for Bextra showed no increased risk of cardiovascular thrombotic events in patients with OA and RA.

442. Also on October 20, 2004, Pfizer filed as an exhibit to a Form 8-K a press release (the "October 20, 2004 Press Release") announcing its third quarter 2004 financial results. The October 20, 2004 Press Release contained the following statements and/or omissions of material fact that constituted misrepresentations for the same reasons as the Third Quarter 2004 Conference Call:

> 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.***

(Emphasis added).

443. On November 4, 2004, Pfizer issued a press release (the "November 4, 2004 Press Release") falsely asserting the cardiovascular safety of Celebrex following a report in Canada's *National Post*. The November 4, 2004 Press Release entitled "Pfizer Affirms Celebrex Safety" contained the following materially false and misleading statements and/or omissions of material fact:

> 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.***

(Emphasis added). The November 4, 2004 Press Release contained false and misleading statements regarding the cardiovascular safety of Celebrex in that Defendants failed to disclose material adverse information then known by or recklessly disregarded by them concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein. Defendants also misrepresented that Celebrex has a well established safety profile showing no increased cardiovascular risks.

444. On November 5, 2004, Pfizer filed with the SEC its Form 10-Q for the third quarter of 2004 (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.***

(Emphasis added). The emphasized statements were materially false and misleading for the same reasons set forth above in connection with the November 4, 2004 Press Release.

445. On the November 10, 2004 episode of the *Nightly Business Report*, a segment was aired where defendant McKinnell was interviewed by Stephanie Woods ("Woods"). During that interview, defendant McKinnell made the following materially false and misleading statements and/or omissions of material fact (emphasis added):

> 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 made false and misleading statements during the *Nightly Business Report* episode regarding the cardiovascular safety of Celebrex and Bextra in that he failed to disclose

material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, by misrepresenting that Celebrex and Bextra were safe and that Celebrex might even offer cardio-protective benefits.

446. On November 12, 2004, *Newsweek* reported that defendant Cawkwell made the following statement: "We have not seen increased cardiovascular-type risks."

447. The foregoing statement by defendant Cawkwell was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that Pfizer had not seen increased cardiovascular-type risks.

448. On November 30, 2004, Pfizer held a conference call with securities analysts (the "November 30, 2004 Conference Call"). Among other Pfizer executives, Defendants McKinnell, Katen and Feczko participated in the call. The November 30, 2004 Conference Call contained the following materially false and misleading statements and/or omissions of material fact:

> FECKZO (sic): . . . 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 (sic): . . . ***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.***

(Emphasis added). The emphasized portions of the November 30, 2004 Conference Call were materially false and misleading statements when made as Defendants failed to disclose material adverse information then known by or recklessly disregarded by them concerning the cardiovascular risks associated with Celebrex and Bextra, as demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein. The

statements were also false and misleading by virtue of the results of the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein.

449. On December 1, 2004, defendant McKinnell was quoted in an interview (the "December 1, 2004 McKinnell Interview") with Neil Cavuto published in *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.

(Emphasis added). The December 1, 2004 McKinnell Interview made false and misleading statements regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular and risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that Celebrex was safe and might even offer cardio-protective benefits.

450. 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 placebo. Pfizer executives attempted to downplay the cardiovascular risks associated with Celebrex. In an *Associated Press*

published interview entitled "Pfizer Finds Heart Attack Risk with Celebrex, Plans to Continue to Sell Drug," defendant Feczko stated that "it has not [been] shown in totality that it [Celebrex] increases the risk of heart attacks."

451. Later, in a *Nightly Business Report* interview, defendant McKinnell engaged in the following exchange with correspondent Jeff Yastine ("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.

452. Defendant McKinnell made false and misleading statements in the *Nightly Business Report* interview regarding the cardiovascular safety of Celebrex and Bextra in that he failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, by misrepresenting that Celebrex and Bextra posed no increased cardiovascular risks.

453. 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.

454. The foregoing statement by defendant McKinnell was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that Pfizer's controlled clinical trials showed no evidence of cardiovascular risk.

455. 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.

456. The foregoing statement by defendant McKinnell was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that Pfizer had not seen any early signals of cardiovascular risk in Pfizer's data for Celebrex.

457. Pfizer issued the following statement reported by *PR Newswire* on December 21, 2004:

> 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.

The foregoing statement by defendant Pfizer was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting 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.

G. Analysts Embrace Defendants' False And Misleading Statements In 2004

458. Throughout 2004, analysts followed the 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 the Defendants' statements failed to disclose material facts of the serious cardiovascular risks Celebrex and Bextra posed. Nonetheless, the analysts relied on the Defendants' statements as the basis for recommending that investors purchase the Company's stock, and in this way, made a market hopelessly distorted by false and misleading information. For example:

- On September 30, 2004, William Blair & Co., LLC 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 6, 2004, Friedman Billings Ramsey issued a report on Pfizer entitled "Can't Get Enough – Upgrading to Outperform from Market Perform, Raising Price Target to $38," which stated in part: "Celebrex safety holding up. Given that Celebrex is in the same class as Vioxx, there have been concerns that Celebrex might also harbor some unrecognized safety issues. However, on learning of the cardiovascular risks associated with Vioxx, the company contacted independent safety committees overseeing three long-term trials, two to examine colon cancer (five year studies) and one to examine Alzheimer's disease (which has been running three years). ***According to the safety committees, there were no indications of any increased cardiovascular risk among study patients in any of the trials***. Similar results were seen in retrospective studies, including an FDA funded study examining 1.4 million patient records from Kaiser Permanente. In this study, patients on Vioxx were found to be more likely to have heart problems, and patients who took Celebrex were actually 14% less likely to have heart problems than those who had taken NSAID painkillers. The authors concluded that the differences between risk levels of Vioxx and Celebrex were statistically significant."

(Emphasis added).

459. Clearly reflecting the success of Pfizer's strategy of concealing the cardiovascular risks of Celebrex and Bextra, and clearly 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.

(Emphasis added).

460. Similarly, in a November 4, 2004 Merrill Lynch "FlashNote" pertaining to Pfizer states that "PFE stock is under pressure due to the latest news story highlighting Celebrex concerns" but nevertheless states "[w]e rate Pfizer a 'Buy' with a price target of $40…" In the

"Flash Note's" analysis section entitled "PFE Sponsored Studies Also Demonstrate a Clean CV Safety Profile," the Flash Note states (emphasis added):

> 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)…

461. In addition, even after the announcement of the results of the APC Study, a December 20, 2004 Sanford C. Bernstein & Co. LLC analyst report states: "PFE [i.e., Pfizer] maintains they've seen no CV risk signals on Celebrex until now [i.e., until the APC Study], which we presume is true."

H. 2005 Events And False And Misleading Statements

462. Even after the revelations in late 2004, regarding Celebrex and Bextra and Merck's withdrawal of Vioxx, in 2005 Pfizer kept up its disinformation campaign falsely trying 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.

463. On January 4, 2005, *USA Today* published an article entitled "Pfizer leader steps up to plate for Celebrex," in which defendant McKinnell was interviewed by Ron Insana. During that interview, defendant McKinnell resolutely refused to tell the truth, which Pfizer had long known, about Celebrex's cardiovascular risk – not just by nondisclosure and evasions, but by outright falsehoods:

> [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.

(Emphasis added). Defendant McKinnell made false and misleading statements in the *USA Today* article regarding the cardiovascular safety of Celebrex in that he failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and

other concealed study data and other information alleged earlier herein, by misrepresenting that clinical data for Celebrex showed no evidence of cardiovascular risk.

464. On January 19, 2005, Pfizer filed a Form 8-K with the SEC attaching a press release announcing its financial results for the fourth quarter of 2004 (the "January 19, 2005 Form 8-K"). In its January 19, 2005 Form 8-K, with an attached press release, Pfizer made the following misrepresentations, and further omitted disclosures of the dangerous facts of which Pfizer was already aware:

> 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.

465. In the January 19, 2005 Form 8-K, Pfizer misleadingly spun 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.

466. The January 19, 2005 Form 8-K made false and misleading statements regarding the cardiovascular safety of Celebrex and Bextra in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, by misrepresenting that Celebrex and Bextra were safe.

467. On February 16 through 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 that meeting 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.

At the joint meeting of the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees, defendant Feczko made false and misleading statements regarding the cardiovascular safety of Celebrex and Bextra in that he failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, by misrepresenting that available data supports Celebrex and Bextra's cardiovascular safety profile.

468. On April 5, 2005, Pfizer filed a Form 8-K with the SEC attaching a press release (the "April 5, 2005 Form 8-K"). Although referring to "uncertainties" that included "the outlook for our COX-2 franchise," the April 5, 2005 Form 8-K 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.

469. Rather than come clean with the medically and economically devastating truth that Celebrex posed substantial risks of serious cardiovascular harms, Pfizer chose to conceal those crucial truths. Misleading patients, doctors and investors, Pfizer spun the less damning story 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 Form 8-K made false and misleading statements regarding the cardiovascular safety of Celebrex and Bextra in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex and Bextra, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, by misrepresenting that Celebrex and Bextra were safe.

470. A May 16, 2005 article in UPI entitled "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."

471. The foregoing statement by defendant McKinnell was false and misleading regarding the cardiovascular safety of Bextra in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Bextra, demonstrated by the CABG-1 and CABG-2 Studies and other concealed study data and other information alleged earlier herein, by misrepresenting 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 (emphasis added): "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."

472. 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.

473. The foregoing statement by defendant McKinnell was false and misleading regarding the cardiovascular safety of Celebrex in that it failed to disclose material adverse information then known by or recklessly disregarded by the Defendants concerning the cardiovascular risks associated with Celebrex, demonstrated by the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein, by misrepresenting that Celebrex produces the same or less cardiovascular risk than older arthritis medicines.

X. APPLICABLE VIOLATIONS OF REGULATION S-K

474. Federal Regulations strictly govern what must be included in documents filed with the SEC. Specifically, 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"). *See* 17 C.F.R. § 229.10, *et seq*.

475. Items 303 of Regulation S-K, 17 C.F.R. § 229.303 ("Item 303"), governs what must be contained in the Management Discussion. Item 303 requires, in part, that the Management Discussion must:

> Discuss registrant's financial condition, changes in financial condition and results of operations. The discussion shall provide information as specified in paragraphs (a)(1) through (5) of this Item and also shall 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.

476. Paragraph (a)(3) of Item 303 requires, in part, that the Management Discussion discuss a company's "results of operations" as follows:

(i) Describe any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected. In addition, describe any other significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations.

(ii) Describe any known trends or 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. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.

477. Congress provided instructions in the Notes to Item 303 to clarify what is required of publicly-filing companies like Pfizer. Instructions 1 - 3 provide:

1. The registrant's discussion and analysis shall be of the financial statements and other statistical data that the registrant believes will enhance a reader's understanding of its financial condition, changes in financial condition and results of operations. Generally, the discussion shall cover the three-year period covered by the financial statements and shall use year-to-year comparisons or any other formats that in the registrant's judgment enhance a reader's understanding. However, where trend information is relevant, reference to the five-year selected financial data appearing pursuant to Item 301 of Regulation S-K (§ 229.301) may be necessary.

2. The purpose of the discussion and analysis shall be to provide to investors and other users information relevant to an assessment of the financial condition and results of operations of the registrant as determined by evaluating the amounts and certainty of cash flows from operations and from outside sources.

3. The 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. This would include descriptions and amounts of (A) matters that would have an impact on future operations and have not had an impact in the past, and (B) matters that have had an impact on reported

> operations and are not expected to have an impact upon future operations.

478. The Defendants had knowledge of material adverse information concerning the cardiovascular risks associated with Celebrex and Bextra and the impact that those risks could have on Pfizer and its financial statements during the Class Period and, had an obligation to disclose such risks pursuant to Regulation S-K, Item 303. Their failure to do so renders their Class Period SEC filings materially incomplete, false and misleading. The materially incomplete, false and misleading SEC filings include: November 1, 2000 Form 8-K (all dates are "filed" dates and all filings include attachments such as financial results and press releases); 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.

XI. SCIENTER/FRAUDULENT INTENT

A. General Allegations Of Scienter

479. As described more fully above, the Individual Defendants were active, culpable, and primary participants in the fraud by virtue of (1) their receipt of information reflecting the cardiovascular risks associated with Celebrex and Bextra described herein and/or their failure to review information they had a duty to monitor; (2) their actual issuance and control over Pfizer's materially false and misleading statements; (3) their supervision over employees and actual direction of policies that encouraged the fraud; and (4) their association with the Company which

made them privy to confidential information concerning the Company. The Individual Defendants knew or recklessly disregarded the materially false and misleading nature of the information they caused to be disseminated to the investing public. The Individual Defendants also knew or recklessly disregarded that the cardiovascular risks associated with Celebrex and Bextra that caused Pfizer's financial statements to be materially false and misleading would adversely affect the integrity of the market for the Company's common stock and would cause the price of the Company's common stock to be artificially inflated. The Individual Defendants acted knowingly or in such a reckless manner as to constitute fraud and deceit upon Plaintiffs.

480. As a result of having reviewed or having access to various studies, including the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, the Defendants engaged in a pattern of deceit by failing to disclose such material adverse information. The Defendants also manipulated data from clinical studies on Celebrex and Bextra which was certain to have a material adverse effect on the future expected revenues of Celebrex and Bextra. Accordingly, the Defendants engaged in a scheme to defraud and engaged in a practice that operated as a fraud on Plaintiffs.

481. The Defendants' scienter is evidenced by the intentional concealment of the Alzheimer's 001 Study and other concealed study data and other information alleged earlier herein and the CABG-1 Study, the CABG-2 Study and the other studies alleged earlier herein, the fact that Pfizer had worked closely on all aspects of Celebrex since its co-promotion agreement with Searle in February 1998, the fact that scientific knowledge and the results of trials were widely disseminated among the Celebrex and Bextra brand teams, and the fact that senior management worked closely with the Celebrex and Bextra brand teams.

B. The Individual Defendants Were In Positions Of Actual Control And/Or Supervision Of Pfizer's Manipulative Practices

482. The Individual Defendants directed, knew about or recklessly disregarded the fraudulent practices implemented under their watch. As officers of the Company, Defendants McKinnell, LaMattina, Katen, Cawkwell and Feczko each knew, through direct knowledge or knowledge learned through the supervisory nature of their positions or recklessly disregarded and failed to disclose, material adverse information; were involved in the decisions concerning Celebrex and Bextra made at the Company; and, made false and misleading statements of material fact. As discussed above (and further below), the Individual Defendants also sat on committees relating to Celebrex and Bextra and actually reviewed and had access to all clinical study information relating to Celebrex and Bextra.

483. Dr. John Talley, one of the developers of Celebrex and Bextra, informed Plaintiffs' counsel that senior managers were "right on top of" the clinical studies related to Celebrex in Bextra. Similarly, Paul Dodson, the former Senior Director of Strategic Planning and Regional operations for Pharmacia, acknowledged to Plaintiffs' counsel that decisions on what drugs to bring to market and when to launch such drugs ultimately "comes from the top." He further stated that information on clinical trial findings would be reported to top management and would be reported with some specificity where there was "some negative effect or a problem" with the drug. He specifically noted that the cardiovascular safety profile of Celebrex was a big issue with top management and that Dr. Needleman (the director of research at Searle and Pharmacia) was the person responsible for updating top management on significant developments relating to Celebrex and Bextra.

484. Krista Fox, a former Global Marketing Communications Manager at Pharmacia, explained that information regarding the clinical trials of a drug was disseminated to key decision-makers. She stated that Pharmacia, like all other companies, had a medical information group

within the company that "knows the science of a drug inside and out as well as adverse events, issues and concerns relating to the drug. Anything that you are going to get out to the public as it relates to sales and marketing efforts has to go through a review committee which usually consists of legal, medical and regulatory and they are experts on the drug and they have to approve everything."

485. Pfizer built cohesive teams of cross-functional groups to launch products called "brand teams." Brand team members worked on the same prescription drug such as Celebrex from the beginning. These brand teams would work together for the full period of the drug — often 10 to 12 years — from the period during which the drug was undergoing clinical trial and awaiting regulatory approval through the launch of the drug to the public, and through marketing, advertising and sales. Pfizer and the Individual Defendants, including defendant Katen, encouraged open communication among individuals from various functions, including scientists, physicians, salespeople, and marketers, both before and after FDA product approval.

486. Andrew Watson, a Senior Product Manager on the Celebrex brand, explained how the key information was known to the "brand team" decision makers. He explained that the brand team gets involved in the R&D process through the new drug application stage because "you want to think about how you're going to be able to commercialize a product when it finally comes to market, so as much involvement as you can the better." Watson acknowledged that brand teams would have been aware of the science behind a drug, inclusive of the R&D as well as the risks and efficacy of a brand. He further acknowledged that between the filing of a new drug application with the FDA and final FDA approval of a drug, the brand team is working with many other groups including the marketing people and the finance people in order to get the drug to market.

487. The widespread dissemination of critical information about Pfizer's drugs to the persons within Pfizer who need access to the information was part of Pfizer's (and its

predecessors) usual practice and routine course of business. For example, defendant Katen was Vice Chairman of Pfizer, President, Pfizer Human Health, and was a member of the Company's Executive Committee, its governing management body. Katen was also a member of Pfizer's Leadership Team. As head of Human Health — Pfizer's principal operating group — during the Class Period, she led the business responsible for the discovery, development, manufacture, distribution and commercialization of prescription medicines. From their beginnings, Katen was involved in the marketing of Celebrex and Bextra as head of the Celebrex and Bextra brand teams. In that position, Katen was responsible for anything that touched upon the brand's sales force, sales aids, and anything promotional about the product (including its prescription label).

488. Katen mandated the dissemination of information critical to the development and marketing of drugs throughout the Pfizer organization. Emblematic of her requirement that information be shared is the paperweight that was on her desk with the inscription, ***"Who else needs to know?"*** — a question alluding to the ongoing need to share critical information as widely as possible within Pfizer.

489. As discussed throughout this Complaint, Pfizer and its predecessors Co-Promoter had numerous committees devoted, in whole or in part, to COX-2 inhibitors. These committees were recipients of numerous presentations regarding, among other things, the clinical and other study results relating to Celebrex and Bextra including:

> (1) the Executive Management Committee (on which defendants McKinnell and Katen sat throughout the Class Period) was a joint Pfizer/Co-Promoter committee that reviewed all significant matters and decision-making relating to Celebrex and Bextra;
>
> (2) the DPC, which was a top-level Pfizer committee (on which defendants McKinnell, Katen, LaMattina and Feczko sat, along with more than a dozen other senior Pfizer executives) that reviewed study results and made decisions relating to Celebrex and Bextra;

(3) the GDRC (on which defendants LaMattina and Feczko sat), which was a global Pfizer committee that reviewed study results, tracked study publication status and made decisions relating to Celebrex and Bextra;

(4) the Senior Management Board, which was a top-level board at the Co-Promoter (on which Dr. Needleman and the Co-Promoter's CEO sat) that reviewed study results and made decisions relating to Celebrex and Bextra;

(5) the COX-2 Inhibitors Clinical Safety Committee was a Searle committee (on which Dr. Steven Geis, Dr. Verburg and numerous other Searle executives served), which reviewed and analyzed Celebrex and Bextra study results, including the Alzheimer's 001 Study results;

(6) a joint Searle/Pfizer "task force" with a public relations firm, which was formed early in 1999 at the direction of Dr. Needleman that consisted of numerous Searle and Pfizer employees for the purpose of squelching concerns raised by release of the "Fitzgerald hypothesis." This joint task force was aware of the statistically significant increase for heart attacks in elderly patients in the ISS but the public was told the opposite – that there was no difference in the incidence of cardiovascular events between patients taking Celebrex and those taking placebo;

(7) the "Bextra Publications Working Group" (of which defendant Cawkwell was a member), which was comprised of Pfizer and Pharmcia employees from, among others, the marketing, medical, research and development and public relations departments of the respective companies. This group made recommendations and decisions concerning when and whether to publish studies related to Bextra, including the decision to "embargo" the 047 Study results;

(8) a joint Pfizer/Pharmacia "CABG Action Team" (of which defendant Cawkwell and members of Pfizer's and Pharmacia's public relations departments were members), the purpose of which was to develop a communication strategy relating to the CABG-1 Study;

(9) a joint Pharmacia/Pfizer "Cardiovascular Taskforce" (of which Drs. Gandleman and Dr. Weiner were members) whose responsibilities included defining and communicating the cardiovascular profile of Celebrex and Bextra;

(10) a joint Pharmacia/Pfizer "COX-2 Steering Committee (of which Drs. Gandleman, Weiner and Geis were members), which recommended strategic plans and budgets to the EMC;

(11) a joint Pfizer/Pharmacia "Valdecoxib Global Team" (of which defendant Cawkwell, Dr. Gandleman and Dr. Verburg were members), which had responsibilities for setting brand strategy; and

(12) a joint Pfizer/Pharmacia "Celebrex Risk Management Working Group" (of which Dr. Gandleman was a member), which apparently had responsibilities for managing risk with Celebrex .

490. At Pfizer, all the top management had knowledge of the lack of disclosure of material adverse information concerning the cardiovascular risks associated with Celebrex and Bextra. Plaintiffs' counsel spoke with Dr. John J. Talley, who invented Celebrex in 1993 and Bextra in 1994. Dr. Talley worked under the direction of Dr. Needleman, the chief scientist and head of Pfizer's (then Searle's) research and development on selective COX -2 inhibitors. According to Dr. Talley, members of senior management were well aware of the clinical studies that were conducted on Celebrex and Bextra. Statements by former employees of Pharmacia (now Pfizer) who worked on Celebrex, Krista S. Fox, Paul V. Dodson and Andrew Watson, confirm that any negative effect or problem with a drug was reported to top management. The Celebrex and Bextra brand teams, knew all about the science behind Celebrex and Bextra including early medical trials and the undisclosed negative cardiovascular effects.

i. Defendant McKinnell

491. As Pfizer's President, Chief Executive Officer and Chairman of the Board of Pfizer, defendant McKinnell spearheaded Pfizer's launch of Celebrex and Bextra and steered Pfizer's failure to disclose material adverse information and the issuance of false and misleading statements concerning Celebrex and Bextra throughout the Class Period. Furthermore, as a senior officer and/or through his participation in meetings as a member of the joint Pfizer/Searle EMC and Pfizer's DPC, defendant McKinnell knew about the results of the clinical trials of Bextra and Celebrex.

492. As CEO of Pfizer during the Class Period, defendant McKinnell had the opportunity to commit fraud. Defendant McKinnell signed the Company's SEC filings, made statements during interviews and conference calls which contained materially false and

misleading statements and/or omitted to state material facts. In his position as CEO, defendant McKinnell signed Pfizer's certifications pursuant to §302 of the Sarbanes-Oxley Act of 2002, and he is responsible for the accuracy of the Company's public statements concerning Celebrex and Bextra. McKinnell made materially false and misleading statements concerning Celebrex and Bextra's cardiovascular effects and he failed to disclose in the Company's SEC filings the lack of medical and commercial viability of Bextra, and the constantly increasing liabilities Pfizer was incurring in connection with Celebrex and Bextra which caused Pfizer's financial results and future growth prospects to be materially misleading.

493. Defendant McKinnell had a motive to commit the fraud alleged herein because he had a tremendous stake in Pfizer's success. Indeed, his reputation was intimately connected with the success of the Company and its blockbuster drugs, including Celebrex and Bextra. Furthermore, during the Class Period, defendant McKinnell's compensation was tied directly to the performance of the Company. Defendant McKinnell received more than $17 million in annual salary and bonuses plus millions of dollars in awards of common stock, stock options and other compensation under the Company's various executive compensation incentive award plans, plus other lucrative remuneration and compensation, including the use of the Company's transportation, as well as a handsome retirement package. As noted in the paragraph below, defendant McKinnell was highly motivated to continue to receive the lucrative compensation and ever increasing bonuses until his retirement.

494. As referenced in Pfizer's SEC No Action Letter, filed December 16, 2005, Pfizer's senior executive officers, including defendant McKinnell, were scheduled to receive pension benefits pursuant to Pfizer's Nonfunded Supplemental Retirement Plan (as amended through 1/96). Therefore, upon his retirement in 2008, defendant McKinnell was scheduled to receive a retirement plan, including a pension plan, worth approximately $83 million or

approximately $6.5 million a year. In fact, defendant McKinnell did receive these pension and retirement benefits after he left the Company. Defendant McKinnell's lucrative retirement package provided further incentive to make Celebrex and Bextra "blockbuster" drugs at any cost.

ii. Defendant LaMattina

495. As Pfizer's Senior Vice President and President of Pfizer's Global Research and Development from October 2003 through the end of the Class Period, and having worked at Pfizer for some 30 years, defendant LaMattina knew virtually every fact regarding the Company's research and development. Indeed, defendant LaMattina played an important part in Pfizer's research and development department for thirty years. Furthermore, as a senior officer and/or through his participating in meetings as a member of Pfizer's DPC and/or GDRC, defendant LaMattina knew about the clinical trials of Bextra and Celebrex.

496. As an executive officer and a member of Pfizer's Leadership Team, the highest level decision-making group within the Company, defendant LaMattina had the opportunity to commit fraud. As a member of Pfizer's Leadership Team, defendant LaMattina made major decisions effecting corporate finance, capital investment, operations of Pfizer's core businesses, human resources, legal strategy, corporate affairs and government relations.

497. Defendant LaMattina had motive to commit the fraud alleged herein, because he also had a tremendous stake in Pfizer's success. During the Class Period, defendant LaMattina's compensation was tied directly to the performance of the Company, and over the years, including during the Class Period, he received millions of dollars in annual salary and bonuses, restricted stock and stock options and other lucrative compensation under the Company's various executive compensation and incentive plans. As noted below, defendant LaMattina's salary and bonuses were tied directly to the Company's growth and performance.

iii. Defendant Katen

498. As a member of Pfizer's Leadership Team, defendant Katen had the opportunity to commit fraud by making strategic decisions effecting corporate finance, capital investment, operations of Pfizer's core businesses, human resources, legal strategy, corporate affairs and government relations. As President of Pfizer Human Health during the Class Period, as President of Pfizer-U.S. Pharmaceutical Group and Executive Vice President and President of Pfizer-Global Pharmaceuticals during the Class Period, defendant Katen was actively involved in the launch of every new pharmaceutical product at Pfizer since 1975, including Celebrex and Bextra. Furthermore, as a senior officer and/or through her participation in meetings as a member of the joint Pfizer/Searle EMC and Pfizer's DPC, defendant Katen knew about the clinical trials of Celebrex and Bextra.

499. Since 1975, defendant Katen has been in a high level supervisory position. Katen has personally assembled and supervised cross-functional groups, including scientists, physicians, and sales people, to launch Pfizer's pharmaceutical products. The team members under defendant Katen's supervision often worked together for the full period of a drug, often more than a decade, during which time the product would undergo clinical trials and await regulatory approval by the FDA as well as be marketed and sold.

500. During the Class Period, defendant Katen's compensation was tied directly to the performance of the Company. As one of Pfizer's most senior executives, defendant Katen received millions of dollars in annual salary, bonuses, and awards of common stock, stock options and other compensation and lucrative benefits from the Company under the Company's various executive compensation and incentive plans. As noted below, defendant Katen's salary and bonuses were tied directly to the Company's growth and performance

501. As a public voice for Pfizer, defendant Katen was in the position to communicate, as she did during the Class Period on conference calls and in press releases and other public documents, false and misleading statements concerning Celebrex's and Bextra's cardiovascular effects. Defendant Katen made numerous public statements concerning Celebrex and Bextra during the Class Period that were materially false and misleading and/or omitted material facts concerning the medical and commercial viability of Celebrex and Bextra as a result of the severe cardiovascular and thrombotic risks that Celebrex and Bextra presented.

502. As one of three possible candidates for defendant McKinnell's position, as noted in *BusinessWeek Online*, dated October 13, 2005, defendant Katen needed Bextra and Celebrex to be blockbuster drugs to bolster Pfizer's growth and performance.

iv. Defendant Feczko

503. As Vice President, Executive Vice President of Pfizer Global Research and Development, and President of Pfizer Worldwide Development, defendant Feczko had the opportunity to communicate, as he did during the Class Period on conference calls and in press releases, false and misleading statements concerning Celebrex's and Bextra's cardiovascular safety. Furthermore, as a senior officer at Pfizer and/or through his participation in meetings as a member of Pfizer's DPC and/or GDRC, defendant Feczko knew about the clinical trials of Bextra and Celebrex.

v. Defendant Cawkwell

504. As Pfizer's worldwide medical director for Celebrex, defendant Cawkwell had the opportunity to communicate as she did during the Class Period in statements to the press, false and misleading information about Celebrex and Bextra. Furthermore, as worldwide medical director and/or through her participation in (or membership on) various committees as alleged earlier herein, defendant Cawkwell knew about the clinical trials of Bextra and Celebrex.

vi. Additional Persons

505. In addition to the Individual Defendants and other senior level management members at Pfizer, the following individuals were all high level employees at Pfizer, Pharmacia and/or Searle either prior to or during the relevant time period and each had sufficiently senior level positions and personal knowledge of the falsity of the challenged statements at the time they were made.

a. Dr. Mitchell Gandelman

506. From October 1999 to December 1999, Dr. Mitchell Gandelman was Sr. Associate Medicaal Director, Clinical Safety at Pfizer. From January 2000 to September 2000, he was "Medical Director Celebrex." In this role, he coordinated with Searle on all medical and regulatory activities for Celebrex, was the COX-2 Team Liaison with Worldwide Safety and collaborated with Pfizer's marketing area on medical education and public relations activities. From September 2000 to May 2003, Dr. Gandelman was "Senior Medical Director Worldwide Team Leader Cox-2 (Celebrex & Bextra)." In this role, according to his resume, he collaborated with Pfizer's marketing area to develop US & Major Market Medical/Marketing strategy, led and organized Pfizer's Worldwide COX-2 Medical Team, and managed all medical co-promote activities with Pharmacia. From May 2003 to March 2004, he was "Senior Medical Director Therapeutic Head of Pain and Inflammation." In this role, he assembled and led the Worldwide

Pain and Inflammation Medical Team and led the Special Initiative Task Force to develop, obtain approval, and initiate programs for Celebrex GI and CV issues. From March 2004 to the end of the Class Period, he was "Vice President Worldwide Medical Oncology, Pain and Inflammation." In this role, he collaborated with Pfizer's marketing area to devlop Worldwide Strategy for Oncology and Pain & Inflammation products, including Celebrex and Bextra.

507. In August 2001, an article was published in the August 22/29 issue of the Journal of the American Medical Asssociation ("JAMA") which questioned the cardiovascular safety of COX-2 inhibitors. Although completed in April 2000, more than fifteen months earlier, as described in detail below, certain individuals at Pfizer, including Dr. Gandleman, knew that the SUCCESS Study results had still not been published in a peer-reviewed manuscript as of the date of this article.

508. In response to the JAMA article, the Pfizer/Pharmacia "Review Council," a committee comprised of senior executives from both Pfizer (including Dr. Gandleman) and Pharmacia (the "RC"), met to discuss a response. The initial draft responsive press release contained the following quotation:

> 'All Celebrex studies have consistently shown no increased risk for heart attack and stroke, compared to traditional NSAIDs studied….'

509. Indeed, the significance of the inclusion of the word "All" in the press release was emphasized in an August 15, 2001 email from a Pfizer employee, Ken Bahrt, to Dr. Gandleman which stated (capitalized emhasis in original):

> Mitch, Here was the PR piece with the ALL language

510. Reflecting Dr. Gandleman's knowledge of the existence of study results which contradicted their public stance (*i.e.*, ALZ 001 and SUCCESS), the RC revised the draft press release to delete the word "All" from the quotation. Pfizer then issued the press release on August 21, 2001 which stated "Celebrex studies have consistently shown no increased risk for heart attack

or stroke compared to traditional NSAIDs studied." The press release further stated that "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."

511. Approximately one month later, on September 20, 2001, a representative of the Uppsala Montoring Centre ("UMC"), which monitors safety signals with drugs using the WHO database (described herein), sent an email to Pharmacia which stated (emphasis added):

> 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.**

The email was forwarded to Dr. Gandleman at Pfizer.

512. Dr. Gandleman was also a recipient at Pfizer of a February 18, 2003 email that set forth a German Rapporteur's (defined below) preliminary assessment report relating to Celebrex which stated that: (a) "[T]here is still a clear signal for an increased risk of myocardial infarctions with celecoxib in comparison to (some) non-selective NSAIDs"; (b) "The analysis of the available findings from CLASS and SUCCESS shows that in both studies a clear trend towards an increased risk for MI [myocardial infarction] is seen, which is significant in a respective meta-analysis"; and (c) "celecoxib was associated with an [sic] dose-dependent increased frequency of myocardial infarction in the celecoxib groups compared to convestional NSAIDs."

513. In an April 24, 2003 email from Dr. Gandleman to defendant Cawkwell, Dr. Gandleman demonstrates his knowledge that Pfizer was not timely publicizing study results that conflicted with Pfizer's public statements, when he wrote that "special committees" need to be set up to address publication of the CABG-1 Study, the SUCCESS Study and "the cancer pain trials with valde." Defendant Cawkwell acknowledges her own knowledge of this same material,

adverse information when she replies that, among other things (emphasis added): "Pfizer publication policy doesn't necessitate that we publish every study, and **we have embargoed a number of celebrex and bextra studies**. Perhaps we should review/discuss our criteria for what gets published, what not, and why, and review the list of not published studies and reconsider. . .."

514. It is clear that Dr. Gandleman was aware that the public statements relating to Celebrex's purported lack of cardiovascular risks were materially false and misleading when made as he had personal knowledge that studies had been hidden and were not reflected in the public statements.

b. Dr. Ethan Weiner

515. From August 1998 to August 2000, Dr. Ethan Weiner was Group Director in the Clincial Research group at Pfizer. From August 2000 to July 2003, he was Vice President and Worldwide Therapeutic Head of Inflammation, Clinical Development in Pfizer's Global Research and Development area. From July 2003 until the end of the Class Period he was Senior Vice President, Therapeutic Area Development Group Head.

516. Much like Dr. Gandleman was aware of the cardiovascular issues with Celebrex, so too was Dr. Weiner with respect to Bextra as reflected in the following information that was either provided to or by Dr. Weiner prior to or during the Class Period.

517. Dr. Weiner is a recipient of an August 15, 2000 e-mail sent by Dr. Eliot Forster pertaining to the recently completed 060 Study (emphasis added): "Of note, there were two MIs in the valdecoxib groups and an increased incidence of edema, hypertension and rash. **There is clearly an increased incidence of MI with valdecoxib compared to placebo and NSAIDs at this point in the data-base**. This data-base is yet to be Qced so the actual numbers may move slightly)."

518. As mentioned above, Dr. Weiner was also an attendee on Pfizer's behalf at the September 2000 Valdecoxib (Bextra) Strategic Summit. A presentation prepared and disseminated in connection with the Strategic Summit discusses and analyzes the cardiovascular issues associated with the CABG-1 Study. Approximately two weeks after the strategic summit, Dr. Weiner, in discussing Study 047, a large, 6-month safety study of high dose valdecoxib, remarked: "[t]he safety profile looks very Vioxx-like in my opinion."

519. Dr. Weiner was also instrumental in fashioning Pfizer's responses in a "Q&A book" for shareholders relating to Bextra as evidenced by his February 19, 2001 email to a number of Pfizer employees, wherein he updated the prior year's Q&A answer related to a description of Bextra with the following (emphasis added):

> Do you have cardiovascular problems like Vioxx? – **ans[wer]: do not disclose[.]**

520. Dr. Weiner shows his personal knowledge of the cardiovascular issues associated with Bextra when upon hearing that Pharmacia's NDA for Paracoxib was rejected by the FDA, he immediately concludes that it must be the cardiovascular safety issue and goes further by stating that the Valdecoxib (Bextra) dossier is also in big trouble.

521. Finally, Dr. Weiner was highly critical of CV safety statements made by Dr. Stephen Geis that appear in the November 19, 2001 issue of *The Wall Street Journal*, such as the following:

> [S]ales growth for [COX-2 inhibitors] has slowed recently amid concerns that they could increase the risk for heart attacks and strokes. An August article in the Journal of American Medical Association highlighted the risks.
>
> 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.

522. In an email sent to Dr. Weiner's boss, Stephen Ryder, on November 20, 2001, Dr. Weiner highlighted Dr. Geis's statement in the article (i.e. the text emphasized above) and wrote (emphasis added):

"Please see highlighted text. After all the trouble with JAMA, they **just don't learn**."

523. Thus, as described in further detail below, it is clear that Dr. Weiner is well versed in the cardiovascular issues surrounding Bextra and has personal knowledge that Pfizer's statements regarding Bextra were materially false and misleading when made.

c. Dr. Ken Verburg

524. In 1997, Dr. Ken Verburg began working on the COX-2 drug development in his role as Director, Clinical Research and Development at Searle. He was one of the Searle doctors who worked on the new drug application for celecoxib that was submitted to the FDA in 1998, and was involved in the preparation of the ISS. In 1999, Dr. Verburg became Senior Director, Clinical Research and Development at Searle. In 2001, after Pharmacia acquired Searle, Dr. Verburg became Clinical Vice President, Arthritis Inflammation and Pain at Pharmacia. From 1999 to 2003, Dr. Verburg reported to Steve Geis, Head of Clinical Development for Pharmacia. After Pharmacia and Pfizer merged in 2003, Dr. Verburg became Vice President, Therapeutic Area Head for Inflammation and Immunology for Pfizer. Dr. Verburg reported to Dr. Weiner from this time until the end of the Class Period.

525. As discussed earlier, Dr. Verburg prepared a memorandum dated July 14, 1999 that was distributed to numerous Searle employees and a Pfizer employee that detailed, among other things, statistically significant increases in cardiovascular events for Celebrex versus placebo in North American arthritis trials that had then been completed.

526. In addition, Dr. Verburg received a March 30, 2001 email from Dr. Steve Geis discussing the cardiovascular results of the SUCCESS Study that acknowledged the 10 to 1

increase in heart attacks and included an analysis showing that: (i) the increase is a "trend [that] contrast with the NDA and CLASS databases," (ii) the "**trend towards an increase in myocardial infarctions may raise additional regulatory concerns";** and (iii) "the potential **negative impact of this aspect of the data may outweigh any potential advantages** when put forth in a regulatory context." The 10 to 1 difference in myocardial infarctions in the SUCCESS Study was not disclosed in a submission prepared for the February 2001 FDA advisory committee hearings that related in part to the cardiovascular safety of COX-2 inhibitors, including Celebrex and Vioxx.

527. As discussed above, Dr. Verburg was fully familiar with the cardiovascular safety results from the Alzheimer's 001 Study shortly after its completion in June 1999 and knew about the statistically significant increases in cardiovascular events for Celebrex versus placebo in the study. In fact, after he joined Pfizer, in 2003, he forwarded the statistically significant cardiovascular results of the Alzheimer's 001 Study to defendant Cawkwell. Thereafter, in late 2004, Dr. Verburg signed a supplemental Alzheimer's 001 Study report that Pfizer intended to submit to the FDA, which failed to state the existence of these statistically significant differences in the text of the report. It was only after the safety committee for the Alzheimer's 001 Study "reminded" Pfizer (in late December 2004) about the adverse cardiovascular safety results from the Alzheimer's 001 Study that Dr. Verburg and Pfizer included these differences in the text of the supplemental report (and, in addition, changed the conclusion in the original report from the study "demonstrated" that Celebrex was safe in the Alzheimer's study population to safety cannot be determined).

528. Thus, at all levels of management of Pfizer and its Co-Promoters, from the Individual Defendants at the highest level of the Company to lower levels, individuals had knowledge of the materially false and misleading statements or omissions challenged herein

concerning the cardiovascular risks associated with two of Pfizer's most important, blockbuster drugs and revenue sources, Celebrex and Bextra.

C. Pfizer's Compensation Policies Provided Motive To The Individual Defendants To Perpetuate The Celebrex And Bextra Fraud

529. Pfizer's 100 highest-ranked employees, including inside directors, were eligible to compete in the 2001 Performance-Contingent Share Award Plan. Employees receive variable long-term incentive stock awards. 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. For example, defendant McKinnell earned 192,000 shares for the 1997-2001 performance period; 169,920 shares for the 1998-2002 performance period; and 75,060 shares for the 1999-2003 performance period. The Individual Defendants received a number of Performance-Contingent Shares in addition to receiving performance–contingent share awards and stock options.

530. Pfizer's executive compensation package was broken into three components: salary, annual incentive and long-term incentive with an emphasis on performance–based incentive compensation. Pfizer's compensation policies – which were reviewed and approved each year by the Compensation Committee of the Board – created a strong incentive for the Individual Defendants to continue to conceal and recklessly disregard that the cardiovascular risks associated with Celebrex and Bextra that caused Pfizer's financial statements to be materially false and misleading which would adversely affect the integrity of the market for the Company's common stock and would cause the price of the Company's common stock to be artificially inflated.

531. As noted below, from at least 2000 through the end of the Class Period, defendants McKinnell, LaMattina, and Katen received lucrative compensation and significant cash bonuses.

532. From 2000 through 2005, defendant McKinnell's aggregate base salary was $10.8 million, he received aggregate bonuses in excess of $20 million, $5.7 million in restricted stock, $42 million in options, and $32 million in long term incentive payouts all tied to the financial performance of the Company.

533. Similarly, from 2002 through 2005, defendant LaMattina's aggregate base salary was close to $3 million, he received aggregate bonuses of over $2.4 million, $1.7 million in restricted stock, more than $4.2 million in options, and $3.6 million in long-term incentive payouts all tied to the financial performance of the Company.

534. Defendant Katen, too, received lucrative compensation. From 2000 through 2005, defendant Katen received aggregate base salary of over $5.9 million, aggregate bonuses of over $6.9 million, $3.3 million in restricted stock awards, $15.2 million in options, and over $17 million in long-term incentive payouts all tied to the financial performance of the Company.

XII. FRAUD ON THE MARKET

535. At all relevant times, the market for Pfizer's common stock was efficient for the following reasons, among others:

a. Pfizer common stock met the requirements for listing, and was listed and actively traded on the NYSE (symbol PFE), a highly efficient and automated market;

b. As a regulated issuer, Pfizer filed regular reports with the SEC;

c. Pfizer regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as

communications with the financial press and other similar reporting services;

d. Pfizer was regularly followed by numerous securities analysts employed by major brokerage firms headquartered in the United States and overseas who wrote reports that were distributed to the sales forces and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;

e. The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Pfizer's securities; and

f. Without knowledge of the misrepresented or omitted facts, Plaintiffs purchased or otherwise acquired Pfizer common stock between the time that the Defendants made the material misrepresentations and omissions and the time that the truth was revealed, during which time the price of Pfizer common stock was artificially inflated by the Defendants' misrepresentations and omissions.

536. As a result of the foregoing, the market 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.

XIII. NO SAFE HARBOR

537. As alleged herein, the Defendants acted with scienter because at the time that they issued public documents and other statements in Pfizer's name, they knew or recklessly disregarded the fact that such statements were materially false and misleading or omitted material facts. Moreover, the Defendants knew such documents and statements would be issued or disseminated to the investing public, knew that persons were likely to rely upon those misrepresentations and omissions, and knowingly and recklessly participated in the issuance and dissemination of such statements and documents as primary violators of the federal securities laws.

538. As set forth in detail throughout this Complaint, the Defendants, by virtue of their control over, and/or receipt of Pfizer's materially misleading statements and their positions with the Company that made them privy to confidential proprietary information concerning Celebrex and Bextra, used such information to artificially inflate Pfizer's financial results. The Defendants created, were informed of, participated in and knew of the scheme alleged herein to distort and suppress material information pertaining to Celebrex's and Bextra's medical risks and tenuous commercial viability. With respect to non-forward looking statements and omissions, the Defendants knew and recklessly disregarded the falsity and misleading nature of that information, which they caused to be disseminated to the investing public.

539. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements pleaded in this Complaint. None of the statements pleaded herein are "forward-looking" statements and no such statement was identified as a "forward-looking statement" when made. Rather, the statements alleged herein to be false and misleading by affirmative misstatement and/or omissions of material fact all relate to facts and conditions existing at the time the statements were made. Moreover, cautionary statements, if any, did not identify important factors that could cause actual results to differ materially from those in any putative forward-looking statements.

540. In the alternative, to the extent that the statutory safe harbor does apply to any statement pleaded herein which is deemed to be forward-looking, the Defendants are liable for such false forward-looking statements because at the time each such statement was made, the speaker actually knew and/or recklessly disregarded the fact that forward-looking statements were materially false or misleading and/or omitted facts necessary to make statements previously made not materially false and misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Pfizer who actually knew or recklessly

disregarded the fact that each such statement was false and/or misleading when made. None of the historic or present tense statements made by the Defendants was an assumption underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such an assumption underlying or relating to any projection or statement of future economic performance when made nor were any of the projections or forecasts made by the Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

XIV. LOSS CAUSATION

541. Plaintiffs were damaged as a result of the Defendants' fraudulent conduct set forth herein. Throughout the Class Period, Defendants repeatedly misrepresented the safety of Celebrex and Bextra and failed to disclose material information. From the close of trading on October 6, 2004, the day preceding the first partial disclosure of the fraud,to October 19, 2005, the day preceding Pfizer's pre-market opening announcement of third quarter earnings, Pfizer's stock experienced a series of statistically significant drops, falling from $31.18 per share to $21.90 per share on October 20, 2005 (a decline of $9.28 per share or 29.7%), representing a loss in market capitalization of $68.39 billion.

542. During this time, Plaintiffs, composed of TRSL, other named plaintiffs and thousands, if not millions of class members, purchased Pfizer stock at artificially inflated prizes. Plaintiffs suffered damages as the truth gradually came out which negatively affected Pfizer's stock price. Beginning in early to mid-October 2004, Pfizer stock began to decline as the market started to learn the true dangers of Celebrex and Bextra and that they are not, and never should have been, the blockbuster drugs that Pfizer had touted to the market for so many years.

543. On October 7, 2004, *Reuters News* reported that "an editorial published in The New England Journal of Medicine late on Wednesday [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 same day, *Dow Jones News Service* reported that "Pfizer shares drop 6% as a report in New England Journal of Medicine raises concerns about Celebrex …."

544. Before the market opened on October 15, 2004, *Reuters News* reported that Pfizer "said two clinical trials [*i.e.*, the CABG-1 Study and the CABG-2 Study] showed patients taking its anti-inflammatory drug Bextra had a higher risk of cardiovascular events during high-risk coronary bypass surgery." On the same day, analysts at CIBC World Markets reported that this disclosure knocked 4% off of Pfizer's shares.

545. 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." *Reuters News* reported that "Pfizer Inc.'s (PFE.N) shares fell as much as 6.2 percent on Thursday after a report in a Canadian newspaper said the company's arthritis drug Celebrex was linked to 14 deaths."

546. Before the stock market opened on November 10, 2004, *The New York Times* disclosed that according to a preliminary study presented at an American Heart Association meeting, "[t]he incidence of heart attacks and strokes among patients given Pfizer's painkiller Bextra was more than double that of those given placebos." *Reuters News* reported that "[s]hares of Pfizer Inc. (PFE.N) fell 2.1 percent before the bell on Wednesday after the New York Times reported that a study had found a higher incidence of heart attack and stroke among patients taking Pfizer's arthritis drug Bextra."

547. Before the market opened on December 17, 2004, Pfizer disclosed that "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" and that "[b]ased on

these statistically significant findings, the sponsor of the trial, the [National Cancer Institute], has suspended the dosing of Celebrex in the study." *Reuters News* reported that "[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."

548. On December 17, 2004, the NIH finally revealed what Pfizer had known for years -- that Celebrex, one of Pfizer's largest-selling drugs, was linked to an increased risk of heart attack. The market reacted swiftly and negatively, punishing Pfizer's stock. Between the close on December 16, 2004 and December 20, 2004, Pfizer's shares fell $4.69 from $28.98 to close at $24.29 per share – a 16.2% decline that reduced Pfizer's market capitalization by more than $35.3 billion.

549. On Sunday, December 19, 2004, *Reuters News* reported that the FDA asked Pfizer "to suspend advertisements for arthritis drug Celebrex" while regulators reviewed data from the clinical trials. *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."

550. But Pfizer's shares still remained artificially inflated because the Company continued to deny that there was increased cardiovascular risk for Celebrex and Bextra and conceal the true facts. More specifically, a December 22, 2004, *Wall Street Journal* article states: "Pfizer climbed 68 cents, or 2.8%, to $24.97 [on December 21, 2004]. New data from a government study that implicated naproxen, an older painkiller, as harmful to the heart may help take the negative spotlight off of Pfizer's Celebrex. The study found that Celebrex didn't lead to a higher risk of cardiovascular problems than a dummy pill." A December 22, 2004 *Reuters* article reported that Pfizer's stock price rose again to $25.82 – adding to gains on Tuesday [December

21, 2004], which came after a study of Alzheimer's patients eased investors' fears that U.S. regulators will force Pfizer to withdraw….Celebrex." Later, a February 18, 2005 *Associated Press* article stated that FDA "advisory panel recommendations concerning the risks and benefits of…Cox-2 inhibitors sent shares of drug makers Pfizer…and Merck…soaring…Pfizer shares rose $1.74, or 6.9 percent….The panel…voted 31-1 that Celebrex should remain on the market and 17-13 in favor of Bextra with two abstaining."

551. Thereafter, on October 20, 2005, Pfizer released its results for the Third Quarter of 2005, and informed the market that the declines in its revenue caused by the revelations about Celebrex and Bextra were not short-term phenomena, but would continue into the future. The market again reacted negatively, and between the close on October 19, 2005 and October 26, 2005, Pfizer's shares fell $2.91 from $23.97 to $21.06 per share – a 12.1% decline that reduced Pfizer's market capitalization by more than $21.4 billion.

XV. TOLLING ALLEGATIONS

552. Between December 15, 2004 and June 16, 2005, numerous class actions were filed in various federal district courts, including 23 actions in the Southern District of New York, three actions in the District of Connecticut, two actions in the District of New York, and one action in the Northern District of Illinois. These securities class actions were consolidated under *In re Pfizer Securities Litigation*, MDL 05-1688 (RO). Thus, because the proposed class period does not extend back beyond five years, *see* 28 U.S.C. § 1658(b)(2), none of Plaintiffs' claims are time-barred.

553. In any event, statements by the Defendants during the Class Period assured Plaintiffs and the investing public that any partly cloudy skies or mild winds were not warnings of a storm. By falsely assuring Plaintiffs and the investing public that no study showed an increased risk for heart attack and stroke, the Defendants acted like weathermen in connection with any

early storm warnings – the Defendants had all the information, technology and expertise to render the forecast. They assured Plaintiffs and the investing public that the clouds would surely break and the wind would surely die down, giving way to an overall calm and sunny day for Celebrex and Bextra. In this way, any statute of limitations is tolled. Plaintiffs and the investing public were not at fault for being caught without their umbrellas after the Defendants assured them that no umbrellas were necessary because no storm was coming.

XVI. CLASS ACTION ALLEGATIONS

554. Lead Plaintiff and the named plaintiffs bring this action as a class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons and entities who purchased and/or otherwise acquired Pfizer common stock during the Class Period and who suffered damages as a result of their purchases (the "Class"). Lead Plaintiff and the named plaintiffs further bring this action on behalf of a sub-class (the "20A Subclass") consisting of all persons or entities who purchased contemporaneously with sales of Pfizer common stock by Individual Defnedants McKinnell, Katen and LaMattina on 10/26/00, 11/6/00, 10/19/01, 10/23/01, 10/29/01, 02/21/02, 02/25/02, 02/27/03, 11/18/03, 02/25/04, 02/26/04, 02/24/05, 05/06/05, 5/10/05, and 8/16/05. Excluded from the Class and the 20A Subclass are (1) the Company and the Individual Defendants; (2) members of the immediate family of each of the Individual Defendants; (3) the subsidiaries or affiliates of the Company or any of the Defendants; (4) any person or entity who is, or was during the Class Period, a partner, officer, director, employee or controlling person of the Company or any of the Defendants; (5) any entity in which any of the Defendants has a controlling interest; (6) the legal representatives, heirs, successors or assigns of any of the excluded persons or entities specified in this paragraph; and (7) the insurance carriers, or their affiliates who insure the Defendants.

555. The members of the Class and 20A Subclass are so numerous that joinder of all members is impracticable. As of February 16, 2006, there were approximately 7.37 billion shares of Pfizer common stock outstanding. While Plaintiffs do not know the exact number of Class or 20A Subclass members, Plaintiffs believe that there are, at minimum, thousands of members of the Class or 20A Subclass who purchased Pfizer common stock during the Class Period.

556. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

557. Common questions of law and fact exist as to all members of the Class and/or 20A Subclass and predominate over any questions affecting solely individual members of the Class and/or 20A Subclass. Among the questions of law and fact common to the Class and/or 20A Subclass are:

a. Whether the federal securities laws were violated by the Defendants' acts as alleged herein;

b. Whether the SEC filings, and other public statements published and disseminated to the investing public and purchasers of the common stock during the Class Period omitted and/or misrepresented material facts about the business affairs, financial condition and present and future prospects of the Company;

c. Whether the Defendants omitted to state and/or misrepresented material facts about the financial condition, profitability and present and future prospects of the Company;

d. Whether the Defendants acted willfully or recklessly in omitting to state and/or misrepresenting material facts about the financial condition, profitability and present and future prospects of the Company;

e. Whether the market price of Pfizer common stock during the Class Period was artificially inflated due to the non-disclosures and/or misrepresentations complained of herein; and

f. Whether the members of the Class and 20A Subclass have sustained damages, and, if so, what is the proper measure thereof.

558. Plaintiffs' claims are typical of the claims of the members of the Class and/or 20A Subclass. Plaintiffs will fairly and adequately protect the interests of the members of the Class and/or 20A Subclass and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests that are adverse or antagonistic to the Class and/or 20A Subclass.

559. A class action is superior to other available methods for fair and efficient adjudication of the controversy since joinder of all members of the Class and/or 20A Subclass is impracticable. Furthermore, the expense and burden of individual litigation make it impossible for the Class and/or 20A Subclass members individually to redress the Defendants' wrongful conduct. Furthermore, Lead Plaintiff knows of no difficulty which will be encountered in the management of this litigation which would preclude its maintenance as a class action.

COUNT ONE
(VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5(b) PROMULGATED THEREUNDER)

560. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein. This claim is asserted against all of the Defendants.

561. During the Class Period, the Defendants: (a) deceived the investing public, including Plaintiffs, as alleged herein; (b) artificially inflated and maintained the market prices of

Pfizer securities; and (c) caused Plaintiffs to purchase or otherwise acquire Pfizer common stock at artificially inflated prices.

562. The Defendants made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, and/or substantially participated in the creation of the alleged misrepresentations, which operated as a fraud and deceit upon Plaintiffs, in an effort to maintain artificially high market prices for Pfizer common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b). The Defendants consistently made materially false and misleading statements and omitted to state material facts regarding the cardiovascular dangers that Celebrex and Bextra posed during the Class Period, thus materially misrepresenting Celebrex and Bextra's medical and commercial viability.

563. 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.

564. The Defendants, directly and indirectly, by use of the means and instrumentalities of interstate commerce and/or the mails, made, or substantially participated in the creation of, untrue statements of material facts and/or omitted to state material facts necessary in order to make the statements made about the Company and/or Celebrex and Bextra in light of the circumstances under which they were made, not misleading, as set forth herein.

565. The Defendants had actual knowledge of the misrepresentations and/or omissions of material fact set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

566. The facts alleged herein give rise to a strong inference that each of the Defendants acted with scienter. The Defendants' own internal information concerning Celebrex and Bextra provided the Defendants with statistically significant information showing that Celebrex and Bextra carried severe cardiovascular and thrombotic 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 Class Period. The Defendants knew or recklessly disregarded that the financial results publicly disseminated to investors during the Class 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.

567. The Defendants carried out a deliberate scheme to protect the gigantic revenue source that Celebrex and Bextra represented for Pfizer, and the Defendants knew that Celebrex and Bextra's sales results would be incorporated into Pfizer's quarterly and annual financial statements and publicly-disseminated reports to investors.

568. 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 and thrombotic 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 available to the Individual Defendants were heavily dependent on meeting the ever growing financial targets set by Pfizer.

569. 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's common stock was artificially inflated throughout the Class Period. Unaware that the market price of Pfizer common stock was artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Defendants, or upon the integrity of the market in which Pfizer common stock traded, and the truth of any representations made to appropriate agencies and to the investing public, at the times at which any statements were made, and/or in the absence of material adverse information that was known or with deliberate recklessness disregarded by the Defendants but not disclosed in public statements by the Defendants, Plaintiffs purchased or acquired Pfizer's common stock at artificially high prices and were damaged when the truth was revealed over time.

570. 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 and thrombotic 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.

571. 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.

572. 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 Class Period.

COUNT TWO
(VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT)

573. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein. This claim is asserted against defendants McKinnell, LaMattina and Katen (the "Control Defendants").

574. The Control 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 Control 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 Control 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.

575. In particular, the Control 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.

576. As set forth in the preceding paragraphs of this Complaint, Pfizer and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

577. By virtue of their positions as controlling persons, the Individual Defendants named as Control Defendants in this Count are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of their wrongful conduct, Plaintiffs suffered damages in connection with purchases of Pfizer common stock during the Class Period.

COUNT THREE
(VIOLATION OF SECTION 20A OF THE EXCHANGE ACT)

578. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

579. This Claim is asserted against defendants McKinnell, LaMattina and Katen (the "Section 20A Defendants"), and is based upon Section 20A of the Exchange Act, 15 U.S.C. § 78t-1, in connection with their insider trading in Pfizer common stock.

580. Defendant McKinnell engaged in the following sales of Pfizer common stock during the Class Period selling almost 809,134 of the shares he held, reaping $29,755,919 in proceeds. The shares sold by McKinnell during this period represented 14.40% of the shares of Pfizer stock he owned.

Date of Disposition	Number of Shares disposed Of	Price per Share	Proceeds	Holdings	% Monthly Holdings Sold
10/26/2000	180,000	$45.33	$8,149,400	560,690	24.30%
10/23/2001	302,052	$42.61	$12,870,436	715,081	29.70%
02/27/2003	3,597	$29.33	$105,500	1,084,607	0.33%
02/25/2004	15,725	$37.20	$584,970	1,149,087	1.35%
08/16/2005	307,760	$26.110	$8,035,614	1,580,274	16.30%
Total	**809,134**		**$29,755,919**		**Average is: 14.40%**

581. Defendant Katen engaged in the following sales of Pfizer common stock during the Class Period selling almost 372,536 of the shares she held, reaping $13.2 million in proceeds.

The shares sold by Katen during this period represented 7.44% of the shares of Pfizer stock she owned.

Date of Disposition	# Shares Disposed Of	Price per Share	Proceeds	Holdings	% Monthly Holdings Sold
08/18/2000	36,000	$42.71	$1,537,560	365,009	8.98%
11/06/2000	36,000	$44.01	$1,584,360		
10/19/2001	84,960	$42.00	$3,568,320	436,393	16.30%
02/21/2002 02/25/2002	6,098 1,192 = 7,290	$41.03 $40.98	$250,201 $48,848		
02/27/2003	2,157	$29.33	$63,265	635,040	0.34%
11/18/2003	64,800	$34.37	$2,227,176	639,678	
02/26/2004	16,049	$37.15	$596,220	666,097	2.52%
02/24/2005	58,135	$26.20	$1,523,137	811,879	6.68%
05/10/2005	8,045	$27.790	$223,571	807,878	.99%
05/10/2005	59,100	$27.780	$1,641,798	748,778	7.32%
Class Period Totals	**372,536**		**$13,264,107**		**Average is: 7.44%**

582. Defendant LaMattina engaged in the following sales of Pfizer common stock during the Class Period selling almost 67,073 of the shares he held, reaping $1.8 million in proceeds. The shares sold by LaMattina during this period represented 6.08% of the shares of Pfizer stock he owned.

Date of Disposition	# Shares Disposed Of	Price per Share	Proceeds	Holdings	% Monthly Holdings Sold
02/26/2004	5,633	$37.15	$209,266	293,488	1.88%
02/24/2005	21,651	$26.200	$567,256	367,381	5.57%
05/06/2005	39,789	$27.820	$1,106,930	329,302	10.78%
Class Period Totals	**67,073**		**$1,883,452**		**Average is: 6.08%**

583. The Section 20A Defendants collectively sold more than 1,248,743 shares of Pfizer common stock, reaping total proceeds in excess of $44.9 million.

584. The Section 20A Defendants knowingly or with deliberate recklessness sold their Pfizer common stock during the Class Period while in possession of material, adverse, non-public information. As set forth in the certification contained on Schedule A to the CAC and the certification attached as Schedule B to the CAC, and the Certifications of Julie Perusse and Alden Chace, attached as Exhibits 38 and 39 to the Declaration of Mary S. Thomas in Support of Lead Plaintiff's Motion for Class Certification and Appointment of Class Representatives dated March 16, 2011, contemporaneously with sales of Pfizer stock by these Defendants, Plaintiffs purchased Pfizer common stock sold by these Defendants.

585. By reason of Plaintiffs' purchases of Pfizer stock contemporaneously with certain of the Defendants' sales of stock, Plaintiffs suffered recoverable damages. Under Section 20A of the Exchange Act, the Section 20A Defendants are liable to Plaintiffs for all profits gained and losses avoided by them as a result of these contemporaneous transactions.

XVII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding compensatory damages against all of the Defendants, jointly and severally, in favor of Plaintiffs for all losses and damages suffered as a result of the Defendants' wrongdoing alleged herein, in an amount to be determined at trial, together with interest thereon;

C. Awarding Plaintiffs their reasonable costs and expenses incurred in this action, including a reasonable allowance of fees for Plaintiffs' attorneys and experts; and

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

XVIII. JURY DEMAND

Plaintiffs demand a trial by jury as to all issues so triable.

Dated: March 27, 2012

GRANT & EISENHOFER P.A.

By: _____

Jay W. Eisenhofer
Richard S. Schiffrin
James J. Sabella
Charles T. Caliendo
Brenda F. Szydlo
485 Lexington Avenue, 29th Floor
New York, New York 10017
Telephone: (646) 722-8500
Facsimile: (646) 722-8501

and

Geoffrey C. Jarvis
Mary S. Thomas
Michele S. Carino
Ned C. Weinberger
123 Justison Street
Wilmington, DE 19801
Telephone: (302) 622-7000
Facsimile: (302) 622-7100

Attorneys for Lead Plaintiff The Teachers' Retirement System of Louisiana

ADDITIONAL COUNSEL:

David Kessler
Andrew L. Zivitz
Benjamin J. Sweet
Karen E. Reilly
Michelle M. Newcomer
KESSLER TOPAZ MELTZER & CHECK LLP
280 King of Prussia Road
Radnor, Pennsylvania 19087
Telephone: (610) 822-2229
Facsimile: (610) 667-7056

Attorneys for Christine Fleckles, Julie Perusse and Alden Chace

Christopher A. Seeger
David R. Buchanan
SEEGER WEISS LLP
77 Water Street
New York, New York 10005
Telephone: (212) 584-0700
Facsimile: (212) 584-0799

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SECURITIES LITIGATION	No. 04 Civ. 9866 (LTS) (HBP)
	ECF CASE

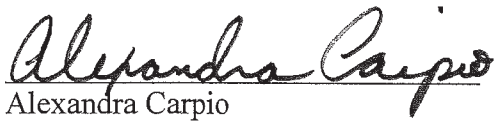
CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2012, copies of the Amended Consolidated Class Action Complaint were served upon the following counsel of record in the action filed in this Court via hand delivery:

Michael Hynes, Esq.
DLA PIPER
1251 Avenue of the Americas
New York, New York 10020

Lynn Neuner Esq.
SIMPSON THACHER & BARTLETT
425 Lexington Avenue
New York, New York 10017

Gregory A. Markel, Esq.
CADWALADER, WICKERSHAM & TAFT LLP
One World Financial Center
New York, NY 10281



Alexandra Carpio