

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

Frankenmuth Financial Group and Linda A. Watters, Commissioner, Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc., individually and on behalf of all others similarly situated,

Plaintiffs,

v.

PFIZER INC., PHARMACIA CORP., and
G.D. SEARLE & CO.,

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT

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I. NATURE OF THIS ACTION

1. Plaintiffs bring this action on behalf of a Class of all persons or entities (excluding those who assert personal injury claims) who paid for the drug Celebrex, manufactured by Defendants Pfizer, Inc. (“Pfizer”), Pharmacia Corporation (“Pharmacia”) and G.D. Searle & Co. (“Searle”).

2. Non-steroidal anti-inflammatory drugs (“NSAIDs”) have been widely used to treat arthritis, acute and chronic pain for nearly 40 years. Although they relieve symptoms in certain patients, such relief comes at the expense of important adverse effects, most notably upper gastrointestinal toxicity. Use of NSAIDs leads to admission to hospital for ulcer complications (bleeding and perforation) in around 1% of users annually and results in thousands of deaths every year.

3. The emergence of NSAIDs that selectively inhibit the cyclo-oxygenase 2 (“COX-2”) isoform, which is inducible and expressed at sites of inflammation, while sparing COX-1, associated with gastroprotection, was an apparent pharmacological breakthrough promising real hope of a better future for NSAIDs.

4. Celebrex was one of the new COX-2 inhibitors, Vioxx was the other. Defendants believed, rightfully so, that Celebrex had the potential to be a new blockbuster drug with yearly sales in the billions of dollars. As part of the unlawful scheme set forth below, Defendants embarked on a massive marketing campaign directed to both doctors and consumers to accomplish that objective. Television, print and other promotional materials gave the impression that Celebrex was a “breakthrough” drug far superior to older and far less expensive NSAIDs.

5. Defendants’ marketing and promotion of Celebrex was part of a scheme to create the impression and demand for Celebrex as a wide ranging pain reliever that would enhance consumers’ abilities to live a normal life or engage in activities such as running, playing a guitar, swimming, walking, taking exercise classes and a host of similar activities that many who suffer from chronic pain have difficulty performing. The scheme was accomplished by unlawful means including, but not limited to, (i) the suppression of data showing the cardiovascular risks

associated with the use of Celebrex, (ii) the manipulation of data in an effort to show statistical significance of fewer serious upper GI events than those using NSAIDs when in fact the complete data failed to demonstrate a statistically significant lower rate of GI complications and, in fact, use of Celebrex for more than six months *increased* the risk of GI complications, (iii) the manipulation of data to give the appearance of superiority over NSAIDs when such superiority did not exist; (iv) false promotional materials directed to doctors and consumers; and (v) the use of reprinted articles from prestigious medical journals that falsely claimed Celebrex was proven to be safer than NSAIDs.

6. From 1999 through 2003, Defendants spent approximately \$400 million on direct-to-consumer advertising for Celebrex. This expensive marketing effort paid off. In the nine months ending in September 2004, worldwide sales of Celebrex were \$2.29 billion, accounting for 6 percent of Pfizer's total sales of \$37.59 billion.

7. As a result of Defendants' scheme, they were able to create a market for Celebrex and to sell Celebrex at a premium price over NSAIDs and to have it become a standard treatment option as opposed to use of less expensive NSAIDs.

8. The success of Defendants' scheme was recently documented in a study released on January 24, 2005, in the ARCHIVES OF INTERNAL MEDICINE, Volume 165, entitled *National Trends in Cyclooxygenase-2 Inhibitor Use Since Market Release*. The authors of that study concluded that the "aggressive marketing techniques to patients and physicians" caused a growth not only in use of COX-2 inhibitors but also in overall market demand, resulting in the use of such drugs for patients who did not need them.

9. In fact, Celebrex has been promoted as a superior pain reliever when for most patients it has no proven superiority over other NSAIDs. Celebrex sells for \$2.53 to \$6.45 per day depending upon the dose, while NSAIDs sell for \$0.21 to \$0.31 per day. Billions of dollars have thus been wasted wherein Plaintiff and Class members have paid a premium price for a drug that is not a premium or superior product. Had the truth been told about its safety and efficacy, Celebrex would have sold at a price similar to that of other NSAIDs and would not

have become a standard in the treatment of arthritis and other forms of pain relief. The study in the ARCHIVES OF INTERNAL MEDICINE found that 63% of patients who received COX-2 inhibitors were at a low risk for developing the ulcers and gastrointestinal problems that the COX-2 inhibitors were aimed at preventing, and that Defendants' marketing scheme had played a significant role in over use of COX-2 inhibitors for this type of patient. In fact, the ARCHIVES study understates the lack of a need for Celebrex. An FDA reviewer found that Celebrex "did not appear to offer a unique advantage to high-risk patients." Thus in both the non-risk and at-risk population, Celebrex was neither more effective nor safer than NSAIDs, meaning that there was a small patient population for which it might be a superior product, but for the vast majority of users, its use was excessive.

10. At best, Celebrex may have a less adverse GI effect in patients who are at highest risk of NSAIDs GI effects. However, Defendants' promotional advertising campaign targeted a broad spectrum of patients, resulting in an increase use by patients with low GI risk for which other NSAIDs were a cheaper and equally effective drug. Given the rising cost of health care for these patients, there is no reason, other than Defendants' financial interests, for so many to use Celebrex.

11. In this action Plaintiff seeks damages arising from the overpayment made on purchases of Celebrex resulting from Defendants' illegal scheme.

II. PARTIES

12. Frankenmuth Financial Group is a citizen of the State of Michigan, maintaining its principal place of business at Frankenmuth, Michigan. Frankenmuth has paid for purchases of Celebrex. Linda A Watters, Commissioner, Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc., is a Michigan official whose function is to collect and liquidate all assets and liabilities of the former private third party payers Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness Plan and OmniCare were private third party payers

whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. Wellness Plan and Omnicare paid for purchases of Celebrex.

13. Each of the plaintiffs (or its members) purchased Celebrex based on the cumulative impact of defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

14. Defendant Pharmacia is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia has been engaged in the business of marketing and selling Celebrex nationwide and in Alabama.

15. Defendant Pfizer is a Delaware corporation with its principal place of business in New York. In 2003, Pfizer acquired Pharmacia for nearly \$60 billion because of Celebrex and Bextra. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Celebrex nationwide and in Alabama.

16. Defendant Searle is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Celebrex nationwide and in Alabama.

17. G.D. Searle was the discoverer and developer of Celebrex. In 1999, Searle and Pfizer joined forces to co-promote Celebrex. Thereafter, Pharmacia acquired Searle in 2000 and Pharmacia merged with Pfizer on April 16, 2003.

III. JURISDICTION

18. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968. This Court also has subject matter jurisdiction under 15 U.S.C. § 1.

19. This Court also has diversity subject-matter jurisdiction over this class action pursuant to the Class action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, as here, "any member of a class of plaintiffs is a citizen of a State different from any defendant" and the

aggregated amount in controversy exceeds five million dollars (\$5,000,000). *See* 28 U.S.C. § 1332(d)(2) and (6). This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and Defendant systematically and continually conduct business throughout the State of Massachusetts, including marketing, advertising, and sales directed to Massachusetts residents.

20. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, and Defendants may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391 and 18 U.S.C. § 1965. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through providers and sales representatives who reside or transact business in this District and thereby affected Class Members, who similarly reside or transact business in this District.

IV. FACTUAL BACKGROUND

A. Development of Celebrex

21. Celebrex is one of the new entries in a class of pain medications called non-steroidal anti-inflammatory drugs (“NSAIDs”). Aspirin and ibuprofen are examples of well-known NSAIDs.

22. NSAIDs reduce pain by blocking the body’s production of pain transmission enzymes called cyclooxygenase or “COX.” There are two forms of COX enzymes, COX-1 and COX-2.

23. In addition to transmitting pain sensations, COX-1 is involved in maintaining and repairing gastrointestinal tissue.

24. In addition to transmitting pain sensations, COX-2 is involved in the production of prostacyclin, a substance responsible for preventing the formation of blood clots.

25. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body’s ability to repair gastric tissue and causes harmful gastrointestinal side-effects, including stomach ulceration and bleeding.

26. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

27. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs cause ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but aspirin reduces the risk of clots and helps to protect heart function.

28. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs.

29. Defendants set out to remedy this problem by developing “selective” inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing pain and inflammation sensations.

30. The emergence of NSAIDs that selectively inhibit the cyclo-oxygenase 2 (COX-2) isoform, which is inducible and expressed at sites of inflammation, while sparing COX-1, associated with gastroprotection, was a pharmacological breakthrough promising real hope of a better future for NSAIDs.

B. FDA Approval

31. Defendant Searle sought FDA approval on June 29, 1998. In its pre-approval marketing plans, Defendants planned that Celebrex would be approved and that such approval would include an indication that it was safer than NSAIDs in protecting against GI complications. The treatment of pain with reduced GI complications was the single most important attribute to the planned marketing and promotion of Celebrex and its place as a new blockbuster drug.

32. Pre-approval marketing plans were to stress that Celebrex was superior to NSAIDs and thus a “breakthrough” in science and safety. Pre-approval plans were to promote Celebrex as offering a significant reduction in GI complications.

33. The FDA granted new drug approval on December 23, 1999. However, Defendants did not obtain approval to promote Celebrex as more effective than NSAIDs in preventing clinically serious GI events. The FDA warned Searle that any promotional activities “that make or imply comparative claims about the frequency of clinically serious GI events compared to NSAIDs or specific NSAIDs will be considered false and/or misleading....” This finding by the FDA was a potentially serious blow to Defendants.

34. As a result, the Celebrex package inserts had to include a warning that its use presented GI risks.

C. The CLASS Study

35. Defendants funded a significant clinical trial to demonstrate that Celebrex had greater gastrointestinal safety than traditional NSAIDs: the Celecoxib Long-Term Arthritis Safety Study (“CLASS”).

36. Defendants expected CLASS to show that Celebrex was statistically significant in reducing serious GI complication over NSAIDs and that the results would allow removal of the warning label. Removal of the warning label was viewed as critical to breaking the NSAID barrier, *i.e.*, competing against NSAIDs based on GI superiority.

37. The CLASS trial was a long-term, double-blind study of gastrointestinal toxicity in 8,059 patients taking Celebrex, ibuprofen or diclofenac to treat arthritis. Patients with heart problems were allowed to participate in the CLASS trial, and were permitted to take low doses of aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

38. When the CLASS study was completed, the results were reported to the U.S. Food and Drug Administration’s Arthritis Drugs Advisory Committee (“the Committee”) as part of a request to exempt Celebrex from including a gastrointestinal safety warning in its package insert.

39. After reviewing the CLASS results, *the Committee concluded that patients taking Celebrex had not experienced fewer gastrointestinal complications than those taking*

traditional NSAIDs. In other words, CLASS showed that Celebrex failed to achieve its primary endpoint of reduced “clinically significant serious gastrointestinal events.” Without any proof of enhanced safety, the Committee then recommended that the Celebrex package insert contain the same gastrointestinal warnings as traditional NSAIDs, and advised further studies to assess the risk of COX-2 inhibitors when taken with aspirin.

40. Thus, Defendants’ clinical studies did not have their intended effect: Celebrex was not permitted to claim increased gastrointestinal safety over traditional NSAIDs.

41. Defendants, prior to the CLASS findings, had initiated extensive pre-release marketing campaigns to convey the uniform message that Celebrex provided effective pain relief without the gastrointestinal side-effects of traditional NSAIDs.

D. The JAMA Publication of CLASS

42. The results of the CLASS study were published in the September 13, 2000 issue of JAMA. CLASS is what’s known as a Phase 4 postapproval study, which was required by the FDA. Before any drug is approved, manufacturers have to submit data to the FDA that demonstrate the drug’s safety and effectiveness.

43. Each of the Defendants played a role in the establishment of the CLASS trial and how the results were then portrayed to the FDA, JAMA and to the medical community.

44. CLASS, which included over 8000 people with rheumatoid and osteoarthritis, compared the risk of gastrointestinal problems in people taking Celebrex with the risk in those taking ibuprofen (Motrin, Advil) and diclofenac (Voltaren). *The article in JAMA concluded that Celebrex, “when used for 6 months ... is associated with a lower incidence of clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac).”* The accompanying editorial supported this conclusion: “The results of this important study ... provide *promising data* to suggest that [Celebrex is] ... *effective in reducing*, but not eliminating, the risk of symptomatic [minor] ulcers and [major] ulcer complications in the enormous number of individuals who might benefit from these drugs”

45. There was, however, one very large problem. The manufacturer’s original research plan, as submitted to the FDA, had defined the duration of the CLASS study that compared Celebrex with ibuprofen as 12 months, and that of the study comparing Celebrex with diclofenac as 16 months. And, indeed, the combined study had run for a full 12 months. ***The authors, however, submitted only the first 6 months for the article in JAMA.*** Left unreported (and unmentioned) in the JAMA article were the data from the *second* 6 months of the study, during which time, as shown in the data on the FDA’s website, ***six of the seven serious gastrointestinal complications that occurred were in patients taking Celebrex.***

46. Pharmacia had presented a statistical argument to the FDA justifying its omission of the data from the second half of its study. The company claimed that since a higher percentage of people taking diclofenac dropped out of the study because of minor symptoms like heartburn, the data from the second half of the study were invalid because of what is called “informed censoring.” Pharmacia argued that these dropouts would have gone on to develop serious gastrointestinal complications, and their dropping out of the study artificially minimized the risk of serious complications from taking diclofenac. The FDA flatly rejected this argument. It countered that there was no proof that the people with heartburn would have developed more serious gastrointestinal problems. Further, if minor symptoms caused people in the study to stop taking diclofenac, people in the real world would similarly stop taking the drug if it caused heartburn and would similarly protect themselves from going on to develop serious gastrointestinal complications.

47. The FDA’s opinion of the manufacturer’s decision to publish only half of the data from its study was clear: “the sponsor’s presentations of 6-month data ... are not statistically valid or supportable.” The FDA’s gastroenterology reviewer concluded that the first 6 months of data – which had been presented in the JAMA article as if they were a report of the entire study – were not worthy of separate consideration: “Based on the lack of adequate rationale, these post-hoc analyses will not be further discussed or presented in this review.” Looking at the data from the entire year of the study, the FDA’s gastroenterology reviewer concluded that “***the sponsor***

has failed to demonstrate a statistically significant lower rate” of serious GI complications in the people who took Celebrex compared with the people who took the other NSAIDs. When the reviewer looked at only the second six months of data (*i.e.*, the data that had not been published in the JAMA article), he *concluded that the risk of serious GI complications appeared to be higher in the people who took Celebrex “compared to both ibuprofen and diclofenac”* (FDA’s emphasis). This was hardly an endorsement for a drug whose only advantage (besides the convenience of a once-daily dosing) was that it caused fewer serious GI problems.

48. The disparity between the CLASS article published in JAMA and the information in the FDA’s files by no means stopped there. The primary question that the CLASS study had been designed to answer had been changed, producing results that were far more favorable to the manufacturer. The original research design submitted to the FDA by the manufacturer of Celebrex had stated: “The primary objective of this study is to compare the incidence of *clinically significant* [major] upper gastrointestinal events ... in patients taking Celebrex to patients taking NSAIDs.” The term “*clinically significant*” refers to complications that would generally require hospitalization: active bleeding, perforation of the stomach or duodenum requiring surgery, or obstruction of the outlet of the stomach. The research plan specifically called for the less serious gastrointestinal side effects to “be categorized and analyzed separately.” Indeed the FDA’s gastroenterology reviewer specifically commented that the plan to identify the “truly significant” serious gastrointestinal complications alone was a “major strength of the current study.”

49. But when the results of the study were published in JAMA, the incidences of major and minor gastrointestinal complications were combined. Why the change? The results of the study as originally designed failed to show that the people who took Celebrex developed significantly fewer major gastrointestinal complications than the people who took ibuprofen or diclofenac, even for just the first six months. *Only by combining the minor GI symptoms with the more serious gastrointestinal complications could the article conclude that Celebrex*

caused a statistically significant decrease in gastrointestinal complications compared with the other NSAIDs. As noted above, when the FDA looked at the results of the CLASS study in terms of the research question that had *originally* been posed, Celebrex was not significantly safer than the other NSAIDs.

50. Finally, the most important measure of safety is the overall frequency of serious side effects – including, but not limited to, gastrointestinal side effects. For the full 12 months of the study, *the people in the CLASS study who took Celebrex experienced 11 percent more serious complications* (in all body systems combined) than the people who took the older and less expensive anti-inflammatory drugs. This difference did not reach statistical significance but certainly is significant in countering Pharmacia’s claim that Celebrex is better than older NSAIDs because it’s safer.

51. These findings contributed to the FDA’s decision to send one of its rare “Warning Letters” to the CEO of Pharmacia in February 2001. The letter cites repeated unsubstantiated marketing claims that Celebrex is the preferred NSAID for people taking a blood thinner and that it is safe and effective for the treatment of acute pain – a use for which it was not approved – and points out that Pharmacia’s marketing material fails to warn of the possibility of serious GI complications caused by the drug. The Warning Letter concludes by saying:

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 ... 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.

52. Also included in the Warning Letter was the requirement that Pharmacia send out the “Dear Healthcare Provider” letter. Of course, the letter sent out by the manufacturer was not quite as specific as the FDA’s Warning Letter. Few doctors, even if they had bothered to wade through the difficult language, had the time or inclination to find out the story behind the letter.

As a result, *doctors continued to prescribe Celebrex for their patients based on the scientific evidence published in JAMA*. It was incomplete and presented an inaccurate picture of the so-called safety advantage of Celebrex over other less expensive NSAIDs.

E. Use of the CLASS Study to Promote Sales of Celebrex

53. The JAMA article falsely concluded that Celebrex was associated with a lower incidence of complications than NSAIDs.

54. The flawed conclusions of CLASS were widely distributed and believed by physicians. About 30,000 reprints of CLASS were brought from the publisher and a recent search of the Science Citation Index yielded 169 articles citing it, more than 10 times as many citations as any other article published in the same issue. The reprints were used by the Celebrex sales team to entice doctors to prescribe Celebrex. The wide distribution of CLASS has coincided with increased sales of Celebrex.

55. According to the BRITISH MEDICAL JOURNAL, Volume 324, June 1, 2002, many physicians still believe the CLASS study:

Publishing and distributing overoptimistic short term data using post hoc changes to the protocol, while omitting disappointing long term data of two trials, which involved large numbers of volunteers, is misleading. While some of the problems related to CLASS were partially covered in the news sections of BMJ and other journals, it was not emphasised how flawed the trial actually was, and how inadequate the authors' justifications. Consequently, CLASS may still be relied on by many physicians without reference to these flaws. In our experience most still believe the findings published originally. For example, most of 58 physicians attending an osteoarthritis workshop in Berne, Switzerland, in December 2001 had not realized that CLASS was seriously biased.

F. Misleading Articles in Medical Journal Used to Establish Celebrex in the Marketplace

56. Defendants also used the placement of articles in prestigious journals as a means to falsely promote Celebrex. Defendants therefore planned on placing articles, through paid consultants, in prestigious journals including JAMA, ARCHIVES OF INTERNAL MEDICINE and other publications.

57. An example is a “Special Article” appearing in *ARTHRITIS & RHEUMATISM*, Vol. 43, No. 9, September 2000, entitled *Recommendations for the Medical Management of Osteoarthritis of the Hip and Knees*. These guidelines, endorsed by the Professional Society of Arthritis Specialists, became the gold standard for treatment of OA. Three out of four of the expert authors had financial relationships with Searle and Pharmacia. These guidelines state that the course of treatment should be initiated with acetaminophen (Tylenol). If acetaminophen provides inadequate relief, the next drugs recommended were COX-2 specific inhibitors, not NSAIDs. Without regard for the proscriptioin included in the FDA’s new drug approval letter to Searle about Celebrex, the guidelines assert that COX-2 inhibitors, based on endoscopic studies, have an advantageous safety profile. That FDA’s letter of 12/31/98 stated:

“ ... any promotional use of endoscopic data without the qualifying explanations of that data found in the approved labeling ... will be considered false and misleading.” [Label: The correlation between findings of endoscopic studies, and the relative incidence of clinically serious upper GI events that may be observed with different products, has not been fully established.]

The authors concluded that COX –2 inhibitors, based on endoscopic studies, have an advantageous safety profile. Referring to the CLASS study, the authors noted that data from this study had not yet been published.

58. Medical journals that publish articles can add substantially to their income selling reprints to drug companies. Drug companies in turn give these reprints to their sales force who provide these to doctors as proof of a drug’s superiority or qualities.

59. The publication of the article established the use of COX-2 inhibitors as the standard course of treatment for OA. Defendants purchased reprints of this article and it was used to promote the use of Celebrex for OA patients. As a result of such use, Celebrex became the standard course of treatment in such patients.

60. At the time these guidelines were written, the results of the CLASS study had not yet been published (the two articles were published almost simultaneously in September of 2000), but Defendants were aware of the results of the CLASS study. When the results of the

CLASS study were published in JAMA, showing that Celebrex does not significantly reduce the risk of serious GI complications in comparison to other NSAIDs, Defendants did not seek to correct the guidelines, and continued to use the reprint despite the fact that it did not reflect the best available scientific evidence. The authors, being paid by the pharmaceutical industry, did not print a correction and this article continued to be used by physicians as the prescribing standard.

61. The guidelines *may* have been formulated on the best evidence that had been published at the time they were issued in the September 2000 issue of ARTHRITIS & RHEUMATISM. But the CLASS study had been completed by March 2000 – and certainly this information *should have been included* in the guidelines that were issued in September 2000 and remained in effect thru the time that Vioxx was taken off the market. These guidelines were available continuously on the government sponsored guidelines website, www.guideline.gov, during that time. There was no revision of the posted guidelines when the results of the CLASS study were (such as they were) published in JAMA the same month, September 2000. The CLASS study showed that there was no GI benefit of Celebrex in patients taking aspirin concurrently – even for the first six months of the study that were published. Nor were they updated when the FDA “Warning Letter” dispelled the claim that Celebrex is safer than other NSAIDs in patients on anti-coagulants. Nor were they updated with the data from the February 2001 Advisory Committee Meeting became available to the public on the FDA’s website.

62. The guidelines listed factors that increase the risk of GI bleeding, and said that COX-2 inhibitors (Celebrex and Vioxx at the time) were the drugs of choice (after acetaminophen) for people at elevated risk. Even though the FDA reviewers dispelled that argument at the February 2001 Advisory Committee Meeting, the guidelines remained in place, not reflecting the updated information that should have caused them to be revised. These guidelines set the standards of good medicine and are admissible in malpractice cases as evidence of community standards.

63. Another example arises from publication of the article *The Coxibs, Selective Inhibitors of Cyclooxygenase-2* that appeared in the NEW ENGLAND JOURNAL OF MEDICINE, Vol. 345, No. 6, on August 9, 2001. Though prohibited by the then editorial policy of the New England Journal of Medicine, both of the authors received money from Searle and/or Pharmacia. The authors concluded that, “clinical trials have demonstrated that treatment with highly selective cyclooxygenase-2 inhibitors [Celebrex and Vioxx] causes significantly fewer serious gastrointestinal adverse events than does treatment with non-selective NSAIDs.” However, with the results of CLASS publicly available on the FDA website for seven months at the time this review article was published, the authors and Defendants were aware that there was no evidence of Celebrex being less likely to cause serious GI complications than other NSAIDs. Despite the error in this report, reprints of it were used by Defendants’ sales force to market Celebrex to doctors.

64. Another example is contained in a corporate-sponsored review article appearing in the BRITISH MEDICAL JOURNAL on September 21, 2002, where one of the authors was employed by Pfizer, which promoted falsely the safety of Celebrex over NSAIDs:

In this review of randomised controlled trials we have shown that celecoxib is as effective as other NSAIDs for the relief from symptoms of osteoarthritis and rheumatoid arthritis. The confidence intervals around the point estimates of efficacy were reasonably narrow, which mean that it is unlikely that there were clinically important differences. Compared with other NSAIDs, however, celecoxib showed increased upper gastrointestinal safety and tolerability. Rates of withdrawal due to gastrointestinal adverse event, dyspepsia, and abdominal pain were 40-60% lower, while the incidence of ulcers and serious upper gastrointestinal events was 40-75% lower.

65. This review occurred after CLASS, and Pfizer was aware that CLASS did not support this conclusion, yet Pfizer took no corrective steps.

G. Defendants Provide Doctors With Misleading Literature

66. Prior to the publication of CLASS, Defendants continuously sent doctors materials that were false and misleading. For example, in 1999, Defendants Searle and Pfizer co-promoted a series of slides claiming that NSAIDs resulted in \$500 million in excess medical

care costs for GI diseases. The implication intended was that Celebrex did not cause GI diseases. There was no scientific basis for such a claim and CLASS demonstrated otherwise, yet these claims stayed alive in the minds of physicians and helped promote Celebrex sales. This claim was never retracted or corrected by Defendants.

67. In 1999, Defendants sent literature to the medical community claiming that Celebrex demonstrated “significantly fewer GI ulcers in 12-week serial endoscopy studies.” After CLASS was published, Defendants never corrected the misleading impressions created by this type of statement.

68. At panel presentations to doctors on Celebrex, Defendants presented statistics showing costs arising from NASID-associated GI diseases, juxtaposed against claims regarding “new Celebrex” and its effectiveness. This juxtaposition was designed to falsely convey the GI safety of Celebrex. Also included were slides stating Celebrex “safely” delivers relief, again intending to create the false impression NSAIDs were not as safe.

69. After CLASS was completed, none of these misleading safety claims were corrected by Defendants.

70. Typical of the 1999 marketing efforts is the following:

Safely delivering ...

- Significantly fewer GI ulcers in 12-week serial endoscopy studies than naproxen (500 mg bid) and ibuprofen (800 mg tid) ($P < 0.001$). The correlation between endoscopic findings and the incidence of clinically serious upper GI events has not been fully established.
- No effect on platelet aggregation or bleeding time.
- No clinically significant drug-drug interactions with methotrexate, warfarin, glyburide, tolbutamide, ketoconazole or phenytoin. Potentially significant interactions with fluconazole or with lithium.
- Exercise caution when using warfarin or aspirin with CELEBREX because of increased risk of bleeding or GI complications, respectively, compared with CELEBREX alone.

- Most common side effects were dyspepsia, diarrhea, and abdominal pain, and were generally mild to moderate.

71. The foregoing is false and misleading in that the correlation between findings in endoscopic studies and the incidence of clinically serious GI events had not been established. In essence, Defendants had no basis for this safety claim, yet it was reported on hundreds if not thousands of occasions in sales presentations and in written materials sent to patients and the medical community.

72. After CLASS rejected such GI claims, Defendants did not correct the misleading impression they had created. Further, these claims were made in written materials *after* the FDA rejected the use of endoscopic studies as a basis for claiming safety:

FROM CELEBREX NEW DRUG APPROVAL LETTER
12/31/98:

Please note that any advertising and/or promotional activity of this product will be considered false and/or misleading under Section 502 of the Act if it presents suggestions or representations that COX-2 selectivity confers on the product any claims of safety beyond what has been demonstrated in clinical studies and presented in the approved labeling. Additionally, promotional activities that make or imply comparative claims about the frequency of clinically serious GI events compared to groups of NSAIDs or specific NSAIDs will be considered false and/or misleading without differences having been demonstrated in adequate, well-controlled studies. Finally, any promotional use of the endoscopic data without the qualifying explanations of that data found in the approved labeling (paragraph beginning on line 251 in the enclosed label text) will be considered false and/or misleading. If you have any questions or concerns about this matter please contact the Center for Drug Evaluation and Research's Division of Drug Marketing, Advertising and Communications.

73. In a January 2000 letter to thousands of "Healthcare Professionals," jointly authored by Searle and Pfizer, Defendants described Celebrex as the "#1 selling brand of prescription arthritis medicine" and noted that "serious GI toxicity can occur with ... NSAIDs." The message, no such GI toxicity occurs with Celebrex. This claim was unsupported and later proven to be false and its falsity was never corrected.

74. In 2000, Pfizer and Searle sent doctors a description of Celebrex indicating that it has “excellent GI tolerability.” Again, this was part of a successful effort to create the impression that Celebrex had no GI effects while NSAIDs did. This statement was misleading when made and never corrected.

75. In other 2000 materials jointly sent by Defendants to doctors, claims were made that Celebrex had no effect on warfarin users. The FDA in 2001 found such claims to be misleading. In the same materials, Defendants cite to endoscopic studies as supportive of GI superiority, the FDA prohibited the making of such claims.

76. In 2000, Defendants jointly agreed to send doctors materials describing Celebrex as a “scientific breakthrough” which was not the case. Celebrex has no “breakthrough” advantage over NSAIDs.

77. In 2000, Defendants jointly agreed to send doctors materials claiming that Celebrex was more effective in pain relief than naproxen. In fact, the JAMA article noted that all doses of celecoxib demonstrated similar efficacy to naproxen.

78. All of the above materials were false and misleading and conveyed superiority claims that persisted in the medical community and led to the astounding success of Celebrex.

H. Marketing and Promotion

79. With the knowledge that Celebrex provides no better pain relief than older anti-inflammatory drugs (in fact, all doses of Celebrex provide significantly less relief in studies of dental pain than two over the counter Advil tablets) and that Celebrex is no less likely to cause serious GI complications, Defendants continued pouring money into advertising campaigns that uniformly emphasized the gastrointestinal safety of Celebrex and its relief of symptoms.

80. Pharmacia and Searle spent more than \$78 million on consumer advertising for Celebrex in the year 2000. Defendants spent more than \$400 million on direct-to-consumer advertising for Celebrex from 1999 to 2003. Defendant’s direct-to-consumer advertising had as its goal making Celebrex something that patients requested their doctor to prescribe. This was accomplished by use of the messages set forth below.

81. In addition, Defendants' sales forces have blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Celebrex was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. They aggressively promoted Celebrex as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote or provide any balanced presentation of Celebrex.

82. Such marketing efforts to physicians have become commonplace in recent years. Drugs, including Celebrex, that might once have been used primarily by specialists are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs' full research record. Drug companies, with Pfizer in the forefront, spent \$8 billion on such "detailing" to physicians – *i.e.*, sales people dropping by to leave marketing materials and speaking to physicians about their companies' drugs – in the 12 months through October 2004.

83. Such large-scale marketing efforts have paid huge dividends to Defendants and other drug companies. The number of blockbuster drugs, defined as drugs with more than \$1 billion in annual retail prescription sales, was only 15 in 1999 but grew to 34 in 2003.

84. As a result of Defendants' uniformly misleading advertising campaigns, Celebrex was wildly successful. Celebrex became Pharmacia's best selling drug with more than \$2.6 billion in sales for 2000 and \$3.1 billion in sales for 2001. After acquiring Pharmacia, Pfizer has continued to enjoy blockbuster sales of Celebrex, with \$2.3 billion in revenue through the first three quarters of 2004.

I. Examples of Misleading Materials Designed to Promote Celebrex as Offering a Heretofore Unavailable Improvement in the Quality of Life and/or as Providing Superior Pain Relief

85. Despite the lack of scientific evidence to support such claims, Defendants' advertisements had two themes that were either expressly stated or implied by the words and images. One was that Celebrex provided previously unavailable improvements in quality of life. The second was that Celebrex provided superior pain relief.

86. The marketing plans for Celebrex were premised on an FDA approval that did not require a GI warning so that Defendants could claim that Celebrex was superior to NSAIDs and Vioxx. The marketing plan went forward in large measure with a concerted effort to disguise the true efficacy of Celebrex.

87. From 1999 through the present, Defendants have repeatedly engaged in misleading advertising devised to portray Celebrex as safer than other pain relievers.

88. For example, on October 16, 1999, the FDA sent Searle a letter regarding misleading claims with respect to Celebrex. The FDA found as follows:

NDA #20-998

- Searle claims that, “With more than 5 million patients on Celebrex, physicians know what to expect when they prescribe Celebrex — the new standard of care for analgesic and anti-inflammatory therapy in the management of pain for OA and RA.” This statement makes a broad superiority claim comparing Celebrex to not only the class of NSAIDs, of which Celebrex is a member, but to all analgesic and anti-inflammatory therapies available for the management of osteoarthritis (OA) and rheumatoid arthritis (RA). However, this global superiority claim has not been demonstrated by substantial evidence. Therefore, this claim is false or misleading.
- Searle also presents several unsubstantiated comparative claims to Vioxx (rofecoxib), including but not limited to, “Why should I use Celebrex over Vioxx? My first response to your question leads me to ask, ‘With all the experience that you and thousands of other physicians just like you have with the proven efficacy and benefit of superior safety of Celebrex, why wouldn’t you want to prescribe Celebrex?’” (emphasis added). This claim suggests Celebrex has a “superior safety” profile compared to Vioxx, when such has not been demonstrated by substantial evidence. Therefore, DDMAC considers this unsubstantiated comparative claim to be false or misleading.

Misrepresentation of Safety Information

- Searle presents claims that misrepresent the safety profile for Celebrex, including but not limited to,

Celebrex has been studied for use in patients taking low dose aspirin. Approximately 440 patients in 4 of the 5

initial endoscopy trails [sic]. Patients taking an aspirin a day were excluded from the other product's clinical trials, so there's no information regarding the safety in combination use.

These statements make an unsubstantiated comparative claim by implying that Celebrex used in combination with low dose aspirin, is safer than Vioxx's use with aspirin when such has not been demonstrated by substantial evidence. In addition, the claim fails to disclose material facts concerning Celebrex's concomitant use with aspirin. Specifically, the approved product labeling states, "... concomitant administration of aspirin with CELEBREX may result in an increased rate of GI ulceration or other complications, compared to use of CELEBREX alone." Therefore, failure to disclose this material fact misrepresents the safety profile for Celebrex and is thus misleading. Furthermore, the statement, "Patients taking an aspirin a day were excluded from the other product's clinical trials, so there's no information regarding the safety in combination use," is not accurate.

89. Typical of Defendants' misleading advertising is an advertisement called "Guitar TV ad." The Guitar TV advertisement in its entirety makes a representation about the indication and benefits of Celebrex for osteoarthritis or rheumatoid arthritis. A woman playing an acoustic guitar is featured. The visuals focus on her hands/fingers and playing ability (*i.e.*, she finger-picks the strings with one hand while executing chord changes with the other hand). These images are accompanied by a voice-over: "With Celebrex, I will play the long version." Together, these images and claim suggest that because of using Celebrex, there is a direct benefit to this patient's wrist/hand/finger joints related to movement and flexibility such that she can now play the long version of the song whereas she previously could not.

90. This advertisement is just one of many designed to have consumers believe they can live better lives with Celebrex.

91. Recently, the FDA issued a warning letter noting as to the lawfulness of this advertisement:

While the Guitar TV ad suggests a direct benefit to this patient's wrist/hand/finger joints related to movement and flexibility, it fails to state the actual approved indication (*e.g.*, relief of signs and symptoms of osteoarthritis). It also fails to include any risk information about Celebrex, thus omitting the major side effects and contraindications (including warnings and precautions) of Celebrex as required by 21 CFR 202.1(e)(1). Omission of this

information implies that there are no risks to the patient who takes Celebrex, which overstates the drug's safety.

92. Similarly the FDA found another Celebrex TV advertisement to be misleading.

The FDA described this advertisement as follows:

Announcer: "Celebrex presents, arthritis tips."

Woman dressed as doctor: "Arthritis is the most wide-spread crippling disability in the United States today. Arthritis is the predominant cause of activity limitations and is a major determinate of nursing home institutionalization for the elderly. One out of every 7 people and 1 in every 3 families is affected by arthritis. If you feel any pain or discomfort in your joints, contact your local doc."

Announcer: "These arthritis tips have been brought to you by Celebrex."

93. The FDA found this advertisement to be misleading.

The Arthritis Tips TV ad is a product-specific drug ad for Celebrex that is misleading because it omits important information about the drug's safety and effectiveness and makes unsubstantiated effectiveness claims. The ad promotes Celebrex by identifying the drug by name at the beginning and end of the ad. Moreover, stating that Celebrex is presenting/bringing you arthritis tips clearly suggests that Celebrex is an arthritis treatment. The Arthritis Tips TV ad purports to quantify the disease burden of "arthritis" ("the most wide-spread crippling disability in the United States today ... the most predominant cause of activity limitations and ... a major determinate of nursing home institutionalization for the elderly. One out of every 7 people and 1 in every 3 families is affected by arthritis.") Finally, the Arthritis Tips TV ad directs viewers to contact their local doctor "if you feel any pain or discomfort in your joints" and follows this statement with another reference to Celebrex.

Overstatement of Effectiveness. The Arthritis Tips TV ad is misleading because it overstates the proven effectiveness of Celebrex for the treatment of "arthritis." The Arthritis Tips TV ad discusses the serious progressive effects of arthritis, noting that it commonly can lead to "crippling disability" and "nursing home institutionalization of the elderly." The viewer is then instructed "if you feel any pain or discomfort in your joints, contact your local doc. These arthritis tips have been brought to you by Celebrex." The totality of this presentation therefore suggests that Celebrex is an effective treatment for preventing or modifying the progression of arthritis, such that crippling disability and nursing home institutionalization may be avoided.

Celebrex is indicated only for relief of the signs and symptoms of OA and RA. Celebrex is not indicated for disease modification (i.e., altering the course of the progression of arthritis). Moreover, we are not aware of substantial evidence or substantial clinical experience demonstrating that treatment with Celebrex will prevent crippling effects or disability due to arthritis or prevent nursing home institutionalization of elderly patients with arthritis. Therefore, your Arthritis Tips TV ad greatly overstates the proven benefits of Celebrex.

Omission of Risk Information. The Arthritis Tips TV ad fails to disclose any risk information about Celebrex and thus omits the major side effects and contraindications (including warnings and precautions) of Celebrex as required by 21 C.F.R. 202.1(e)(1). Omission of this information implies that there are no risks to the patient who takes Celebrex, thus overstating its safety.

94. In the same letter the FDA found that various Celebrex print advertisements made unsubstantiated claims with respect to less expensive alternative drugs:

Unsubstantiated Superiority Claims

The print ad features the prominent headline “Strength They Can Stay With” and shows a chart comparing Celebrex, Ibuprofen and Naproxen, titled “6-Month Patient Persistency Rate.” Over the chart is the statement, “In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months.” The tagline below the Celebrex logo in the print ad is “Proven strength that lasts.”

The above referenced claims imply that Celebrex is more effective (i.e., stronger) than ibuprofen and naproxen for treatment of osteoarthritis or rheumatoid arthritis and that patients “stay with” or are more compliant with Celebrex therapy than the compared products. We are not aware of substantial evidence or substantial clinical experience to support these claims. The cited retrospective retail pharmacy database analyses by NDC Health, “Persistency Analysis: Celebrex, Vioxx, and All Other NSAIDs,” August 2002 and “Persistency Analysis: Celebrex, Vioxx, Ibuprofen, and Naproxen,” from November 2002 (almost 2 years ago), do not contain any data or information demonstrating that patients found Celebrex to be more effective than the other products, or that patients will be more “persistent” or compliant with Celebrex therapy. Moreover, the database information did not note the indication for which the drug was prescribed, so the suggestion that these rates reflect specifically OA/RA patients is misleading. In addition, the analyses do not account for factors that affect persistence or compliance such as cost insurance coverage, side effects, dosage regimen, and ease of use. Therefore, the analyses do not constitute substantial evidence or substantial clinical experience demonstrating that OA/RA patients are more compliant

with Celebrex or stay on Celebrex longer because it is more effective than other products for the treatment of OA or RA.

95. Since its introduction, Defendants have issued promotional material designed to tie Celebrex to improving quality of life. It has distributed materials making numerous dramatic claims tied to the drug regarding quality of life, in terms of being able to do personal and work-related activities. A Pfizer infomercial shows people returning to their work and activities. These patients go from not being able to work or do anything they want to do, to being able to work and do everything they want to do, pain-free. Patients talk about being able to “do anything,” “do as much as I want to do,” being “back to doing what I do,” and such. They talk about “enjoying life” again, how the drug improved their “quality of life,” and how the drug “gave them back their lives” (a theme repeated over and over in the advertisement and in the background music). One person states that “you can be free.” Another states that the medicine “brought new vitality in life.” Everyone portrayed has 100% efficacy in all of these outcomes.

96. Such claims are misleading and purport to promote Celebrex as superior. In fact, as the FDA has recently noted, “none of the comparative studies with naproxen, ibuprofen, and diclofenac to-date has been designed to demonstrate superiority or a specified degree of similarity in a rigorous way.”

97. In addition, Defendants caused to be published the following advertisements which were designed to appeal to consumers or doctors which misstated or deceptively conveyed Celebrex’s superiority.

98. TELEVISION ADVERTISEMENT: **The “I Will Not” advertisement.** This campaign, run in October 2003 and April 2004, portrays people engaging in various physical activities. The tag line for the advertisement is “With Celebrex I will not ...” This is followed by various variations in this theme.

a. The advertisement shows a woman jogging with announcer stating: “With Celebrex I will no longer give in to the joint pain of osteoarthritis. Just one Celebrex provides up to 24 hour relief from the pain of osteoarthritis.”

b. The advertisement shows a woman playing golf with announcer stating: “With Celebrex I will not stop at 9 when I really want to play 18.” The announcer further states: With Celebrex I will not settle for part time relief. If you are struggling with joint pain maybe you should stop trying to manage it by yourself.”

c. The advertisement shows a woman running on a beach, a woman playing golf, people doing tai chi, a man pitching softball, a couple hiking, a man pushing a child on a merry-go-round, a man swimming and a woman kayaking. The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says, “Individual results may vary.”

99. Each of the “I Will Not” foregoing advertisement scenes overstate the effectiveness of Celebrex. Each implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results hardly counteracts the overall message of this advertisement.

100. The “I Will Not” advertisement makes unsubstantiated superiority claims. By stating that “if you are struggling with joint pain maybe you should stop trying to manage it by yourself” the advertisement falsely implies that Celebrex is superior to over-the-counter NSAIDs. By stating that “with Celebrex I will not settle for part time relief” the advertisement implies that it is superior other arthritis treatments which is not supported in clinical trials.

101. TELEVISION ADVERTISEMENT: **The “Fixing the Preschool” advertisement.** The theme of this campaign, run during May 2001, is a group of people fixing up a building that will be a preschool. The advertisement starts out with the announcer: “If you have osteoarthritis there is reason to celebrate ... Celebrex.” The advertisement then shows people engaging in various activities repairing the schoolhouse. It shows a man on a ladder taking down a sign with the text: “Mark, arthritic shoulder.” It shows a woman cleaning a blackboard with the text: “Sarah, arthritic back.” The announce states, “Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain. Celebrex relieves arthritis pain

plus stiffness too.” The advertisement shows a woman working with a trowel with the text: “Julia, arthritic hands.” The announcer states: “Powerful 24 hour relief from osteoarthritis pain, inflammation and stiffness.” The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says “Individual results may vary.”

102. This campaign overstates the effectiveness of Celebrex and implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

103. This advertisement campaign makes unsubstantiated superiority claims. By stating that “Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain” it falsely implies that it is superior to other NSAIDs.

104. TELEVISION ADVERTISEMENT: **“The Softball Game” Advertisement.** The theme of this advertisement, run during September 2000 and May 2001, is a softball game. The advertisement starts out with the announcer stating: “If you have osteoarthritis there is reason to celebrate ... Celebrex.” The announcer states: “Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain. 24 hour relief from pain and stiffness.” The ad shows a woman helping a young boy to bat with the text: “Jill, arthritic hands.” It shows a group of women doing the wave with the text: “Rita, arthritic back.” It shows the umpire raising his arms with the text: “John arthritic shoulder.” The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says “Individual results may vary.”

105. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

106. This advertisement makes unsubstantiated superiority claims. By stating that “Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain” it falsely implies that it is superior to other NSAIDs.

107. TELEVISION ADVERTISEMENT: **“A Day in the Park” Advertisement.** The theme of this advertisement, run during November 2000, is people engaging in various activities in a park. The advertisement starts with theme song “celebrate, celebrate do what you like to do.” The announcer states: “If you have osteoarthritis there is reason to celebrate it’s Celebrex. Powerful 24 hour relief from osteoarthritis pain and stiffness. Celebrex is the first arthritis medicine that targets only the Cox-2 enzyme.” The advertisement shows people doing tai chi with the text: “Ann, arthritic shoulder.” The ad shows a man and a child riding push scooters with the text: “Bill, arthritic knee.” It shows a man rowing a boat with the text: “Dave, arthritic shoulder.” It shows a woman pushing a child on a swing with the text: “Liz, arthritic back.” The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says “Individual results may vary.”

108. This advertisement overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

109. This advertisement makes unsubstantiated superiority claims. By stating: “Powerful 24 hour relief from osteoarthritis pain and stiffness. Celebrex is the first arthritis medicine that targets only the Cox-2 enzyme” the ad falsely implies that Celebrex is superior to other NSAIDs.

110. TELEVISION ADVERTISEMENT: **“I Will Not ...” Advertisement #2.** The advertisement portrays people engaging in various physical activities. The tag line for the ad is: “With Celebrex I will not give in to the pain of osteoarthritis.” The advertisement shows a man swimming, a couple canoeing and a woman running. The announcer states: “Just one Celebrex provides up to 24 hour relief from the pain of osteoarthritis.” The ad shows a woman playing golf with a voice over: “With Celebrex I can line up my putt.” It shows woman playing a guitar with the voice over: “I can play the long version.” The announcer states: “One pill, 24 hours so you can live your life the way you want. With Celebrex I will not settle for part time relief.”

The advertisement shows people hiking, a woman painting a chair, a man fishing, a woman playing a guitar, people doing yoga and a man pushing a merry-go-round. The announcer states, “If you are suffering from pain, inflammation or stiffness maybe you should stop trying to manage it on your own.” The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says “Individual results may vary.”

111. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results hardly counteracts the overall message of this advertisement.

112. The advertisement makes unsubstantiated superiority claims. By stating that “if you are suffering from pain, inflammation or stiffness maybe you should stop trying to manage it on your own” the advertisement implies that it is superior to over-the-counter NSAIDs which is not supported in clinical trials. By stating, “with Celebrex I will not settle for part time relief” the advertisement implies that it is superior other arthritis treatments which is not supported in clinical trials.

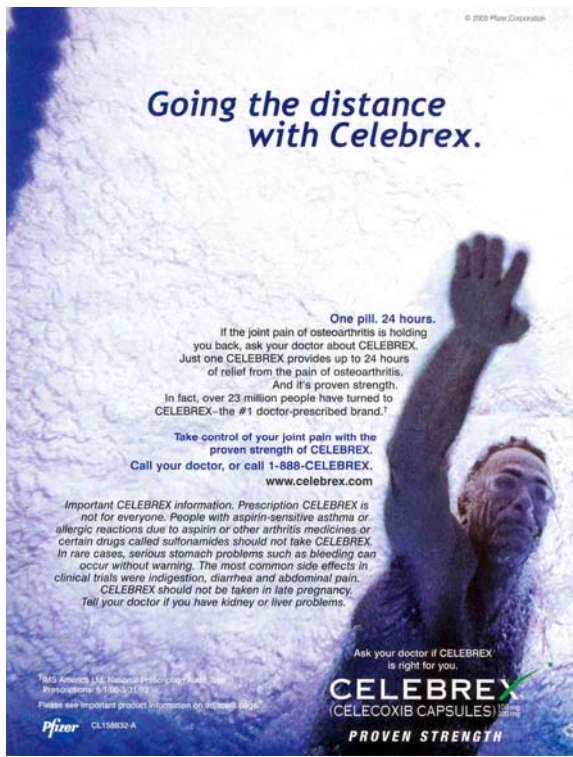
113. TELEVISION ADVERTISEMENT: **“Dancing” Advertisement**. The theme of this advertisement, run during July 2002, is people dancing.. The advertisement shows a couple dancing with a voice over that states: “Even with osteoarthritis these arms still have a way with the ladies.” The text on screen says: “Arthritic Elbow.” The next scene shows a woman dancing with a voice over that states: “These legs hardly miss a beat” with text “arthritic knee.” The next scene shows a couple dancing with the voice over: “These hands haven’t lost their touch” with text “arthritic hands.” The announcer states: “Just one Celebrex last 24 hours. Provides powerful arthritis pain relief that is non-narcotic.” The advertisement has additional footage of the above people dancing. The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says “Individual results may vary.”

114. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not

representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

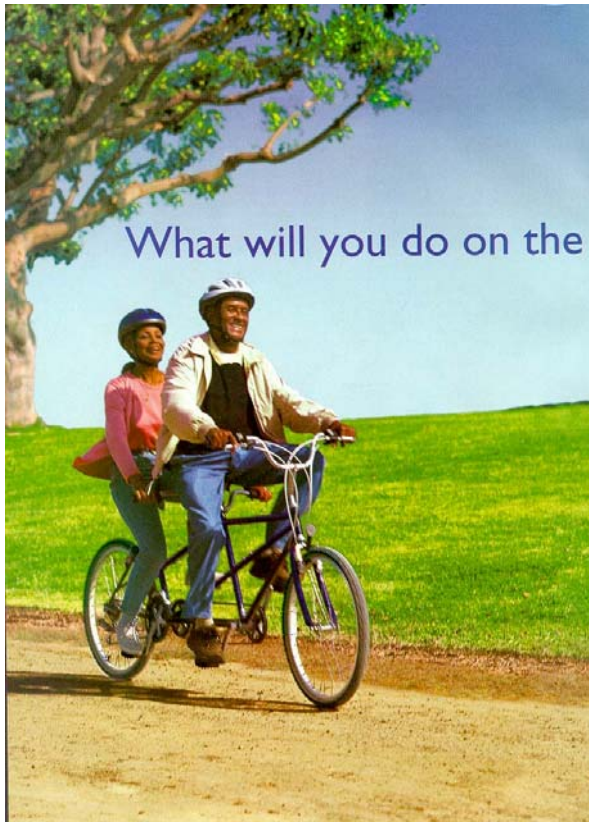
115. Each of the foregoing advertisements also failed to disclose the increased risk of heart problems that were known to Defendants at the time Celebrex was launched. A 1999 study that Defendants concealed found that Celebrex patients suffered heart attacks at four times the rate of those taking a placebo. The study was never published and was concealed from the FDA.

116. As part of the scheme alleged herein, Defendants engaged in a massive direct to consumer advertising campaign in the print media designed to create consumer demand for Celebrex. The following is a sampling of such advertisements.



117. This advertisement which ran during October 2003, in its entirety, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. It also seeks to bolster its image and acceptance by claiming that 23 million people are using it and by virtue of the fact it is the “#1 doctor-prescribed drug.”

However, these figures, if true, are misleading by virtue of acceptance of Celebrex was the result in large measure to Defendants' deceptive scheme for marketing Celebrex.



Discover what millions have turned to for arthritis pain relief.

The #1 selling brand of prescription arthritis medication* delivers powerful relief of your arthritis pain and inflammation. Celebrex is a scientific breakthrough: the first product to target only the COX-2 enzyme. By effectively reducing pain, inflammation and stiffness, Celebrex can help you through the day with activities like standing, walking or climbing stairs, and through the night while resting in bed.

What will you do on the day you discover Celebrex?

You should not take Celebrex in late pregnancy or if you have had aspirin-sensitive asthma or allergic-type reactions to aspirin, arthritis medications or certain sulfa drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Be sure to tell your doctor if you have kidney or liver problems.

Celebrex has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%) was similar to sugar pill (6.1%).

This information cannot replace your doctor's advice. Only your doctor can assess the benefits and risks to decide if Celebrex is right for you.

The #1 selling brand of prescription arthritis pain medicine.


CELEBREX™

(CELECOXIB CAPSULES) 100 mg
200 mg

Call 1-888-326-8469 or visit www.celebrex.com for more information.

*Does not include generic products.
IMS National Prescription Audit 1/1/99 - 9/30/99
© 1999 Seale CE105441

Please see following page for important product information.

SEARLE 

118. This advertisement which ran during January 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a “breakthrough” implying that it is superior to other NSAIDS which is not supported in clinical trials, and in fact is misleading given the lack of statistical significance between Celebrex and older NSAIDs. It also represents that it is the “#1 selling brand” which would not have been the case if Defendants had not engaged in the unlawful scheme described herein.

What will you do on the day you discover Celebrex?

The #1 selling brand of prescription arthritis medication* delivers powerful relief of your arthritis pain and inflammation. Celebrex is a scientific breakthrough: the first product to target only the COX-2 enzyme. By effectively reducing pain, inflammation and stiffness, Celebrex can help you through the day with activities like standing, walking or climbing stairs, and through the night while resting in bed.

You should not take Celebrex in late pregnancy or if you have had aspirin-sensitive asthma or allergic-type reactions to aspirin, arthritis medications or certain sulfa drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Be sure to tell your doctor if you have kidney or liver problems.

Celebrex has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%) was similar to sugar pill (6.1%).

This information cannot replace your doctor's advice. Only your doctor can assess the benefits and risks to decide if Celebrex is right for you.


The #1 selling brand of prescription arthritis pain medicine.


CELEBREX[™]
(CELECOXIB CAPSULES) 100 mg / 200 mg

Call 1-888-326-8469 or visit www.celebrex.com for more information.

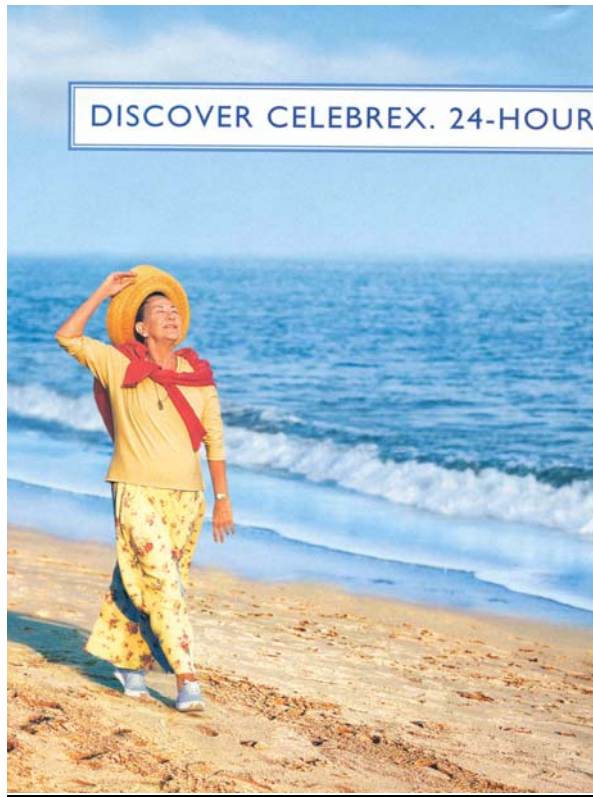
*Does not include generic products.
IMS National Prescription Audit 1/1/99 - 9/30/99
© 1999 Seale (1218297)

Please see following page for important product information.

SEARLE 



119. This advertisement which ran during March 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a “breakthrough” implying that it is superior to other NSAIDS which is not supported in clinical trials.



RELIEF FROM OSTEOARTHRITIS PAIN.

Celebrex, the #1 selling brand of prescription arthritis medication,* delivers powerful 24-hour relief of your osteoarthritis pain and inflammation. Celebrex is a scientific breakthrough; the first product to target only the COX-2 enzyme. By effectively reducing pain, inflammation and stiffness 24 hours a day, Celebrex can help you with everyday activities like standing, walking or climbing stairs, and through the night while resting in bed.

Celebrex should not be taken in late pregnancy or if you have allergic reactions, such as asthma, to aspirin or other arthritis medicines or certain sulfa drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Tell your doctor if you have kidney or liver problems.

Celebrex has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%) was similar to sugar pill (6.1%).

This information cannot replace your doctor's advice. Only your doctor can assess the benefits and risks to decide if Celebrex is right for you.

Discover Celebrex.
Powerful 24-hour relief from osteoarthritis pain.

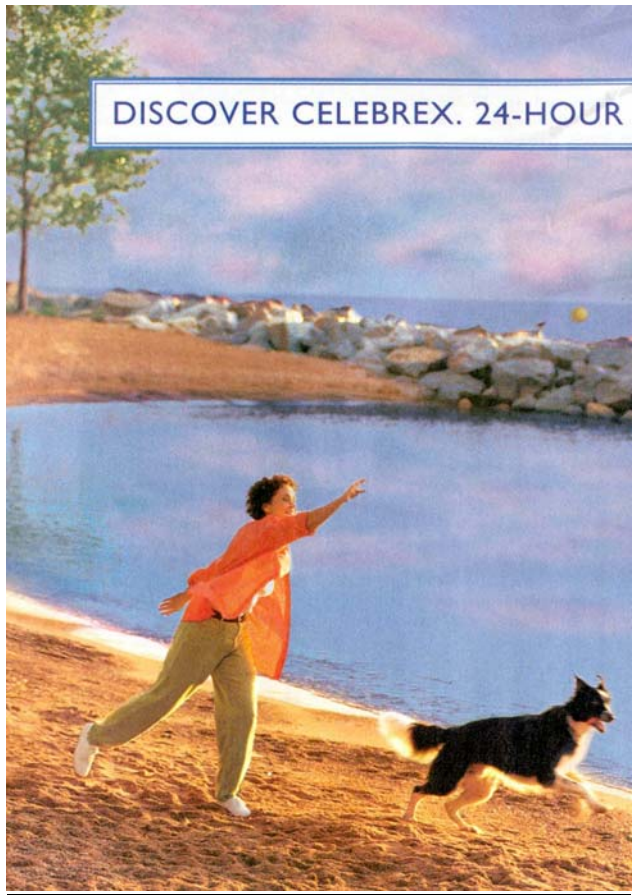
CELEBREX
(CELECOXIB CAPSULES) ^{100 mg} _{200 mg}

Call 1-888-326-8469 or visit www.celebrex.com for more information.

*Does not include generic products.
IMS National Prescription Audit 1/1/99 - 12/31/99
© 2000 Searle CE189007

Please see following page for important product information.
SEARLE

120. This advertisement which ran during May 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a “breakthrough” implying that it is superior to other NSAIDS which is not supported in clinical trials. In fact, Celebrex was not a “breakthrough” and did not show a statistically significant different between Celebrex and other NSAIDS.



RELIEF FROM OSTEOARTHRITIS PAIN.

Celebrex, the #1 selling brand of prescription arthritis medication, delivers powerful 24-hour relief of your osteoarthritis pain and inflammation. Celebrex is a scientific breakthrough; the first product to target only the COX-2 enzyme. By effectively reducing pain, inflammation and stiffness 24 hours a day, Celebrex can help you with everyday activities like standing, walking or climbing stairs, and through the night while resting in bed.

Celebrex should not be taken in late pregnancy or if you have allergic reactions, such as asthma, to aspirin or other arthritis medicines or certain sulfa drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Tell your doctor if you have kidney or liver problems.

Celebrex has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%) was similar to sugar pill (6.1%).

This information cannot replace your doctor's advice. Only your doctor can assess the benefits and risks to decide if Celebrex is right for you.

Discover Celebrex.
Powerful 24-hour relief from osteoarthritis pain.

CELEBREX
(CELECOXIB CAPSULES) 100 mg / 200 mg

Call 1-888-326-8469 or visit www.celebrex.com for more information.

*Does not include generic products. Please see following page for important product information.
IMS National Prescription Audit 1/1/99 - 12/31/99
© 2000 Searle CE18321T

SEARLE Pfizer

121. This advertisement which ran during June 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a “breakthrough” implying that it is superior to other NSAIDS which is not supported in clinical trials.

DISCOVER CELEBRIX. 24-HOUR RELIEF FROM OSTEOARTHRITIS PAIN.

Celebrex, the #1 selling brand of prescription arthritis medication*, delivers powerful 24-hour relief of your osteoarthritis pain and inflammation. Celebrex is a scientific breakthrough: the first product to target only the COX-2 enzyme. By effectively reducing pain, inflammation and stiffness 24 hours a day, Celebrex can help you with everyday activities like standing, walking or climbing stairs, and through the night while resting in bed.

Celebrex should not be taken in late pregnancy or if you have allergic reactions, such as asthma, to aspirin or other arthritis medicines or certain sulfa drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Tell your doctor if you have kidney or liver problems.

Celebrex has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%) was similar to sugar pill (6.1%).

This information cannot replace your doctor's advice. Only your doctor can assess the benefits and risks to decide if Celebrex is right for you.



Discover Celebrex. Powerful 24-hour relief from osteoarthritis pain.

CELEBRIX
(CELECOXIB CAPSULES) 100 mg
200 mg

Call 1-888-326-8469 or visit www.celebrex.com for more information.

*Does not include generic products.
IMS National Prescription Audit 1/1/99 - 12/31/99
© 2000 Searle CE187587

Please see following page for important product information.
SEARLE 

122. This advertisement which ran during December 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a “breakthrough” implying that it is superior to other NSAIDS which is not supported in clinical trials.

Ann, Arthritic Shoulder*

*Individual results may vary.

Celebrate

Arthritis Pain Relief.

Celebrex. The #1 selling prescription arthritis medicine.*

Celebrex. The first arthritis medicine that targets only the COX-2 enzyme.

Celebrex. Powerful 24-hour relief from osteoarthritis pain and stiffness.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information call 1-888-Celebrex or visit www.celebrex.com.

Ask Your Doctor If Celebrex Is Right For You.

CELEBREX
(CELECOXIB CAPSULES) 100 mg / 200 mg

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123. This advertisement which ran during January 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first arthritis medicine that targets only the COX-2 enzyme” it wrongly implies that it is superior to other NSAIDS.

Celebrate

Liz, Arthritic Back

*Individual results may vary.

Arthritis Pain Relief.

Celebrex. The #1 selling prescription arthritis medicine.¹

Celebrex. The first arthritis medicine that targets only the COX-2 enzyme.

Celebrex. Powerful 24-hour relief from osteoarthritis pain and stiffness.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information call 1-888-Celebrex or visit www.celebrex.com.

Ask Your Doctor If Celebrex is Right For You.

CELEBREX
(CELECOXIB CAPSULES) 100 mg / 200 mg

1 IMS National Prescription Audit 10/1/99-9/31/00
© 2001 Searle, a division of Pharmacia UJ0010170

Please see important product information on following page.

PHARMACIA **Pfizer**

124. This advertisement which ran during June 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first arthritis medicine that targets only the COX-2 enzyme” it falsely implies that it is superior to other NSAIDS.

Mark, Arthritis Free

*Individual results may vary.

Celebrate

Arthritis Pain Relief.

- Celebrex.** The #1 selling prescription arthritis medicine.†
- Celebrex.** The first arthritis medicine that targets only the COX-2 enzyme.
- Celebrex.** Powerful 24-hour relief from osteoarthritis pain and stiffness.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information call 1-888-Celebrex or visit www.celebrex.com.

Ask Your Doctor If Celebrex Is Right For You.

CELEBREX
(CELECOXIB CAPSULES) 100 mg 200 mg

Official Sponsor

Please see important product information on adjacent page.

† IMS National Prescription Audit 10/1/00-9/31/00
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PHARMACIA **Pfizer**

125. This advertisement which ran during May 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first arthritis medicine that targets only the COX-2 enzyme” it falsely implies that it is superior to other NSAIDS.

Individual results may vary.

Jill, Arthritic Hands.

Celebrate

Powerful 24-hour Relief from Osteoarthritis
PAIN • INFLAMMATION • STIFFNESS.

Celebrex is the first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain. Celebrex can help you through the day with activities like walking, standing or climbing stairs, and through the night while resting in bed. And that's definitely worth celebrating.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems, such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information, call 1-888-Celebrex or visit www.celebrex.com.

Ask Your Doctor If A Free Sample Of Celebrex Is Right For You.

CELEBREX
 (CELECOXIB CAPSULES) 100 mg / 200 mg

Please see important product information on adjacent page.
 © 2001 Sealed, a subsidiary of Pharmacia Corporation. UN0012114

PHARMACIA **Pfizer**

126. This advertisement which ran during September 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain” it falsely implies that it is superior to other NSAIDS.

Celebrate

Rita, Arthritic Back

*Individual results may vary.

**Powerful 24-hour Relief from Osteoarthritis
PAIN • INFLAMMATION • STIFFNESS.**

Celebrex is the first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain. Celebrex can help you through the day with activities like walking, standing or climbing stairs, and through the night while resting in bed. And that's definitely worth celebrating.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems, such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information, call 1-888-Celebrex or visit www.celebrex.com.

Ask Your Doctor if A Free Sample Of Celebrex Is Right For You.

CELEBREX
(CELECOXIB CAPSULES) 100 mg
200 mg

Please see important product information on adjacent page.
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PHARMACIA Pfizer

127. This advertisement which ran during October 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain” it falsely implies that it is superior to other NSAIDS.

Celebrate

**Individual results may vary.*

Sarah, Arthritic Back.*

Powerful 24-hour Relief from Osteoarthritis
PAIN • INFLAMMATION • STIFFNESS

Celebrex is the first prescription arthritis medicine that specifically targets only the COX-2 enzyme—a key source of arthritis pain. Celebrex can help you through the day with activities like walking, standing or climbing stairs, and through the night while resting in bed. And that's definitely worth celebrating.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems, such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information, call 1-888-Celebrex or visit www.celebrex.com.

Ask Your Doctor If A Free Sample Of Celebrex Is Right For You.

CELEBREX
 (CELECOXIB CAPSULES) 100 mg
 200 mg

Please see important product information on adjacent page.
 ©2001 Searle, a subsidiary of Pharmacia Corporation UX0012326

PHARMACIA

128. This advertisement which ran during October 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain” it falsely implies that it is superior to other NSAIDS.

Celebrate

*Individual results may vary.

LEN COOL

Mike, Arthritic Shoulder.*

Powerful 24-hour Relief from Osteoarthritis
PAIN • INFLAMMATION • STIFFNESS

Celebrex is the first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain. Celebrex can help you through the day with activities like walking, standing or climbing stairs, and through the night while resting in bed. And that's definitely worth celebrating.

Important Celebrex Information. Celebrex should not be taken in late pregnancy or if you've had aspirin-sensitive asthma or allergic reactions to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases serious stomach problems, such as bleeding can occur without warning. The most common side effects in clinical trials were indigestion, diarrhea and abdominal pain. Tell your doctor if you have kidney or liver problems. For more information, call 1-888-Celebrex or visit www.celebrex.com.

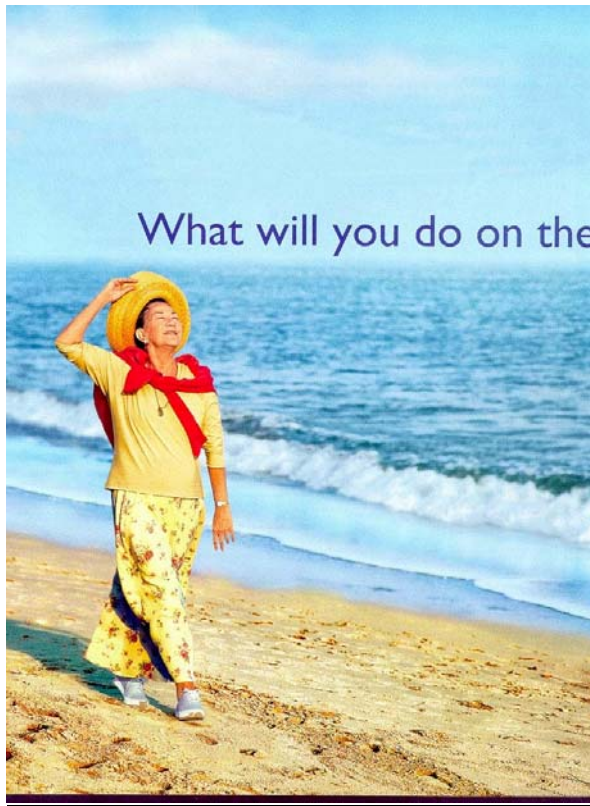
Ask Your Doctor if A Free Sample Of Celebrex Is Right For You.

CELEBREX
 (CELECOXIB CAPSULES) 100 mg / 200 mg

Please see important product information on adjacent page.
 ©2001 Searle, a subsidiary of Pharmacia Corporation UX0012324

PHARMACIA

129. This advertisement which ran during November 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the “first prescription arthritis medicine that specifically targets only the COX-2 enzyme – a key source of arthritis pain” it falsely implies that it is superior to other NSAIDS.



Discover what millions have turned to for arthritis pain relief.

The #1 selling brand of prescription arthritis medication* delivers powerful relief of your arthritis pain and inflammation. Celebrex is a scientific breakthrough: the first product to target only the COX-2 enzyme. By effectively reducing pain, inflammation and stiffness, Celebrex can help you through the day with activities like standing, walking or climbing stairs, and through the night while resting in bed.

What will you do on the day you discover Celebrex?

You should not take Celebrex in late pregnancy or if you have had aspirin-sensitive asthma or allergic-type reactions to aspirin, arthritis medications or certain sulfa drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Be sure to tell your doctor if you have kidney or liver problems.

Celebrex has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%) was similar to sugar pill (6.1%).

This information cannot replace your doctor's advice. Only your doctor can assess the benefits and risks to decide if Celebrex is right for you.

The #1 selling brand of prescription arthritis pain medicine.

CELEBREX

(CELECOXIB CAPSULES) 100 mg / 200 mg

Call 1-888-326-8469 or visit www.celebrex.com for more information.

*Does not include generic products.
IMS National Prescription Audit 1/1/99 - 9/30/99
© 1999 Seale - CE170111

Please see following page for important product information.

SEARLE Pfizer

130. This advertisement which ran during February 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a “breakthrough” falsely implying that it is superior to other NSAIDs.


With Celebrex, I will play the long version.

One pill. 24 hours.
If you've been managing the joint pain of osteoarthritis on your own, it might be time to ask your doctor about CELEBREX. Just one CELEBREX provides up to 24 hours of relief from joint pain, inflammation and stiffness. So next time you play, you can play the long version.

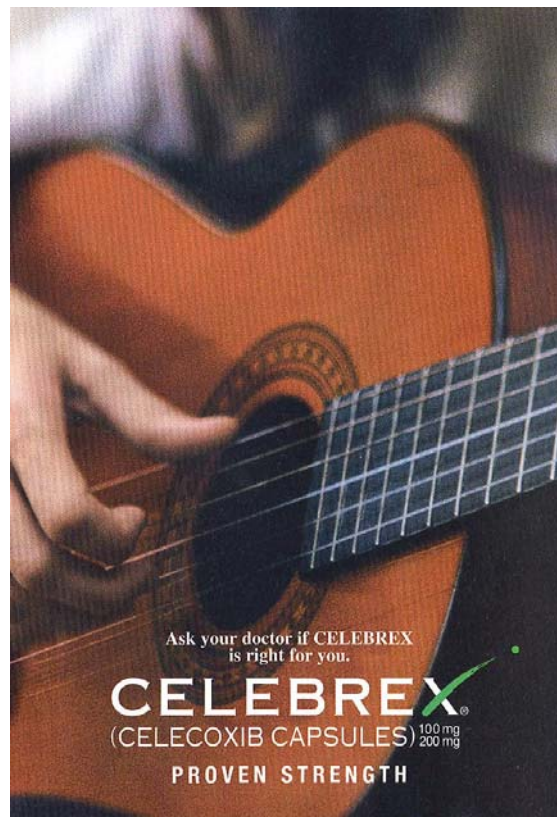
Take control of your joint pain with CELEBREX. Call your doctor, or call 1-888-CELEBREX (235-3273). www.celebrex.com

CELEBREX should not be taken if you've had aspirin sensitive asthma or allergic reactions due to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Tell your doctor if you have kidney or liver problems.

Please see important product information on adjacent page.



© 2004 Pfizer Corporation CL194613C



Ask your doctor if CELEBREX is right for you.

CELEBREX[®]

(CELECOXIB CAPSULES) 100 mg
200 mg

PROVEN STRENGTH

132. This advertisement which ran during July 2004 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials.

Celebrex Physician Directed Ads

Indicated for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis in adults.

Contraindications—CELEBREX is contraindicated in patients with known hypersensitivity to celecoxib; in patients who have demonstrated allergic-type reactions to sulfonamides; and in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. CELEBREX should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. CELEBREX should be avoided during late pregnancy.

Serious GI toxicity can occur with or without warning symptoms in patients treated with NSAIDs.

Most common side effects were dyspepsia, diarrhea, and abdominal pain, and were generally mild to moderate.

Please see brief summary of prescribing information on the last page of this advertisement.

Reference: 1. Data on file, GD Searle & Co.

PERSISTENT POWER

Over the pain and inflammation of OA and RA

RELIEF
Efficacy in OA and RA as powerful as 1000 mg naproxen¹

RELIABILITY
Excellent GI tolerability¹

RESULTS
Improved patient function and vitality as measured by SF-36¹

PAIN

ARTHRITIS

CELEBREX
(CELECOXIB CAPSULES) 100 mg / 200 mg

PERSISTENT POWER OVER ARTHRITIS PAIN

© 2000 Searle SEARLE

133. This advertisement which ran during July 2000 makes unsubstantiated superiority claims. By comparing the effectiveness of Celebrex to naproxen the advertisement falsely implies that it is superior to other NSAIDs. The statement excellent GI tolerability is false and misleading, particularly in light of the reference to GI complications for NSAIDs with no such mention of complications for Celebrex. Further, Celebrex did not show excellent GI tolerability. Rather, its tolerability was no different than NSAIDs and in fact the class study showed increased complications from Celebrex.

FOR OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS
POWERFUL RELIEF. SAFELY

© 1999 Seale
SEALE Pfizer

DELIVERED. CELEBREX
(CELECOXIB CAPSULES) 100 mg 200 mg

POWERFUL RELIEF OF INTENSE ARTHRITIS PAIN

- Power as strong as naproxen 1000 mg daily

FEWER ENDOSCOPIC GI ULCERS

- Significantly fewer GI ulcers than naproxen ($P < 0.05$), as shown in 12-week endoscopy studies. The correlation between endoscopic findings and the incidence of clinically serious upper GI events has not been fully established
- Serious GI toxicity such as bleeding, ulceration, and perforation can occur with or without warning symptoms in patients treated with NSAIDs. These GI events appear to occur in approximately 1% of patients treated for 3 to 6 months, and in 2% to 4% treated for 1 year. It is unclear at present how the above rates apply to CELEBREX
- In patients with a history of these conditions, NSAIDs should be prescribed with extreme caution. To minimize GI risk, use the lowest effective dose for the shortest possible duration
- As with all NSAIDs, most spontaneous reports of fatal GI events are in elderly or debilitated patients and, therefore, special care should be taken in treating this population

CONTRAINDICATIONS — CELEBREX is contraindicated in patients with known hypersensitivity to celecoxib; in patients who have demonstrated allergic-type reactions to sulfonamides; and in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs

- CELEBREX should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. CELEBREX should be avoided during late pregnancy
- Most common side effects were dyspepsia (8.8% vs 6.2% for placebo), diarrhea (5.6% vs 3.8% for placebo), and abdominal pain (4.1% vs 2.8% for placebo), and were generally mild to moderate

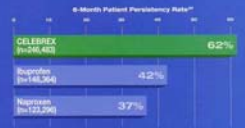
Please see brief summary of prescribing information on the last page of this advertisement.

134. This advertisement which ran during November 1999 makes unsubstantiated superiority claims. By comparing the effectiveness of Celebrex to naproxen the advertisement falsely implies that it is superior to other NSAIDs, and falsely claims that there are “significantly fewer GI ulcers” when in fact this is not statistically proven. This advertisement is misleading by referring to significantly lower endoscopic ulcers, which were found by the FDA not to be significant and is further misleading for the failure to balance that statement with the FDA finding that Celebrex was not better in safety than NSAIDs. In addition, by referring to NSAIDs and GI complications without reference to Celebrex and GI complications the advertisement is unbalanced and misleading.

STRENGTH THEY CAN STAY WITH.



In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months*



*All patients, including continuing patients and nonusers on therapy through month 6 (June 2002, N=95,053). Similar results were seen in each of the 12 study cohorts. Information was provided by a subset of retail pharmacies. Patients included cash payers as well as those covered by Medicaid and third-party insurers. NDC Health COX-2 and NSAIDs Persistency Analysis, November 2002. Patients with a prescription for 15 days or less were excluded. Prescription indication and reason for discontinuation were not identified. Reference: 1. Data on file.

CELEBREX
(CELECOXIB CAPSULES)
Proven strength that lasts

CELEBREX is contraindicated in patients with a known hypersensitivity to celecoxib, in patients who have demonstrated allergic-type reactions to sulfonamides, and in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Serious GI toxicity such as bleeding, ulceration, and perforation can occur with or without warning symptoms in patients treated with NSAIDs. Most common side effects were dyspepsia, diarrhea, and abdominal pain, and were generally mild to moderate. Please see brief summary of prescribing information on adjacent page.

STRENGTH THEY CAN STAY WITH.



In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months*



*All patients, including continuing patients and nonusers on therapy through month 6 (June 2002, N=95,053). Similar results were seen in each of the 12 study cohorts. Information was provided by a subset of retail pharmacies. Patients included cash payers as well as those covered by Medicaid and third-party insurers. NDC Health COX-2 and NSAIDs Persistency Analysis, November 2002. Patients with a prescription for 15 days or less were excluded. Prescription indication and reason for discontinuation were not identified. Reference: 1. Data on file.

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STRENGTH THEY CAN STAY WITH.



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(CELECOXIB CAPSULES)
Proven strength that lasts

CELEBREX is contraindicated in patients with a known hypersensitivity to celecoxib, in patients who have demonstrated allergic-type reactions to sulfonamides, and in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Serious GI toxicity such as bleeding, ulceration, and perforation can occur with or without warning symptoms in patients treated with NSAIDs. Most common side effects were dyspepsia, diarrhea, and abdominal pain, and were generally mild to moderate. Please see brief summary of prescribing information on adjacent page.

135. The above three advertisements which ran during February and March 2004 are misleading. In a letter to Pfizer the FDA stated: “The print ad features the prominent headline “Strength They Can Stay With” and shows a chart comparing Celebrex, Ibuprofen and Naproxen, titled “6-Month Patient Persistency Rate.” Over the chart is the statement, “In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months.” The tagline below the Celebrex logo in the print ad is “Proven strength that lasts.”

136. In the letter to Pfizer the FDA stated: “The above referenced claims imply that Celebrex is more effective (*i.e.*, stronger) than ibuprofen and naproxen for treatment of osteoarthritis or rheumatoid arthritis and that patients “stay with” or are more compliant with Celebrex therapy than the compared products. We are not aware of substantial evidence or substantial clinical experience to support these claims. The cited retrospective retail pharmacy database analyses by NDC Health, “Persistency Analysis: Celebrex, Vioxx, and All Other NSAIDs,” August 2002 and “Persistency Analysis: Celebrex, Vioxx, Ibuprofen, and Naproxen,” from November 2002 (almost 2 years ago), do not contain any data or information demonstrating that patients found Celebrex to be more effective than the other products, or that patients will be more “persistent” or compliant with Celebrex therapy. Moreover, the database information did not note the indication for which the drug was prescribed, so the suggestion that these rates reflect specifically OA/RA patients is misleading. In addition, the analyses do not account for factors that affect persistence or compliance such as cost insurance coverage, side effects, dosage regimen, and ease of use. Therefore, the analyses do not constitute substantial evidence or substantial clinical experience demonstrating that OA/RA patients are more compliant with Celebrex or stay on Celebrex longer because it is more effective than other products for the treatment of OA or RA.”

J. Concealment of Cardiovascular Risks and Dangers

137. The CLASS study published in 2000 assessed the incidence of clinically significant upper GI events seen over one year of treatment with Celebrex compared to ibuprofen

and diclofenac. A post hoc analysis was done between those patients taking low-dose aspirin for cardiac protection and those patients not taking low-dose aspirin. The published article found that the incidence of cerebrovascular accident, myocardial infarction, and angina was not statistically different between patients taking the three drugs. However, the published data only reflected a 6-month period used by the company to espouse an unsupportable claim of decreased GI toxicity.

138. The 12-month data set available from the FDA revealed that the rate of combined anginal adverse events was 1.4% in the celecoxib group versus 1.0% in either NSAID group, a non-statistically significant difference. However, this tendency toward increased cardiovascular toxicity was described by the FDA Medical Officer Dr. Witter, “For anginal disorders (especially the combined disorders), *there seems to be a trend toward more [cardiac adverse] events in those patients receiving celecoxib*, regardless of aspirin use.

139. This trend was *magnified* in those patients not taking low-dose aspirin. Combined anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0% in the diclofenac and ibuprofen groups, respectively. There were also more combined atrial serious cardiac adverse events with celecoxib, 0.3% compared to 0.1% and 0% in the diclofenac and ibuprofen groups, respectively. Dr. Witter commented, “In the non-aspirin users, there appears to be a slight trend toward more [serious cardiac adverse] events in those patients receiving celecoxib for combined atrial and anginal disorders.” Additionally, the rate of myocardial infarction was higher in the celecoxib group, 0.2%, compared with the other two drugs, 0.1%. Dr. Witter also referred to data from the original NDA for celecoxib in his discussion, “There were suggestions of a dose-response relationship (...100mg BID celecoxib, 0% crude mortality rate vs. 400 mg BID celecoxib, 0.64% crude mortality rate) between cardiovascular mortality and [increased] celecoxib use that could not be adequately addressed by the data.”

140. The FDA was concerned enough that they ordered a cardiorenal consult by Medical Officer Dr. Throckmorton on the same CLASS study data. In his report he noted, “The

CLASS trial data do not support a large adverse effect of celecoxib on cardiovascular mortality or on serious adverse events related to thrombosis relative to either diclofenac or ibuprofen. The data do not exclude a less apparent pro-thrombotic effect of celecoxib, such as might be reflected in the relative rates of cardiac adverse events related to ischemia.”

141. While none of the CLASS data was statistically significant, they revealed a consistent and worrisome trend toward increased cardiovascular toxicity, particularly that related to increased thrombosis.

142. The reviewers’ recommendations were, “Our findings suggest a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors ... definitive evidence of such an adverse effect will require a prospective randomized clinical trial Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents. Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular morbidity.” Although employing a placebo group from a different trial weakens the validity of their analysis, the author’s call for a prospective randomized clinical trial powered to truly analyze the cardiovascular risk to benefit ratio was then exactly correct. Recently, however, such a placebo-controlled trial of celecoxib has clearly demonstrated this risk.

143. This trial was the APC colon polyp recurrence prevention study, in which approximately 2000 patients took celecoxib or placebo. Interestingly, this was the longest celecoxib trial to date with mean duration of treatment being 33 months as opposed to the much shorter 12-month duration of the CLASS study. A statistically significant elevation in the risk for a major fatal or non-fatal cardiovascular event (a composite endpoint of cardiovascular death, acute myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in the placebo group. This followed a dose-response relationship: the relative risk at 400mg/day of celecoxib was 2.5 while the relative risk at 800mg/day was 3.4. Because of this unacceptable danger, the trial was prematurely halted. The FDA released an explanatory statement which said, “While we have not seen all available data on Celebrex, these findings are

similar to recent results from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently voluntarily withdrawn by Merck.”

144. Given the above data and trends, advertising, promotional and other materials, promoting the safety of Celebrex was misleading. This trend and the omission of material facts in Defendants’ promotional materials are more alarming in view of a 1999 study that was unpublished that showed patients taking Celebrex were more likely than those taking a placebo to have heart attacks. Though the study was small, its conclusions contradicted years of claims by Defendants that no trial of Celebrex had ever shown adverse cardio results. Plus, when combined with the CLASS results, this clearly raised a red flag as to risks that physicians should have been made aware of. These risks were concealed by Defendants.

K. Misleading Promotion and Advertising

145. Defendants have spent hundreds of millions of dollars advertising Celebrex directly to consumers. Celebrex advertising and packaging materials do not contain any cardiovascular warnings or precautions. The only mentions of cardiovascular events are located in the “adverse reaction” (0.1%-1.9%) and “other serious adverse reaction” (<0.1%) sections, and do no more than list general cardiovascular problems experienced by participants in “12 controlled studies” involving Celebrex.

146. Defendants’ advertising and packaging materials for Celebrex are uniformly fraudulent and misleading, because they fail to warn consumers that certain studies showed that Celebrex poses known risks of blood clots, heart attack, stroke, unstable angina, cardiac clotting and hypertension for all people who ingest them; and cannot safely be ingested by patients with known heart disease or cardiovascular risk factors.

147. In October 1999, the FDA sent a letter to Searle identifying promotional materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act because they contained unsubstantiated comparative claims of superiority with regard to other NSAIDs, misrepresented the safety profile of Celebrex and lacked fair balance with respect to the risks of taking Celebrex.

148. In April 2000, the FDA sent a letter to Searle identifying promotional materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act because they misrepresented the safety profile of Celebrex, contained unsubstantiated comparative claims of superiority with regard to other NSAIDs, and failed to provide any risk information concerning the use of Celebrex.

149. In November 2000, the FDA sent a letter to Searle identifying promotional materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act because they suggested that Celebrex is more effective than has been demonstrated by substantial evidence.

150. In February 2001, the FDA sent a “Warning Letter” to Pharmacia identifying promotional activities and materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act because they minimize the contraindications and risks associated with Celebrex use and contained unsubstantiated comparative claims of superiority with regard to other NSAIDs. A Warning Letter is the highest level of FDA sanction before the agency takes legal action.

L. Pfizer Halts the Celebrex Promotional Scheme

151. On or about September 30, 2004, Merck withdrew its COX-2 inhibitor from the marketplace. In response, Pfizer issued a statement indicating it was “confident in the long term cardiovascular safety of Celebrex” and indicated that “since the introduction of COX-2 inhibitors, the rate of hospitalizations for gastrointestinal events associated with long term arthritis treatment has declined significantly.”

152. The foregoing statement was misleading in that it failed to show the existence of some studies indicating that Celebrex did present cardiovascular risks and there was no statistically significant evidence to support the claim that Celebrex or other COX-2 inhibitors lead to a decrease in serious GI complications.

153. On December 17, 2004, Pfizer shocked consumers by disclosing a study that demonstrated an increased risk of cardiovascular disease. Pfizer then announced on

December 20, 2004, that it would stop all television, radio, newspaper and magazine advertising. Pfizer did so because it was aware that its previous campaign was misleading.

154. On February 1, 2005, Pfizer admitted it was aware of a 1999 clinical trial finding that elderly patients using Celebrex were far more likely to suffer heart problems than patients taking a placebo. The study was never published and was not submitted to the FDA until 2001, four months after the FDA's review of Celebrex and Vioxx. An FDA reviewer who was unaware of the study has stated that had the Panel known about this study, it might have acted differently on Celebrex. Celebrex, unlike Vioxx, was not required by the FDA to carry warnings of cardiovascular risk. The lack of warning is a main reason why Celebrex has achieved greater commercial success than Vioxx.

V. CLASS ACTION ALLEGATIONS

155. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(b)(1), (2) and (3) as representative of the following Class: All persons in the United States who, since 1999, have paid some or all of the purchase price for Celebrex either on their own behalf or on behalf of someone else who ingested this drug. Defendants' employees, officers and agents and their immediate families are excluded from the Class.

156. The members of the Class are so numerous that joinder of all their members would be impractical. Celebrex has been prescribed to, paid for and ingested by millions of consumers nationwide.

157. There are questions of law and fact common to the Class that predominate over questions affecting only individual members, including, but not limited to:

- a. whether Defendants engaged in a fraudulent and/or deceptive scheme to portray Celebrex as a drug having superior qualities to other NSAIDS;
- b. whether Defendants engaged in a scheme to create consumer demand for Celebrex based on deceptive statements concerning Celebrex's safety and efficacy;
- c. whether as a result of this scheme Celebrex was over prescribed;
- d. whether the price of Celebrex was inflated as a result of the scheme;

- e. whether Defendants formed an enterprise for the purposes of carrying out the scheme;
- f. whether Defendants used the U.S. mails and wires to facilitate the scheme;
- g. whether Defendants' conduct violated RICO;
- h. whether Defendants are liable to Plaintiff and the Class for damages under state consumer protection statutes; and
- i. whether Defendants made material misrepresentations or material omissions about the cardiovascular risks associated with using Celebrex and regarding the effectiveness of Celebrex; and
- j. whether members of the Class are entitled to damages based on their payments for Celebrex, and, if so, the nature and amount of such damages.

158. Plaintiff's claims and defenses are typical of the claims and defenses belonging to absent members of the Class, because Defendants have uniformly misrepresented that Celebrex is safer and more effective than traditional NSAIDs and uniformly failed to disclose the material cardiovascular risks associated with Celebrex. Defendants' actions have deprived Plaintiff and the members of the Class of their ability to make an informed decision about whether to pay for Celebrex and if so at what price.

159. Plaintiff will fairly and adequately assert and protect the interests of absent members of the Class, because Plaintiff has retained counsel competent and experienced in complex class action litigation and have no interest adverse to any absent Class members.

160. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(A), because the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class and establish incompatible standards of conduct for Defendants.

161. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(B), because the prosecution of separate actions by individual Class members would create a risk of adjudications with respects to individual Class members which would, as a practical matter, be

dispositive of the interest of the other members not parties to these adjudications and/or substantially impair their ability to protect these interests.

162. Class certification is proper under Federal Rule of Civil Procedure 23(b)(2), because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate for the Class.

163. Class certification is proper under Federal Rule of Civil Procedure 23(b)(3), because common issues of law and fact predominate over any questions affecting only individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

164. The need for Class-wide notice does not provide a barrier to certification, in that notice can be effectively disseminated to Class by techniques customarily used in consumer class actions, including published notice, Internet notice and direct mailings based on readily available computer databases (such as the one Defendants used to send their “Dear Patient” correspondence).

FIRST CLAIM FOR RELIEF
(Violations of 18 U.S.C. § 1962(c))

165. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein.

166. This claim, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against Defendants on behalf of the Class.

167. Plaintiff, the members of Class, and Defendants are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

168. At all relevant times, in violation of 18 U.S.C. § 1962(c), Defendants conducted the affairs of an association-in-fact enterprise identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

Celebrex Enterprise

169. For purposes of this claim, the RICO “enterprise” is an association-in-fact consisting of each of the Defendants, including their directors, employees and agents and includes outside advertising agencies utilized by Defendants and the Medical Directors of Searle and Pfizer. While maintaining their separate legal identities and titles, each of these entities and persons joined together to run the Enterprise. The association-in-fact is referred to herein as the “Celebrex Enterprise.” At all relevant times, the Celebrex Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating information about Celebrex, which all too often includes disseminating false and misleading information for the purpose of trying to make Celebrex a blockbuster drug, (b) jointly presenting data to the FDA and other medical journals that is misleading and/or has been manipulated to distort the results of clinical trials, (c) selling, promoting, and distributing Celebrex to Plaintiff and Class members, (d) achieving as a goal breaking the NSAID barrier, *i.e.*, having Celebrex replace NSAIDs as the preferred treatment, and (e) deriving profits from these activities beyond those that could have been attained without operation of the Enterprise. The Enterprise had as a common purpose creating a demand for Celebrex in a class of consumers who could have used NSAIDs and achieved the same pain relief at a lower cost. Defendants have this as a purpose because without the Celebrex Enterprise, they would not be able to sell Celebrex at the prices at which it was sold. During most of the time relevant to this complaint, each Defendant maintained a separate legal identity while operating the Enterprise and others associated with and part of the Enterprise maintained their separate identities. The Enterprise continues to operate through Pfizer and through the instructions it issues to its agents for the purpose of carrying out the objectives of the Celebrex Enterprise. Agents and members of the Enterprise include advertising agencies used to create Celebrex advertisements and doctors who co-author articles promoting the efficacy of Celebrex. As to each Defendant, the association-in-

fact met on a regular basis to discuss the operations of the Enterprise and the Enterprise's efforts were coordinated and agreed to by each Defendant.

170. Each of the members of the Enterprise had a systemic linkage, because there are contractual relationships, financial ties and continuing coordination of activities between the Defendants and the Enterprise. As to each Defendant, there was a common communication network by which information concerning the Celebrex Enterprise was exchanged on a regular basis. Typically this communication occurred by the use of electronic mail or the telephone in which Defendants plan the operation of the Enterprise alleged herein and ran its continuing operation.

171. As part of their conduct of the Celebrex Enterprise and as part of the Enterprise's decisional marketing structure, Defendants agreed to maintain close communication between scientists at each company who were studying safety and efficacy, agreed to control media access to safety news and to provide each company's sales force with an agreed response to safety issues. Defendants also agreed to issue jointly sponsored advertisements that furthered the purposes of the Enterprise.

172. With the merger of Pfizer and Pharmacia and the purchase of Searle by Pharmacia, the Enterprise is now an association-in-fact consisting of the individuals at Pfizer in charge of running the Celebrex Enterprise, including the sales executive in charge of marketing efforts, executives in charge of advertising and those in charge of developing responses to safety issues. This association-in-fact meets on a regular basis to guide the operation of the Enterprise.

173. At all relevant times, each of the Defendants was a knowing participant in the Enterprise and benefited from its operation.

Defendants' Use of the U.S. Mails and Interstate Wire Facilities

174. The Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: The transmission and publication of false and misleading information concerning Celebrex; the sale, promotion and/or distribution of Celebrex; and/or the transmission and/or receipt of sales and marketing literature; and/or the

transmission and/or receipt of invoices, statements and payments related to the use or administration of Celebrex.

175. Defendants' illegal conduct and wrongful practices were carried out by an array of employees, as well as by consultants and doctors, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

176. The nature and pervasiveness of the Celebrex Enterprise, which was orchestrated out of the corporate headquarters of Defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the various local district managers overseeing the sales force(s), the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the public.

177. Many of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the Celebrex Enterprise alleged herein depended upon secrecy, and as alleged above, Defendants took deliberate steps to conceal their wrongdoing. However, Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Celebrex Enterprise, and do so below.

178. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the Enterprise involved thousands of communications, including *inter alia*:

- a. Marketing materials about Celebrex, which were sent by Defendants to health care providers located across the country;
- b. Written representations made by Defendants, which were made at least annually and in many cases several times during a single year;

- c. Documents submitted to the FDA, JAMA and other medical journals designed to conceal the risks of Celebrex and to falsely promote its safety and superiority;
- d. Written and oral communications directed to U.S. Government agencies that fraudulently misrepresented Celebrex;
- e. Written and oral communications with health insurers and patients, including Plaintiff and members of the Class, inducing payments that were made in reliance on the safety and effectiveness of Celebrex;
- f. Receipts of money sent on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Celebrex Enterprise; and
- g. In addition to the above-referenced RICO predicate acts, it was foreseeable to Defendants that others would distribute publications containing false information about the effectiveness of Celebrex through the U.S. mails and by interstate wire facilities. Further, Defendants' corporate headquarters have, in furtherance of the Enterprise, communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions. These uses of the U.S. mails include some of the documents referenced in this Amended Complaint.

Conduct of the RICO Enterprise's Affairs

179. Defendants exerted control over their Celebrex Enterprise and, in violation of Section 1962(c) of RICO, conducted or participated in the conduct of the affairs of that RICO enterprise, directly or indirectly, in the following ways:

- (a) Each Defendant has directly or indirectly controlled the written and televised promotional materials with respect to Celebrex;
- (b) Each Defendant has directly or indirectly controlled some of the medical literature regarding the effectiveness of Celebrex;

- (c) Each Defendant has directly or indirectly controlled the goals of the Enterprise, *i.e.*, to have Celebrex break the NSAID barrier;
- (d) Each Defendant has controlled the sales and marketing plans for Celebrex;
- (e) Each Defendant has directly controlled the creation and distribution of marketing, sales, and other materials used to inform health care providers nationwide of the benefits of using Celebrex;
- (f) Each Defendant has controlled and participated in the affairs of its Celebrex Enterprise by using a fraudulent scheme to manufacture, market and sell Celebrex; and
- (g) Each Defendant intended to (and did) distribute publications containing false information through the U.S. mails and by interstate wire facilities.

180. The Celebrex Enterprise had a joint decision-making structure, under which each Defendant jointly agreed on how Celebrex was to be promoted and agreed as to how the affairs of the Enterprise should be conducted.

181. Each of the members of the Enterprise had a systemic linkage, because there are contractual relationships, financial ties and continuing coordination of activities between the Defendants and the Enterprise. As to each Defendant, there was a common communication network by which information concerning the Celebrex Enterprise is exchanged on a regular basis. Typically this communication occurs by the use of electronic mail or the telephone in which Defendants plan the operation of the Enterprise alleged herein and ran its continuing operation. This communication also occurred at meetings of the sales departments of each Defendant.

182. As part of their conduct of the Celebrex Enterprise and as part of the Enterprise's decisional marketing structure, Defendants agreed to maintain close communications between scientists at each company who were studying safety, agreed to control media access to safety news and to provide each company's sales force with an agreed response to safety issues.

183. In violation of Section 1962(c) of RICO, each Defendant conducted the affairs of the Celebrex Enterprise with which they associated by reporting fraudulent, false, deceptive

and/or incomplete information as to the safety of Celebrex that were then disseminated nationwide.

Defendants' Pattern of Racketeering Activity

184. Each Defendant conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), by means of which Defendants intended to defraud Plaintiff, members of the Class and other intended victims of the Enterprise.

185. Defendants' fraudulent and unlawful Enterprise consisted, in part, of disseminating by means of the U.S. mails and interstate wire facilities fraudulent information as to the safety and superiority of Celebrex. As a result, Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

186. Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiff and members of the Class. Each separate use of the U.S. mails and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff and members of the Class. Each Defendant has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Enterprise.

Defendants' Motive

187. Defendants' motive in creating and operating the Enterprise and conducting the affairs of the Enterprise described herein was to fraudulently obtain sales and profits.

188. The Enterprise was designed to, and did, encourage others, including health care providers, to advocate the use of Celebrex. Thus, each Defendant used the Enterprise to sell more Celebrex, thereby fraudulently gaining sales and market share and profits.

Damages Caused by Defendants' Enterprise

189. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiff and members of the Class to be injured in their business or property because Plaintiff and members of the Class have paid billions of dollars in inflated reimbursements or other payments for Celebrex.

190. Plaintiffs' harm is caused by an indivisible course of conduct. It is impossible to segregate the cumulative and compounding effect of defendants' multi-faceted wrongful conduct in creating the artificial demand for Celebrex as well as its price inflation. The intent of defendants' conduct was to have the multi-faceted nature of its conduct increase demand for Celebrex and inflate its price.

191. Defendants used the U.S. mails or interstate wire facilities in furtherance of their conduct. Plaintiff and members of the Class have made inflated payments for Celebrex.

192. Under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiff and members of the Class for three times the damages that Plaintiff and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

**SECOND CLAIM FOR RELIEF
(Violation of the Michigan Deceptive Trade Practices Act)**

193. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein.

194. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes when it engaged in a course of conduct designed to induce the Class to purchase and/or pay for or reimburse for the purchase of Celebrex. Defendant misrepresented the alleged benefits of Celebrex; failed to

disclose material information concerning known side effects of the drug; misrepresented the quality of the drug as compared to much lower-cost alternatives; and otherwise engaged in fraudulent and deceptive conduct creating the likelihood of confusion and misunderstanding.

32. As a direct result of Defendant's, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and the Class were and continue to be damaged.

33. Plaintiffs purchased and/or reimbursed its participants for purchases of Celebrex that were made primarily for personal, family or household purposes. Through its actions and omissions, Defendant has engaged in unfair competition or deceptive acts or practices in violation of Mich. Stat. §445.901 et seq.

195. Defendant intended that Plaintiffs and the proposed class members rely on its materially deceptive practices and purchase Celebrex as a consequence of the deceptive practices, including Defendant's misrepresentations and omissions of material fact with respect to the true nature of Celebrex:

a. Defendants' promotions of Celebrex were unfair and unlawful in that Celebrex actually had undisclosed risks of adverse cardiovascular events, did not have added benefits over NSAIDs and was promoted solely for financial reasons and not due to any material increase in medical safety of efficacy over NSAIDs;

b. Defendants' conduct was unfair, unlawful and deceptive in that Defendants knew that at least one study indicated that Celebrex was unsafe and increased the risk of adverse cardiovascular events, such as heart attack and stroke, to unacceptable levels, but omitted to disclose these facts to doctors and patients until 2005;

c. Defendants' conduct was unfair, unlawful and deceptive in that they suppressed, manipulated and conceded information that would demonstrate Celebrex was not superior to NSAIDs in the majority of patients;

- d. Defendants portrayed Celebrex as a relief for symptoms and diseases without any statistically significant evidence for doing so;
- e. Defendants omitted material information known to them in order to induce doctors to prescribe Celebrex and consumers to purchase Celebrex at a price that exceeded its actual worth; and
- f. Defendants established Celebrex as a standard course of treatment based upon the use of reprints of articles appearing in prestigious medical journals which Defendants knew were false and/or misleading.
- g. Defendants committed unlawful acts by promoting and advertising Celebrex in a manner that violated the Federal Food, Drug and Cosmetic Act. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n) and 355(a).

196. Plaintiffs and members of the class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at physicians and consumers was to artificially create demand for Celebrex at an artificially inflated price. Each aspect of Defendants' conduct combined to artificially create sales of Celebrex.

197. Had Defendants not engaged in the deceptive conduct described above, plaintiffs and members of the class would not have purchased Celebrex or would have done so at a price that was substantially reduced.

198. Defendant's deceptive representations and material omissions to Plaintiffs and the proposed class members were, and are unfair and deceptive acts and practices.

199. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, significant sums of money from Plaintiffs and the proposed class members.

200. Plaintiffs were deceived by Defendant's misrepresentations.

201. As a proximate result of the Defendant's misrepresentations, Plaintiffs and the proposed class members have suffered an ascertainable loss, in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF
(Violation of the Consumer Protection Statutes of the 50 States)

202. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

203. Alternatively, Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes listed below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

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

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

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

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

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

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

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

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1b, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

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

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

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

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

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

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

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

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

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

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

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

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

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

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

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

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

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

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

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

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

(qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

(rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

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

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

(uu) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

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

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

(xx) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

204. Plaintiffs and members of the class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at physicians and consumers was to artificially create demand for Celebrex at an artificially inflated price. Each aspect of Defendants' conduct combined to artificially create sales of Celebrex.

205. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class have suffered actual economic damage by paying for Celebrex at an artificially inflated price.

**FOURTH CLAIM FOR RELIEF
(Unjust Enrichment)**

206. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

207. To the detriment of Plaintiffs and members of the Class, Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, *inter alia*, payments for Celebrex.

208. Plaintiffs and members of the class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at physicians and consumers was to artificially create demand for Celebrex at an artificially inflated price. Each aspect of Defendants' conduct combined to artificially create sales of Celebrex.

209. Defendants have unjustly benefited through the unlawful and/or wrongful collection of, *inter alia*, payments for Celebrex and continue to so benefit to the detriment and at the expense of Plaintiffs and members of the Class.

210. Accordingly, Plaintiffs and members of the Class seek full restitution of the Defendants' enrichment, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring Plaintiffs as representative of the Class and Plaintiff's counsel as counsel for the Class;

B. The conduct alleged herein be declared, adjudged and decreed to be unlawful;

C. Plaintiffs and the Class be granted an award of damages in such amount to be determined at trial, with trebled damages as provided by law;

D. Plaintiffs and the Class be granted an award of punitive damages in such amount to be determined at trial;

E. Defendants be enjoined from continuing the illegal activities alleged herein;

F. Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

G. Plaintiffs and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

VII. DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

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