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10  
11 IN THE SUPERIOR COURT OF THE STATE OF ARIZONA  
12 IN AND FOR THE COUNTY OF MARICOPA  
13

14 DOROTHY GREAVES, individually and  
15 as representative of a class of all others  
16 similarly situated,

17 Plaintiff,

18 v.

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

21 Defendants.

No.

**CLASS ACTION COMPLAINT**

22  
23  
24 Plaintiff, by and through counsel undersigned alleges upon personal knowledge as to  
25 herself and her own acts, and upon information and belief (based on the investigation of  
26 counsel) as to all other matters, as to which allegations she believes substantial evidentiary

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1 support will exist after reasonable opportunity for further investigation and discovery as  
2 follows:

3  
4 **I. NATURE OF THE ACTION**

5 1. Plaintiff brings this action on behalf of a Class of all persons (excluding those  
6 who assert personal injury claims) who while residents of the State of Arizona paid for or the  
7 drug Celebrex, manufactured by Defendants Pfizer Inc. (“Pfizer”), Pharmacia Corporation  
8 (“Pharmacia”), Monsanto Co. (“Monsanto”) and G.D. Searle & Co. (“Searle”).

9  
10 2. Defendants advertised and marketed Celebrex as providing safe and effective  
11 pain relief without the side-effects inherent to other, similar drugs. In conveying this  
12 marketing message, Defendants intentionally and uniformly hid from consumers that  
13 Celebrex affects the clotting mechanism of human blood and can cause serious  
14 cardiovascular problems including: heart attack, unstable angina, cardiac clotting, ischemic  
15 stroke and hypertension. Defendants also promoted Celebrex as more effective than less-  
16 expensive anti-inflammatory drugs, which is not the case.

17  
18 3. From 1999 through 2003, Defendants spent about \$400 million on direct-to-  
19 consumer advertising for Celebrex. The marketing paid off. In the nine months ending in  
20 September 2004, worldwide sales of Celebrex were \$2.29 billion, accounting for 6 percent of  
21 Pfizer’s total sales of \$37.59 billion.

22  
23 4. As a result of Defendants’ aggressive direct-to-consumer advertising demand  
24 for Celebrex exceeded what would have been the case had Defendants not engaged in a  
25 misleading marketing campaign. Further, as a result of Defendants’ unlawful conduct, the  
26



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1 price of Celebrex was artificially inflated beyond that it would have been had the truth been  
2 told. In this action Plaintiffs seeks to recover the difference in price between Celebrex  
3 selling at its inflated price and that of a comparable drug.  
4

## 5 **II. PARTIES**

6 5. Plaintiff Dorothy Greaves is a resident of Arizona. She purchased Celebrex in  
7 Arizona. Had she known the truth about Celebrex, she would not have purchased it and/or  
8 certainly not at the price she paid when it was substantially inflated. Plaintiff pursues this  
9 class action on behalf of herself and all others similarly situated.  
10

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

15 7. Defendant Monsanto, a subsidiary of Pharmacia, is a Delaware corporation  
16 with its principal place of business in Missouri. At all relevant times, Monsanto has been  
17 engaged in the business of developing, manufacturing, marketing and selling Celebrex  
18 nationwide and in Arizona.  
19

20 8. Defendant Pfizer is a Delaware corporation with its principal place of business  
21 in New York. In 2003, Pfizer acquired Pharamcia for nearly \$60 billion because of  
22 Celebrex. During the relevant time period, Pfizer has been engaged in the business of  
23 marketing and selling Celebrex nationwide and in Arizona.  
24  
25  
26

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1           9. Defendant Searle is a Delaware corporation with its principal place of business  
2 in Illinois. At all relevant times, Searle has been engaged in the business of marketing and  
3 selling Celebrex nationwide and in Arizona.  
4

5 **III. JURISDICTION AND VENUE**

6           10. This Court has subject-matter jurisdiction pursuant to A.R.S. § 12-123. This  
7 Court has personal jurisdiction over the parties because Plaintiff submits to the jurisdiction  
8 of the Court and Defendants systematically and continually conducted business in the  
9 County of Maricopa and the State of Arizona.  
10

11           11. Venue is proper in this Court pursuant to A.R.S. § 12-401 because Defendants  
12 conduct business in the County of Maricopa in the State of Arizona, including marketing,  
13 advertising, and sales directed to Arizona residents. Further, at all times mentioned in this  
14 Complaint, Defendant made misrepresentations and material omissions to residents of the  
15 County of Maricopa and the State of Arizona.  
16

17           12. Federal court subject-matter jurisdiction over this representative action does  
18 not exist. Complete diversity of citizenship between Plaintiff and Defendant does not exist.  
19 Under applicable federal law, damages, punitive damages, attorneys' fees and costs cannot  
20 be aggregated to meet the minimum jurisdictional amount for federal court subject-matter  
21 jurisdiction. Plaintiff asserts no federal question and/or violations of federal law.  
22  
23  
24  
25  
26



1 **IV. FACTUAL ALLEGATIONS**

2 **A. Development of Celebrex**

3  
4 13. Celebrex is one of the new entries in a class of pain medications called non-  
5 steroidal anti-inflammatory drugs (“NSAIDs”). Aspirin and ibuprofen are examples of well-  
6 known NSAIDs.

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

10  
11 15. In addition to transmitting pain sensations, COX-1 is involved in maintaining  
12 and repairing gastrointestinal tissue.

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

16  
17 17. It is generally accepted in the medical community that blocking the COX-1  
18 enzyme hampers the body’s ability to repair gastric tissue and causes harmful gastrointestinal  
19 side-effects, including stomach ulceration and bleeding.

20  
21 18. It is generally accepted in the medical community that blocking the COX-2  
22 enzyme encourages the formation of blood clots and causes various clot-related  
23 cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and  
24 hypertension.  
25  
26



1           19.    Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both  
2 COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs  
3 cause ulcers in the stomach and intestines. However, because of a complex chemical balance  
4 in the human body, traditional NSAIDs do not cause blood clots, but actually reduce the risk  
5 of clots and help to protect heart function.  
6

7           20.    For decades, in the absence of other treatment options, consumers seeking pain  
8 relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs.  
9

10          21.    Defendants set out to remedy this problem by developing “selective” inhibitors  
11 that would block only COX-2 production, thus (supposedly) allowing the proper  
12 maintenance of gastric tissue while still reducing pain sensations. In making this decision,  
13 Defendants either intentionally ignored or recklessly disregarded current medical knowledge  
14 that selective COX-2 inhibition lowers prostacyclin levels, causes blood clots and gives rise  
15 to various clot-related cardiovascular events, including: heart attack, stroke, unstable angina,  
16 cardiac clotting and hypertension.  
17

18          22.    Pharmacia and Monsanto completed Phase I, II and III trials for their selective  
19 COX-2 inhibitor, Celebrex, by 1998. During these trials, they learned that selectively  
20 inhibiting the COX-2 enzyme lowers prostacyclin levels, causes blood clots and gives rise to  
21 various clot-related cardiovascular events, including: heart attack, stroke, unstable angina,  
22 cardiac clotting and hypertension.  
23  
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1           **B.     The CLASS Study**

2           23.     Thus, Defendants knew by 1998 that selective COX-2 inhibitors posed serious  
3 cardiovascular risks for anyone who took them, and presented a specific additional threat to  
4 anyone with existing heart disease or cardiovascular risk factors.  
5

6           24.     Despite knowing that Celebrex posed serious cardiovascular risks for anyone  
7 who took them, Defendants made a business decision to push Celebrex to market on claimed  
8 improvements in gastrointestinal safety while downplaying their cardiovascular dangers.  
9

10          25.     In order to justify this position, Defendants funded a significant clinical trial to  
11 demonstrate that Celebrex had greater gastrointestinal safety than traditional NSAIDs: the  
12 Celecoxib Long-Term Arthritis Safety Study (“CLASS”).  
13

14          26.     The CLASS trial, paid for by Pfizer, Pharmacia, Monsanto and Searle, was a  
15 long-term, double-blind study of gastrointestinal toxicity in 8,059 patients taking Celebrex,  
16 ibuprofen or diclofenac to treat arthritis. Patients with heart problems were allowed to  
17 participate in the CLASS trial, and were permitted to take low doses of aspirin to reduce the  
18 risk that they would suffer an adverse cardiovascular event during the study.  
19

20          27.     Despite the fact that the CLASS studies secretly acknowledged the likelihood  
21 of cardiovascular events (as shown by the attention paid to whether participants would be  
22 permitted to take aspirin, a known cardio-protector, and the fact that the studies were both set  
23 up to record cardiovascular event data), Defendants intentionally diverted attention from  
24 Celebrex’s cardiovascular risks by providing the bare minimum of information on this issue:  
25 the CLASS trial did not publish any cardiovascular event data.  
26



1           28.    When the CLASS study was completed, the results were reported to the U.S.  
2 Food and Drug Administration’s Arthritis Drugs Advisory Committee (“the Committee”) as  
3 part of a request to exempt Celebrex from including a gastrointestinal safety warning in its  
4 package insert.  
5

6           29.    After reviewing the CLASS results, the Committee concluded that patients  
7 taking Celebrex had not experienced fewer gastrointestinal complications than those taking  
8 traditional NSAIDs. Without any proof of enhanced safety, the Committee recommended  
9 that the Celebrex package insert contain the same gastrointestinal warnings as traditional  
10 NSAIDs, and advised further studies to assess the risk of COX-2 inhibitors when taken with  
11 aspirin.  
12

13           30.    Since the CLASS study did not report any cardiovascular event data and the  
14 Celebrex Defendants were not seeking an exemption from any cardiovascular warning  
15 requirement (because traditional NSAIDs do not cause cardiovascular problems), the  
16 Committee did not consider the cardiovascular safety of Celebrex.  
17

18           31.    Defendants’ clinical studies did not have their intended effect: neither drug  
19 was permitted to claim increased gastrointestinal safety over traditional NSAIDs.  
20

21           32.    Defendants initiated extensive pre-release marketing campaigns to convey the  
22 uniform message that Celebrex provided effective pain relief without the gastrointestinal  
23 side-effects of traditional NSAIDs. Defendants intentionally omitted any mention of  
24 cardiovascular risks from their marketing and advertising statements to benefit from the  
25  
26



1 inference that Celebrex, as a pain reliever in the NSAID family, had a cardio-protective  
2 effect.

3  
4 33. Defendants also pushed ahead with their efforts to win approval from the U.S.  
5 Food and Drug Administration (“FDA”) to sell Celebrex in the United States.

6 34. Without having performed any significant tests on cardiovascular safety, the  
7 Celebrex Defendants filed a new drug approval application with the FDA in August 1998.  
8 After an expedited review that addressed the CLASS gastrointestinal safety results but did  
9 not touch on any cardiovascular safety issues, the FDA approved Celebrex for the relief of  
10 osteoarthritis and adult rheumatoid arthritis in December 1998. Celebrex was released for  
11 sale in the United States in February 1999.

12  
13 35. By this time, Defendants’ intensive marketing campaigns were already  
14 showing positive results. Sales projections for both Celebrex based on early orders and  
15 inquiries surpassed \$2 billion per year.

16  
17 36. Relying on these projections, Defendants made a “business decision” that their  
18 profits from the sale of Celebrex could easily finance the defense or settlement of any  
19 litigation related to Celebrex.

20  
21 37. The results of the CLASS study were published in the September 13, 2000,  
22 issue of JAMA. CLASS is what’s known as a Phase 4 postapproval study, which was  
23 required by the FDA. Before any drug is approved, manufacturers have to submit data to the  
24 FDA that demonstrate the drug’s safety and effectiveness.  
25  
26



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

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

23           40. Pharmacia, the manufacturer of Celebrex, presented a statistical argument to  
24 the FDA justifying its omission of the data from the second half of its study. The company  
25 claimed that since a higher percentage of people taking diclofenac dropped out of the study  
26



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1 because of minor symptoms like heartburn, the data from the second half of the study were  
2 invalid because of what is called “informed censoring.” The manufacturer argued that these  
3 dropouts would have gone on to develop serious gastrointestinal complications, and their  
4 dropping out of the study artificially minimized the risk of serious complications from taking  
5 diclofenac. The FDA flatly rejected this argument. It countered that there was no proof that  
6 the people with heartburn would have developed more serious gastrointestinal problems.  
7 Further, if minor symptoms caused people in the study to stop taking diclofenac, people in  
8 the real world would similarly stop taking the drug if it caused heartburn and would similarly  
9 protect themselves from going on to develop serious gastrointestinal complications.  
10  
11

12           41. The FDA’s opinion of the manufacturer’s decision to publish only half of the  
13 data from its study was clear: “the sponsor’s presentations of 6-month data ... are not  
14 statistically valid or supportable.” The FDA’s gastroenterology reviewer concluded that the  
15 first 6 months of data – which had been presented in the JAMA article as if they were a  
16 report of the entire study – were not worthy of separate consideration: “Based on the lack of  
17 adequate rationale, these post-hoc analyses will not be further discussed or presented in this  
18 review.” Looking at the data from the entire year of the study, the FDA’s gastroenterology  
19 reviewer concluded that “the sponsor has failed to demonstrate a statistically significant  
20 lower rate” of serious GI complications in the people who took Celebrex compared with the  
21 people who took the other NSAIDs. When the reviewer looked at only the second six  
22 months of data (*i.e.*, the data that had not been published in the JAMA article), he concluded  
23 that the risk of serious GI complications appeared to be higher in the people who took  
24  
25  
26



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1 Celebrex “compared to both ibuprofen and diclofenac” (FDA’s underscore). This was  
2 hardly an endorsement for a drug whose only advantage (besides the convenience of a once-  
3 daily dosing) was that it caused fewer serious GI problems.  
4

5 42. The disparity between the CLASS article published in JAMA and the  
6 information in the FDA’s files by no means stopped there. The primary question that the  
7 CLASS study had been designed to answer had been changed, producing results that were  
8 far more favorable to the manufacturer. The original research design submitted to the FDA  
9 by the manufacturer of Celebrex had stated: “The primary objective of this study is to  
10 compare the incidence of *clinically significant* [major] upper gastrointestinal events ... in  
11 patients taking Celebrex to patients taking NSAIDs.” The term “*clinically significant*”  
12 refers to complications that would generally require hospitalization: active bleeding,  
13 perforation of the stomach or duodenum requiring surgery, or obstruction of the outlet of the  
14 stomach. The research plan specifically called for the less serious gastrointestinal side  
15 effects to “be categorized and analyzed separately.” Indeed the FDA’s gastroenterology  
16 reviewer specifically commented that the plan to identify the “truly significant” serious  
17 gastrointestinal complications alone was a “major strength of the current study.”  
18  
19  
20

21 43. But when the results of the study were published in JAMA, the incidences of  
22 major and minor gastrointestinal complications were combined. Why the change? The  
23 results of the study as originally designed failed to show that the people who took Celebrex  
24 developed significantly fewer major gastrointestinal complications than the people who took  
25 ibuprofen or diclofenac, even for just the first six months. Only by combining the minor GI  
26



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1 symptoms with the more serious gastrointestinal complications could the article conclude  
2 that Celebrex caused a statistically significant decrease in gastrointestinal complications  
3 compared with the other NSAIDs. As noted above, when the FDA looked at the results of  
4 the CLASS study in terms of the research question that had *originally* been posed, Celebrex  
5 was not significantly safer than the other NSAIDs.  
6

7         44. Finally, the most important measure of safety is the overall frequency of  
8 serious side effects – including but not limited to gastrointestinal side effects. For the full 12  
9 months of the study, the people in the CLASS study who took Celebrex experienced 11  
10 percent more serious complications (in all body systems combined) than the people who took  
11 the older and less expensive anti-inflammatory drugs. This difference did not reach  
12 statistical significance but certainly is significant in countering Pharmacia’s claim that  
13 Celebrex is better than older NSAIDs because it’s safer.  
14  
15

16         45. These findings contributed to the FDA’s decision to send one of its rare  
17 Warning Letters to the CEO of Pharmacia in February 2001. The letter cites repeated  
18 unsubstantiated marketing claims that Celebrex is the preferred NSAID for people taking a  
19 blood thinner and that it is safe and effective for the treatment of acute pain – a use for which  
20 it is not approved – and points out that Pharmacia’s marketing material fails to warn of the  
21 possibility of serious GI complications caused by the drug. The Warning Letter concludes  
22 by saying:  
23  
24

25                 Your promotional activities described above raise significant  
26                 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,

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1 2000, we objected to your dissemination of promotional  
2 materials for Celebrex that ... contained unsubstantiated  
3 comparative claims, and lacked fair balance. Based upon your  
4 written assurances that this violative promotion of Celebrex had  
5 been stopped, we considered these matters closed. Despite our  
6 prior written notification, and notwithstanding your assurances,  
7 Pharmacia has continued to engage in false or misleading  
8 promotion of Celebrex.

9 46. Also included in the Warning Letter was the requirement that Pharmacia send  
10 out the "Dear Healthcare Provider" letter that had landed on my desk. Of course, the letter  
11 sent out by the manufacturer was not quite as specific as the FDA's Warning Letter. Few  
12 doctors, even if they had bothered to wade through the difficult language, had the time or  
13 inclination to find out the story behind the letter. As a result, *doctors continued to prescribe*  
14 *Celebrex for their patients based on the scientific evidence published in JAMA*. It was  
15 incomplete and presented an inaccurate picture of the so-called safety advantage of Celebrex  
16 over other less expensive NSAIDs.

### 17 C. Marketing and Promotion

18 47. Thus, rather than financing studies to quantify the cardiovascular risks posed  
19 by Celebrex, Defendants continued pouring money into advertising campaigns that  
20 uniformly emphasized the gastrointestinal safety of Celebrex while avoiding any mention  
21 of cardiovascular risks. Defendants pursued this strategy to benefit from the assumption  
22 that, in the absence of information to the contrary, Celebrex possessed the same cardio-  
23 protective properties as traditional NSAIDs.

24 48. Defendants' advertising expenditures quickly reached historic levels.  
25 Pharmacia and Monsanto spent more than \$78 million on consumer advertising for Celebrex  
26

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1 in the year 2000. Defendants spent more than \$400 million on direct-to-consumer  
2 advertising for Celebrex from 1999 to 2003.

3  
4 49. In addition, Defendants' sales forces have blitzed doctors' offices with  
5 literature and verbal presentations designed to convince both doctors and consumers that  
6 Celebrex was a superior drug for treatment of osteoarthritis, acute pain in adults, painful  
7 menstrual cycles and other types of disease. They have aggressively promoted Celebrex as  
8 an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower  
9 risk of side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote  
10 or provide any balanced presentation as to Celebrex as having an unacceptably high risk of  
11 other side effects, such as heart attack and stroke.  
12

13  
14 50. Such marketing efforts to physicians have become commonplace in recent  
15 years. Drugs, including Celebrex, that might once have been used primarily by specialists  
16 are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs'  
17 full research record. Drug companies, with Pfizer in the forefront, spent \$8 billion on such  
18 "detailing" to physicians – i.e., sales people dropping by to leave marketing materials and  
19 speaking to physicians about their companies' drugs – in the 12 months through October  
20 2004.  
21

22 51. Such large-scale marketing efforts have paid huge dividends to Defendants and  
23 other drug companies. The number of blockbuster drugs, defined as drugs with more that \$1  
24 billion in annual retail prescription sales, was only 15 in 1999 but grew to 34 in 2003.  
25  
26



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1           52.    As a result of Defendants’ uniformly misleading advertising campaigns,  
2           Celebrex was wildly successful. Celebrex became Pharmacia’s best selling drug with more  
3           than \$2.6 billion in sales for 2000 and \$3.1 billion in sales for 2001. After acquiring  
4           Pharmacia, Pfizer has continued to enjoy blockbuster sales of Celebrex, with \$2.3 billion in  
5           revenue through the first three quarters of 2004.  
6

7                           **D.    Examples of Misleading Materials Designed to Promote Celebrex as the**  
8                           **Life Saving Pain Reliever**

9           53.    Typical of misleading advertising is the recent “Guitar TV ad.” The Guitar TV  
10          ad in its entirety makes a representation about the indication and benefits of Celebrex for  
11          osteoarthritis or rheumatoid arthritis. A woman playing an acoustic guitar is featured. The  
12          visuals focus on her hands/fingers and playing ability (i.e., she finger-picks the strings with  
13          one hand while executing chord changes with the other hand). These images are  
14          accompanied by a voice-over “With Celebrex, I will play the long version.” Together, these  
15          images and claim suggest that because of using Celebrex, there is a direct benefit to this  
16          patient’s wrist/hand/finger joints related to movement and flexibility such that she can now  
17          play the long version of the song whereas she previously could not.  
18

19                   54.    This ad is just one of many designed to have consumers believe they can live  
20          better lives without Celebrex.  
21

22                   55.    Recently, the FDA issued a warning letter noting:  
23

24                           While the Guitar TV ad suggests a direct benefit to this patient’s  
25                           wrist/hand/finger joints related to movement and flexibility, it  
26                           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



1 and contraindications (including warnings and precautions) of  
2 Celebrex as required by 21 CFR 202.1(e)(1). Omission of this  
3 information implies that there are no risks to the patient who  
4 takes Celebrex, which overstates the drug's safety.

5 56. Similarly the FDA found another TV ad to be misleading.

6 *Announcer: "Celebrex presents, arthritis tips."*

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

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

16 The Arthritis Tips TV ad is a product-specific drug ad for  
17 Celebrex that is misleading because it omits important  
18 information about the drug's safety and effectiveness and makes  
19 unsubstantiated effectiveness claims. The ad promotes Celebrex  
20 by identifying the drug by name at the beginning and end of the  
21 ad. Moreover, stating that Celebrex is presenting/ bringing you  
22 arthritis tips clearly suggests that Celebrex is an arthritis  
23 treatment. The Arthritis Tips TV ad purports to quantify the  
24 disease burden of "arthritis" ("the most wide-spread crippling  
25 disability in the United States today ... the most predominant  
26 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.

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

6 Omission of Risk Information. The Arthritis Tips TV ad fails to  
7 disclose any risk information about Celebrex and thus omits the  
8 major side effects and contraindications (including warnings and  
9 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.

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

12 Unsubstantiated Superiority Claims

13 The print ad features the prominent headline “Strength They Can  
14 Stay With” and shows a chart comparing Celebrex, Ibuprofen  
15 and Naproxen, titled “6-Month Patient Persistency Rate.” Over  
16 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.”

17 The above referenced claims imply that Celebrex is more  
18 effective (i.e., stronger) than ibuprofen and naproxen for  
19 treatment of osteoarthritis or rheumatoid arthritis and that  
20 patients “stay with” or are more compliant with Celebrex therapy  
21 than the compared products. We are not aware of substantial  
22 evidence or substantial clinical experience to support these  
23 claims. The cited retrospective retail pharmacy database analyses  
24 by NDC Health, “Persistency Analysis: Celebrex, Vioxx, and  
25 All Other NSAIDs,” August 2002 and “Persistency Analysis:  
26 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

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1 of use. Therefore, the analyses do not constitute substantial  
2 evidence or substantial clinical experience demonstrating that  
3 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.

4 58. Since its introduction, defendants have issued promotional material designed to  
5 tie Celebrex to improving quality of life. It has distributed materials making numerous  
6 dramatic claims tied to the drug regarding quality of life, in terms of being able to do  
7 personal activist and work-related activities. The infomercial shows people returning to their  
8 work and activities. These patients go from not being able to work or do anything they want  
9 to do, to being able to work and do everything they want to do, pain-free. Patients talk about  
10 being able to “do anything,” “do as much as I want to do,” being “back to doing what I do,”  
11 and such. They talk about “enjoying life” again, how the drug improved their “quality of  
12 life,” and how the drug “gave them back their lives” (a theme repeated over and over in the  
13 ad and in the background music). One person states that “you can be free.” Another states  
14 that the medicine “brought new vitality in life.” Everyone portrayed has 100% efficacy in all  
15 of these outcomes.  
16  
17  
18

19 59. Such claims are misleading and purport to promote Celebrex as superior. In  
20 fact, as the FDA has recently noted, “none of the comparative studies with naproxen,  
21 ibuprofen, and diclofenac to-date has been designed to demonstrate superiority or a specified  
22 degree of similarity in a rigorous way.”  
23  
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1           **E.     Risks Posed by Celebrex**

2           60.     Despite the effectiveness of their advertising campaigns, Defendants uniform  
3 failure to disclose Celebrex's risk of cardiovascular injury did not quell concerns about  
4 selective COX-2 inhibitors in the medical community.  
5

6           61.     In 1997, the link between COX-2 inhibition, prostacyclin levels and blood  
7 clotting was receiving sporadic attention in medical journals.  
8

9           62.     In 1998, independent doctors established a link between selective COX-2  
10 inhibitors and increased blood clotting, and suggested that these drugs would cause an  
11 increase in clot-related cardiovascular events. These doctors suggested that these drugs  
12 should not be given to patients with known cardiovascular disease, and that patients taking  
13 these drugs would have to be monitored for cardiovascular complications.  
14

15           63.     In light of the blockbuster sales of Celebrex and the related increase in serious  
16 cardiovascular events among patients taking such drugs, the link between selective COX-2  
17 inhibition and cardiovascular problems received increased attention.  
18

19           64.     The cardiovascular safety of Celebrex was directly challenged for the first time  
20 in August 2001, when independent doctors from the Cleveland Clinic published a meta-  
21 analysis of the CLASS trial that concluded these drugs posed an increased risk of adverse  
22 cardiovascular events compared to naproxen, a traditional NSAID. These doctors,  
23 specifically concerned with the increased number of heart attacks experienced by patients  
24 taking selective COX-2 inhibitors, urged Defendants to conduct trials to assess the  
25 cardiovascular risks of Celebrex.  
26



1           65. Over the next eight months, many pre-eminent doctors and medical  
2 organizations continued to discuss the cardiovascular risk of Celebrex. The vast majority,  
3 regardless of whether they were on Defendants' payrolls, agreed that cardiovascular risk  
4 factors should be considered in deciding whether to prescribe Celebrex, and that well-  
5 designed, comprehensive studies were needed to assess the effects of selective COX-2  
6 inhibitors on human heart function.  
7

8           66. Despite the mounting evidence that Celebrex cause or exacerbate clot-related  
9 cardiovascular disorders, Defendants have continued to issue uniformly misleading  
10 advertisements and promotional materials that tout Celebrex as being safe and more  
11 effective than traditional NSAIDs for all patients without regard for cardiovascular risks.  
12

13           67. The FDA has issued repeated warnings identifying these marketing statements  
14 as deceptive and illegal.  
15

16           68. In October 1999, the FDA sent a warning letter to Searle identifying  
17 promotional materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act  
18 because they contained unsubstantiated comparative claims of superiority with regard to  
19 other NSAIDs, misrepresented the safety profile of Celebrex and lacked fair balance with  
20 respect to the risks of taking Celebrex.  
21

22           69. In April 2000, the FDA sent a warning letter to Searle identifying promotional  
23 materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act because they  
24 misrepresented the safety profile of Celebrex, contained unsubstantiated comparative claims  
25  
26



1 of superiority with regard to other NSAIDs, and failed to provide any risk information  
2 concerning the use of Celebrex.

3  
4 70. In November 2000, the FDA sent a warning letter to Searle identifying  
5 promotional materials for Celebrex that violated the Federal Food, Drug and Cosmetic Act  
6 because they suggested that Celebrex is more effective than has been demonstrated by  
7 substantial evidence.

8  
9 71. In February 2001, the FDA sent a warning letter to Pharmacia identifying  
10 promotional activities and materials for Celebrex that violated the Federal Food, Drug and  
11 Cosmetic Act because they minimize the contraindications and risks associated with  
12 Celebrex use and contained unsubstantiated comparative claims of superiority with regard to  
13 other NSAIDs.

14  
15 72. Despite knowing the cardiovascular risks associated with Celebrex, and having  
16 received numerous warnings from the FDA for downplaying risks associated with these  
17 drugs, Defendants sent “Dear Doctor” letters to thousands of physicians nationwide in  
18 August 2001 “strongly support[ing] the cardiovascular safety profile” of Celebrex.

19  
20 73. Despite knowing the cardiovascular risks associated with Celebrex and having  
21 received numerous warnings from the FDA for downplaying risks associated with these  
22 drugs, Defendants also sent “Dear Patient” letters from a prescription database of thousands  
23 of consumers in August 2001 that minimized the risk of “safety issues, specifically heart  
24 attacks and strokes” associated with Celebrex while emphasizing that these drugs were  
25  
26



1 “innovative, effective and safe” treatment options for osteoarthritis, without any mention of  
2 cardiovascular risks.

3  
4 **F. More Misleading Promotion and Advertising**

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

11  
12 75. Celebrex advertising and packaging materials uniformly omit to disclose the  
13 following material facts: that there is a relationship between COX-2 inhibition and blood  
14 clotting; that Celebrex poses a known risk of cardiovascular harm, not only to patients with  
15 heart disease and/or cardiovascular risk factors, but to all consumers; and that no clinical  
16 studies have been performed to test the safety of Celebrex for patients with cardiovascular  
17 risk factors.  
18

19  
20 76. Defendants’ advertising and packaging materials for Celebrex are uniformly  
21 fraudulent and misleading, because they fail to warn consumers that Celebrex poses known  
22 risks of blood clots, heart attack, stroke, unstable angina, cardiac clotting and hypertension  
23 for all people who ingest them; and cannot safely be ingested by patients with known heart  
24 disease or cardiovascular risk factors.  
25  
26



1           77. As an example, 1999 print advertisements ask: “What will you do on the day  
2 you discover Celebrex?” The advertisements then state: “Discover what millions have  
3 turned to for arthritis pain relief.” The advertisements claim that Celebrex was a “scientific  
4 breakthrough: the first product to target only the COX-2 enzyme.” They failed to explain,  
5 however, that Celebrex is more expensive than other NSAIDs and is no more effective than  
6 those drugs. Those advertisements also state: “Celebrex has been extensively studied in  
7 large clinical trials. The most common side effects were indigestion, diarrhea and abdominal  
8 pain. The percentage of patients who stopped taking Celebrex due to all side effects (7.1%)  
9 was similar to sugar pill (6.1%).” The advertisements did not provide any information about  
10 potential adverse effects on consumers’ hearts. Instead, at the end of a separate page in very  
11 small print, the advertisements state that the following adverse events, among others,  
12 occurred in 0.1-1.9% of patients regardless of causality: “**Cardiovascular:** Aggravated  
13 hypertension, angina pectoris, coronary artery disease, myocardial infarction.” The  
14 advertisements then state, again in very small print: “Other serious adverse reactions which  
15 occur rarely (<0.1%), regardless of causality: The following serious adverse events have  
16 occurred rarely in patients, taking CELEBREX. **Cardiovascular.** Syncope, congestive heart  
17 failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral  
18 gangrene, thrombophlebitis....”  
19  
20  
21  
22  
23

24           78. As another example, 2001 print advertisements state: “TRUSTED SAFETY –  
25 No dose-related increase in hypertension or peripheral edema.” Instead, at the end of a  
26 separate page in very small print, the advertisements state that the following adverse events,



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1 among others, occurred in 0.1-1.9% of patients regardless of causality: “*Cardiovascular:*  
2 Aggravated hypertension, angina pectoris, coronary artery disease, myocardial infarction.”  
3  
4 The advertisements then state, again in very small print: “Other serious adverse reactions  
5 which occur rarely (<0.1%), regardless of causality: The following serious adverse events  
6 have occurred rarely in patients, taking CELEBREX. Cases reported only in the post-  
7 marketing experience are indicated in italics. *Cardiovascular.* Syncope, congestive heart  
8 failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral  
9 gangrene, thrombophlebitis, *vasculitis....*”  
10

11 79. Defendants again failed to inform consumers of the risks of heart problems in  
12 print advertisements for the year 2003. For example, one such advertisement shows a father  
13 and son, and states: “Lasting strength. Lasting relationships.” The advertisement does not  
14 reveal any risk of heart problems, although it refers to other potential risks. In very small  
15 print on a separate page, however, the advertisement sets forth the same cardiovascular risks  
16 that the 2001 advertisements set forth.  
17

## 18 19 **V. CLASS ALLEGATIONS**

20  
21 80. Plaintiff brings this action on behalf of herself and a class defined as follows:  
22 All persons or entities in Arizona who purchased Celebrex in the four (4) years preceding the  
23 filing of this Complaint up to and including the present.  
24  
25  
26



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1           81.    The Class consists of millions of individuals and entities throughout Arizona,  
2 making individual joinder impractical. The disposition of the claims of the Class members in a  
3 single class action will provide substantial benefits to all parties and to the Court.  
4

5           82.    The claims of the representative Plaintiff are typical of the claims of the Class  
6 because she, like all Class members, has purchased Celebrex and has been harmed by  
7 Defendants' misconduct because she would not have purchased Celebrex had she known the  
8 truth.  
9

10          83.    The factual and legal bases of Defendants' misconduct are common to all Class  
11 members and represent a common thread of deception and other misconduct resulting in injury  
12 to the representative Plaintiff and all members of the Class.  
13

14          84.    There are many questions of law and fact common to the representative Plaintiff  
15 and the Class, and those questions substantially predominate over any questions that may  
16 affect individual Class members. Common questions include, but are not limited to, the  
17 following:  
18

- 19               (a)    Whether Defendants' active concealment of and/or failure to disclose the  
20 true nature of Celebrex had the capacity to mislead or deceive within the  
21 meaning of the CFA;  
22               (b)    Whether Defendants' active concealment of and/or failure to disclose the  
23 true nature of Celebrex is unlawful within the meaning of the CFA;  
24  
25  
26



- 1 (c) Whether Defendants’ knowingly and with intent to sell represented that  
2 Celebrex has characteristics, uses, benefits, or qualities that it does not  
3 have and advertised it with intent not to sell it as advertised;  
4  
5 (d) Whether Defendants should be declared financially responsible for  
6 notifying all Class members of the true nature of Celebrex; and  
7  
8 (e) Whether Defendants should be ordered to disgorge, for the benefit of the  
9 Class, all or part of its ill-gotten profits received from the sale of  
10 Celebrex, and/or to make restitution and pay damages to Plaintiff and the  
11 members of the Class.

12 85. Plaintiff will fairly and adequately represent and protect the interests of the  
13 Class. Plaintiff has retained counsel with substantial experience in prosecuting consumer  
14 class actions, including actions involving pharmaceutical sales. Plaintiff and her counsel  
15 are committed to vigorously prosecuting this action on behalf of the Class, and have the  
16 financial resources to do so. Neither Plaintiff nor her counsel has any interests adverse to  
17 those of the Class.  
18

19 86. Plaintiff and the members of the Class suffered, and will continue to suffer,  
20 harm as a result of Defendants’ unlawful and wrongful conduct. A class action is superior to  
21 other available methods for the fair and efficient adjudication of the controversy. Absent a  
22 class action, most members of the Class likely would find the cost of litigating their claims to  
23 be prohibitive, and will have no effective remedy at law. Because of the relatively small size  
24 of each individual Class member’s claims, few Class members likely could afford to seek legal  
25  
26



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1 redress for Defendants' misconduct. Absent a class action, Class members will continue to  
2 suffer harm and Defendants' misconduct will proceed without remedy. The class treatment of  
3 common questions of law and fact is also superior to multiple individual actions or piecemeal  
4 litigation in that it conserves the resources of the courts and the litigants, and promotes  
5 consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to  
6 act on grounds generally applicable to the representative Plaintiff and the Class and require  
7 Court imposition of relief as to the Class as a whole.  
8  
9

10 **FIRST CAUSE OF ACTION**  
11 **Violations of Arizona Consumer Fraud Act**  
12 **(A.R.S. § 44-1522)**

13 87. The preceding paragraphs of this Complaint are realleged and incorporated by  
14 reference as if fully set forth herein. Plaintiff asserts this claim on behalf of herself and the  
15 members of the Class.  
16

17 88. Defendants' actions, as complained of herein, constitute unfair, and deceptive  
18 unlawful practices committed in violation of the Arizona Consumer Fraud Act, A.R.S. § 44-  
19 1522.  
20

21 89. For example, Defendants violated the CFA by engaging in the following  
22 conduct:

23 (a) Defendants' promotions of Celebrex as a safe drug for the treatment of  
24 pain and as having fewer side effects than comparable drugs on the market were deceptive,  
25 unfair, and unlawful in that Celebrex actually had an unacceptably high risk of adverse  
26



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1 cardiovascular events and/or was not significantly superior to less expensive pain relievers  
2 and was promoted solely for financial reasons and not due to any material increase in  
3 medical safety or efficacy;  
4

5 (b) Defendants' conduct was unfair, unlawful and deceptive in that  
6 Defendant knew Celebrex increased the risk of adverse cardiovascular events, such as heart  
7 attack and stroke, but omitted to disclose these facts to doctors and patients until January  
8 2005, and failed to disclose studies and facts indicating that it was not superior to less  
9 expensive pain relievers;  
10

11 (c) Defendants omitted material information known to them in order to  
12 induce doctors to prescribe Celebrex and consumers to purchase Celebrex at a price that  
13 exceeded its actual worth; and  
14

15 (d) Defendants committed unlawful acts by promoting and advertising  
16 Celebrex in a manner that violated the Federal Food, Drug and Cosmetic Act. *See* 21  
17 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n) and 355(a).  
18

19 90. All of the conduct alleged herein occurred in the course of Defendants'  
20 business. Defendants' wrongful conduct was part of a pattern or generalized course of  
21 conduct repeated on thousands of occasions daily.

22 91. Plaintiff and the Class have all been directly and proximately injured as the  
23 result of Defendants' wrongful conduct.  
24  
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