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SAN JOSE

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

CV13- 0414 PSG

LAURA A. PLUMLEE, an individual, on behalf of herself and all other persons similarly situated, Plaintiff, vs. PFIZER, INC., a New York Corporation, Defendant.	Case No. _____ COMPLAINT CLASS ACTION DEMAND FOR JURY TRIAL

This matter arises out of Defendant Pfizer, Inc.'s ("Pfizer") deceptive and unlawful marketing of the "blockbuster" antidepressant Zoloft (generically known as sertraline). Since Zoloft first entered the antidepressant market in 1991, Pfizer has engaged in a calculated campaign to mislead consumers and prescribing healthcare professionals about Zoloft's ability to treat depression. Pfizer knew that Zoloft's efficacy in treating depression was, at best, marginal and, at worst, nonexistent. However, in an

effort to turn a profit, Pfizer deliberately withheld material information from consumers and prescribing healthcare professionals and orchestrated a massive marketing campaign designed to convince consumers and prescribing healthcare professionals, in the face of the vast majority of clinical trial data to the contrary, that Zoloft was an effective and safe treatment for depression. This class action, brought on behalf of consumers nationwide and in California, seeks to enjoin Pfizer's continued unlawful conduct and recover damages for the millions of consumers who were tricked into purchasing a side-effect-ridden drug that was, at best, marginally better than a sugar pill in treating depression.

For her Complaint, Plaintiff Laura A. Plumlee ("Plaintiff"), alleges as follows:

NATURE OF ACTION

1. The vast majority of clinical trials designed to test Zoloft's efficacy have shown that Zoloft is no better than a sugar pill (placebo) at treating depression. The trials show that any perceived benefit consumers receive from taking Zoloft in treating their depression is primarily explained by the placebo effect—the perceived efficacy of a drug based upon one's belief that the drug works.

2. Long before Zoloft was put to market, Pfizer recognized it had an efficacy problem. Early clinical trials indicated Zoloft lacked efficacy and, under federal law, unless two clinical trials demonstrate a drug's efficacy, the Food and Drug Administration ("FDA") will not approve the drug. Knowing it only needed two positive trials, Pfizer organized several efficacy trials that, based on previous trial results, were carefully designed to show that Zoloft could beat a sugar pill in treating depression. However, despite Pfizer's best efforts, four of the six trials that were ultimately submitted to the FDA showed that Zoloft was no more effective than placebo and only two showed that Zoloft had some statistically significant effect. Additionally, even the two "successful" trials, which were marred by design flaws and sampling-bias, showed that Zoloft's effect on depression over placebo was very limited.

3. Pfizer submitted these two "successful studies" to the FDA, seeking approval for Zoloft in the treatment of depression. The FDA, however, found it difficult

to find efficacy in the face of so many clinical trials showing no efficacy. The FDA was also concerned that the observed benefit of Zoloft over placebo was marginal. After wrestling with the issues, the FDA ultimately concluded that the two trials were sufficient to meet the lax FDA efficacy requirements. Accordingly, Zoloft was approved for the treatment of depression.

4. Thereafter, Pfizer concocted a comprehensive and aggressive scheme to mislead consumers and prescribing healthcare professionals about Zoloft's efficacy. The scheme started with Zoloft's drug label[1], which was and continues to be directed at every consumer and prescribing healthcare professional in the United States. Knowing that consumers and prescribing healthcare professionals rely heavily on the risk and efficacy disclosures in the drug label, Pfizer artfully omitted material information that contradicted the "efficacy" message. Zoloft's drug label, as it existed in 1991 and until the present, does not mention or discuss the numerous clinical trials in which Zoloft was shown to be no more effective in treating depression than placebo. Moreover, the drug label fails to disclose that the two clinical trials that supposedly demonstrate Zoloft's efficacy only showed a marginal or slight effect on treating depression. Instead, Pfizer concocted a description which, through the artful omission of material facts, conveys the impression that Zoloft is very effective for treating depression. Because the drug label contains material omissions of fact, Pfizer prevented consumers and prescribing healthcare professionals from having enough information to make an informed decision about whether to purchase or prescribe Zoloft.

5. Supplementing the misleading drug label, Pfizer also engaged in a larger scheme to mislead consumers and prescribing healthcare professionals about Zoloft's efficacy. Specifically, as discussed at length in this Complaint, Pfizer:

a. Selectively published clinical efficacy data by actively suppressing negative data and promoting only "good" data;

[1] Throughout this Complaint, the term "drug label" refers to the product insert and various labels that are required by federal law to accompany a prescription medication.

b. Paid well-respected medical professionals to put their names on articles authored by Pfizer to tout specific efficacy messages, all while concealing Pfizer's involvement in the publication;

c. Paid key opinion leaders to tout Zoloft's efficacy;

d. Spent hundreds of millions on direct-to-consumer advertising and physician-targeted "training" and sale-aids, designed to convince consumers and prescribing healthcare professionals that Zoloft was very effective at treating depression.

6. Pfizer knew that disclosing Zoloft's true efficacy to consumers and prescribing healthcare professionals would have drastically reduced the drug's revenue potential. So, instead of being honest and straightforward with consumers and prescribing healthcare professionals and allowing them to decide, for themselves, if Zoloft was worth the risk, Pfizer hid the efficacy data and mislead consumers and prescribing healthcare professionals. The deception worked. Since 1991, Pfizer has sold over $30 billion in Zoloft to consumers within the United States.

7. Plaintiff Laura A. Plumlee ("Plaintiff"), like many Zoloft consumers within the United States and the State of California, purchased and ingested Zoloft for the treatment of depression. She believed, relying on Zoloft's drug label and Pfizer's extensive marketing and promotion, that Zoloft would help her manage the symptoms related to her life-long struggle with depression. Over the course of three years, however, Zoloft was not effective at treating her depression, even after increasing her dosage from fifty (50) mg to two-hundred (200) mg per day. Plaintiff, like many consumers within the United States and in California, was misled into purchasing an expensive and side-effect-ridden antidepressant that, according to most clinical studies, was no better than a sugar pill in treating depression.

8. Plaintiff brings this Complaint in two capacities. First, Plaintiff brings this Complaint on behalf of herself and all consumers within the United States, seeking a declaratory judgment that Zoloft's drug label is misleading and that Pfizer's conduct was

intentional, and an order enjoining Pfizer from continuing to unlawfully market Zoloft with its misleading drug label. Second, Plaintiff brings this Complaint on behalf of herself and all consumers within the State of California, seeking a refund of monies that were used to purchase Zoloft.

PARTIES

9. Plaintiff Laura A. Plumlee is, and was at all material times herein, a citizen, resident, and domicile of the State of California, County of Santa Cruz.

10. Defendant Pfizer Inc. is, and was at all material times herein, a New York corporation with its headquarters in New York, New York. Pfizer is, and was at all material times herein, a pharmaceutical company involved in the research, development, testing, manufacture, production, distribution, marketing, and sale of numerous pharmaceutical products, including Zoloft (generically known as sertraline). Pfizer regularly conducts business, including the sale and marketing of Zoloft, within the State of California and the United States of America.

JURISDICTION AND VENUE

11. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(d). Members of the proposed nationwide class are citizens of different States than Pfizer. Furthermore, the aggregate amount in controversy exceeds $5,000,000.

12. This Court has personal jurisdiction over Pfizer because Pfizer has purposefully directed its marketing and sales of numerous pharmaceutical products to the State of California. Pfizer has had substantial contacts with the State of California such that maintenance of the action is consistent with traditional notions of fair play and substantial justice

13. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(b). A substantial portion of the events giving rise to the claims alleged in this Complaint took place within the Northern District for the District of California, specifically within the San Jose Division's jurisdiction.

FACTUAL BACKGROUND

14. The market for antidepressants is large and competitive. Since the emergence of "blockbuster" antidepressants in the1980's, a multi-billion dollar industry has taken hold in the United States and Europe. The antidepressant industry generates revenue in excess of $11 billion each year and the market continues to grow annually. There are dozens of brand name and generic drugs approved by the Food and Drug Administration ("FDA") for the treatment of depression. Due to the availability of so many different antidepressants, prescribing physicians and consumers typically "shop around" when trying to find the right drug. Thus, in order to remain competitive in the antidepressant market, pharmaceutical companies spend hundreds of millions of dollars each year promoting directly to consumers and the medical community. The number of drug commercials on television today speaks to the competitive nature of the industry.

15. Pfizer is one of the largest pharmaceutical companies in the world with annual revenues exceeding $65 billion. Pfizer is a leader in the antidepressant industry and has enjoyed considerable financial success from the manufacture and sale of Zoloft.

16. Zoloft (generically known as sertraline) is a selective serotonin reuptake inhibitor ("SSRI") in the same class of drugs as Prozac (generically known as fluoxetine) and Paxil (generically known as paroxetine). It has been theorized that reduced levels of serotonin in the brain are the primary physiological cause of depression and, through use of an SSRI such as Zoloft, one could "balance the brain's chemistry" and increase otherwise deficient serotonin levels. Although scientists have never found evidence to prove the "balancing brain chemistry" theory, Pfizer has successfully used the theory to promote the use of Zoloft.

17. The process of gaining FDA approval for a new drug involves several steps. First, the company must conduct laboratory testing in animals to determine whether the drug will be safe and, to some extent, effective. If animal testing indicates that the drug or compound is relatively safe, the company then submits an investigational new drug ("IND") application to the FDA to gain approval to test the product with human

subjects. These tests are called clinical trials and are carried out sequentially in three phases—Phase I, II, and III studies. Each phase increases the number of subjects and are designed to test for safety and efficacy of the drug for specific indications and patient populations. After the clinical trials are completed, the company then compiles the data and analysis in a new drug application ("NDA"). FDA reviews the NDA with three major concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's strength, quality, and identity. Although the FDA evaluates the NDA to determine whether the drug will be salable to the public, the company manufacturing the drug always bears the responsibility of ensuring that the drug is manufactured, promoted, and labeled correctly.[2]

18. The history of Zoloft dates back to the early 1970s. A scientist at Pfizer named Reinhard Sarges discovered a new series of psychoactive compounds based on the structures of thiothixene, neuroleptics and chlorprothixene. This eventually led him to the development of tametraline, a weak dopamine reuptake inhibitor. The initial research into tametraline was halted after scientists noticed unwanted stimulant effects in animals. However, in 1977, two other Pfizer researchers, Kenneth Koe and Willard Welch, began working with some untested tametraline compounds, which produced a serotonin reuptake inhibitor. After the new drug was tested on animals, the chemical compound was named sertraline by Pfizer.

19. In the 1980's, sertraline underwent human clinical trials for the treatment of depression, and in 1991 the FDA approved sertraline for the treatment of major depressive disorder ("MDD"). It was released by Pfizer under the brand name Zoloft in 1991. In later years, Zoloft gained approval for the treatment of other indications

[2] *See Wyeth v. Levine*, 555 U.S. 555, 570 (2009) (holding that, regardless of any FDA approval, pharmaceutical manufactures bear sole responsibility for the sufficiency of a drug label).

including obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder.

20. Commercially, Zoloft has been an enormous success. It is estimated that, since Zoloft's launch in 1991, Zoloft sales have generated over $30 billion in revenue for Pfizer. Prior to Zoloft's patent expiration in 2007, which resulted in a proliferation of less expensive generic versions of the drug, Zoloft's annual sales were over $3 billion annually. Since 2007, however, Zoloft has sold approximately $500 million each year. Currently, over 20 million prescriptions of Zoloft and generic sertraline are filled annually.

Pfizer Knew Zoloft Lacked Efficacy in Treating Depression

21. Despite the general success of Zoloft over the last twenty years, numerous clinical trials and studies have demonstrated time and time again that Zoloft is no better than a sugar pill in treating depression.

22. The primary "benefit" some consumers perceive they get from taking Zoloft is from the placebo effect. The placebo effect is the effect that a drug has on a patient that has nothing to do with the drug, but is simply caused by the patient's *belief* that it works. During clinical trials, researchers must "control" for this effect by dividing a clinical trial population into a treatment group, who receive the drug, and a control group, who receive a sugar pill (placebo). Neither group knows whether the "drug" they receive is placebo or real. Thus, researchers can see if the effect created in the treatment group is significantly different than the control group. If both groups receive essentially the same benefit, then the drug at issue is no more effective than a sugar pill, and any observed benefit is simply a product of the placebo effect.

23. Because Zoloft is an antidepressant, the question of efficacy is particularly susceptible to the placebo effect. Unlike other ailments, where objective measurements are obtainable through blood and tissue samples, there is no physiological test for determining whether a given antidepressant is working on a patient. Rather, researchers must rely exclusively on the subjective articulations of the patient concerning their

depression. Thus, the potential for the placebo effect to drive the actual effectiveness of an antidepressant is very high. For example, in an analysis of efficacy data submitted to the FDA between 1987 and 1999 for six of the most popular SSRI antidepressants, 75 to 80% of the response to medication was duplicated in placebo groups. Irving Kirsch et al., *The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration*, 5 PREVENTION & TREATMENT 23, 1-11 (2002). In another study evaluating the "relative benefit of medication vs. placebo across a wide range of initial symptom severity in patients diagnosed with depression[,]" the authors concluded that the "magnitude of benefit of antidepressant medication compared with placebo . . . may be minimal or non-existent, on average in patients with mild or moderate symptoms." Jay C. Fournier et al., *Antidepressant Drug Effect and Depression Severity: A Patient-Level Meta-analysis*, 303 J. AM. MED. ASSOC. 47-53, 47 (2010); *see also* Irving Kirsch et al., *Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, 5 PLOS MEDICINE 2 (Feb. 2008) (same findings). In fact, an analysis conducted by the FDA in 2006 of adult antidepressant clinical trial data showed that, while five out of every ten patients appear to respond to the drugs, in the same trials, four out of every ten patients respond to placebo. *See* Thomas P. Laughren, Dept. of Health and Human Services, *Memorandum: Overview for December 13 Meeting of Psychopharmacologic Drugs Advisory Committee* (Nov. 16, 2006), *available at* http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4272b1-01-FDA.pdf .

24. Pfizer has known, since long before Zoloft was ever approved by the FDA, that Zoloft had an efficacy problem. In a March 8, 1984 memorandum[3], a Pfizer employee, discussing a Zoloft efficacy report that needed to be submitted to the FDA, stated that the data "are not in favor of sertraline as the placebo group has the most

[3] All internal Pfizer documents referenced herein were produced in prior litigation and were either unsealed by court order or Pfizer agreed to retract its confidentiality designation.

beneficial response in all of these instances. As for the HAM-D [a depression rating scale used in clinical trials to measure changes in depression] . . . placebo still seems to be the most effective group in this subset of patients[.]"

25. Most of the early Zoloft efficacy studies proved to be negative, failed, or were neutral. In the majority of the efficacy studies, there was no clinically or statistically significant difference between Zoloft and placebo in relieving depression. In some studies, placebo actually outperformed Zoloft in treating depression. In other studies, Zoloft was shown to be less effective at treating depression than non-drug therapies such as St. Johns Wort or daily exercise.

26. It was because of Zoloft's lack of efficacy that Pfizer had substantial difficulty in gaining approval from European regulators. In an April 18, 1991 memorandum, a Pfizer employee expressed "serious concerns regarding the approval of sertraline in key European countries." According to another memorandum dated April 11, 1991, Pfizer "received an unfavorable review in a number of countries. The common key issue is that regulators are not convinced of sertraline's efficacy versus placebo." Pfizer recognized that an "analyses of [placebo controlled U.S. studies] strongly indicate that they are not highly convincing of sertraline efficacy versus placebo and will not provide the strong database required to overcome regulatory obstacles." Pfizer, therefore, decided to create a "strongly positive, placebo controlled study . . . to ensure regulatory success." This was to be accomplished by designing a study "to enhance the probability of success drawing on the knowledge gained from past trials[.]"

27. In the United Kingdom ("UK"), Pfizer improperly sought help in obtaining approval of sertraline (known as "Lustral") in the UK from a consultant to the regulators reviewing Zoloft, Dr. Stuart Montgomery. According to an April 24, 1989 memorandum, Dr. Montgomery told Pfizer he would remain a "disinterested party" at the U.K. Regulatory Agency until Pfizer appealed any negative decision and, thereafter, "he would be happy to act as an advisor to Pfizer and declare an interest." In addition, according to a memorandum dated April 26, 1989, Dr. Montgomery provided Pfizer with

inside information that the UK regulators' decision on Zoloft was "borderline" at that time and that the company "should be wary of providing them with efficacy data against placebo[.]"

28. Pfizer submitted its new drug application ("NDA") to the FDA in 1990. As part of the application, six placebo controlled trials were presented to the FDA. Of the six clinical trials, four showed that Zoloft was no more effective than placebo in treating depression and two indicated that Zoloft had slight positive impact on depression.

29. The two studies that showed that Zoloft was more effective than placebo in treating depression, however, were severely flawed.

30. In the first trial that supposedly demonstrated efficacy, researchers enrolled 369 patients in a double-blind trial to test the efficacy of Zoloft at 50mg, 100mg, and 200mg against placebo. Within the treatment groups, *i.e.*, those taking Zoloft and not placebo, about 50% of the patients quit before the trial was completed—22% because of side-effects, 18% because it was not effective, and 10% for unexplained reasons. This large drop-out rate reduced the available patient population to 191. Of the remaining 50%, *i.e.*, the population that did not quit Zoloft, the trial tracked patient changes in depression based on the Hamilton Rating Scale for Depression ("HAM-D") over the course of six weeks. The HAM-D scale is a multiple item questionnaire used to measure a person's perception of depression. It is usually composed of 17-29 questions where the patient rates specific areas on a 0-5 point scale. A person's HAM-D scale rating can be anywhere between 0-70 depending on the scale used. The trial revealed that there was only a slight improvement in those taking Zoloft than those taking placebo. During the first four weeks of treatment, the study did not show any statistically significant difference on the patient's HAM-D scale between those taking Zoloft and those taking a placebo. Then, during weeks 5 and 6, the data showed that there was a slight statistically significant difference for the 50mg treatment group, although there was no significance in the 100mg or 200mg groups. The study showed that, on average, a person taking Zoloft

had a HAM-D scale improvement of about 2.3 points above those taking placebo after six weeks, which, depending on the scale being used, means that Zoloft, with its many documented adverse side effects[4], appeared to be better than placebo by 1-5% after six weeks. This is an extremely small treatment effect and it was not associated with dosage.

31. In the second trial that supposedly demonstrated efficacy, researchers enrolled 448 patients in a double-blind trial and divided the patients into three groups—patients taking Zoloft at doses between 50-200mg, patients taking a different anti-depressant, and patients taking placebo. Much like the first "efficacy-establishing" clinical study, approximately 43% of people in the Zoloft treatment groups quit, 18% because of side effects, 9% because of a lack of efficacy, and 16% for other reasons. Of the remaining patients, the researchers tracked HAM-D scale changes over eight weeks. The trial's data indicated that there was no clinically significant difference between Zoloft for the first six weeks of treatment, and that in weeks 7 and 8, a person taking Zoloft had a HAM-D scale improvement of about 3.5 points above those taking placebo. This was, again, a very small treatment effect, especially when one considers the serious potential side-effects attendant to Zoloft.

32. On November 19, 1990, the Psychopharmacological Drugs Advisory Committee for the FDA convened to discuss Pfizer's Zoloft NDA. The focus of the meeting was to discuss Zoloft's efficacy and safety. However, prior to the meeting, according to an internal Pfizer document dated September 5, 1990, Dr. Paul Leber, Director of the FDA's Division of Neuropharmacological Drug Products, informed Pfizer

[4] Potential side-effects of Zoloft include: Nausea, insomnia, diarrhea, dizziness, dry mouth, fatigue, drowsiness, indigestion, loss of appetite, decreased sex drive (libido), increased sweating, burning or tingling sensation (paresthesias), headache (migraines), weight loss, abdominal pain, constipation, vision changes, hot flashes, nervousness, fever, hyperactivity, urinary incontinence, aggressiveness, sinus infection or inflammation, red or purple discolorations on the skin (purpura), suicidal thoughts or behavior, anxiety, panic attacks, chest palpitations, allergic reactions, impotence, glaucoma, high blood pressure (hypertension), hair loss, acne, weight gain, diverticulitis, muscle pain, menstrual problems, seizures, and ringing in the ears (tinnitus).

that the he would be "solicit[ing] the support of the Advisory Committee that the two key pivotal depression studies are adequate and well controlled." He pointed out problems with the studies Pfizer had submitted to prove Zoloft's efficacy and safety, but assured Pfizer that he thought he could convince the Committee that the studies were sufficient to recommend approval.

33. During the meeting, the committee members discussed the relatively small treatment effect of Zoloft on depression in the only two studies showing efficacy. One committee member explained:

> [W]e have been provided with mean change scores from baselines and the outcome of statistical analyses for the difference in mean change scores between drug and placebo. However, it is difficult to determine the clinical significance of the statistically significant differences in mean change scores, particularly when you are looking at differences in change of only 2 or 3 points on the HAM-D total score . . . which is not a tremendous difference.

Transcript of Psychopharmacological Drugs Advisory Committee Meeting at 48 (Nov. 19, 1990).

34. In addition, the committee members were very concerned with whether two studies, in the context of several others to the contrary, was sufficient to establish that Zoloft was effective for the treatment of depression. As one committee member stated:

> Can I toss a few statistical issues as the statistician here? In a sense, what we have is not just an effect size problem but, in a sense, what we are trying to wrestle with is sort of an intuitive multiple comparison problem. If all we had was the two out-patient studies and they fairly clearly showed some Sertraline effect, we would have what I interpret as the criteria necessary for us to say go ahead and approve the drug. That is, we have more than one well-documented study that demonstrates an effect.
>
> So the question is how do we interpret these two positive results in the context of several more studies that fail to demonstrate that effect? I am not sure I have an answer to that but I am not sure that the law requires me to have an answer to that – fortunately or unfortunately. That would mean, in a sense, that [Pfizer] could just do studies until the cows some home until he gets two of them that are actually statistically significant by chance alone, walks them out and says that he has met the criteria.

Id. at 90-91.

35. Recognizing that the Committee was expressing considerable criticism of Zoloft's efficacy, Dr. Leber, the FDA Director who had previously pledged to help get Zoloft approved, told the Committee that:

> I think it should be understood that all comparisons are probably odious. We do not have a comparative efficacy/safety drug law, although, clearly, clinicians using drugs are interested in determining relative efficacy, relative safety and relative utility - - whatever that means. I think you have to understand that when we face an application from a regulatory perspective, we are asked to face what the law requires us to do. We are obligated to approve an NDA unless our review finds that the drug is unsafe for use; that inadequate testing has been done to show that the drugs is safe. We are required to approve the drug unless we find that the tests submitted failed to contain substantial evidence of efficacy. That means more than one investigation which adequate and well controlled which would allow experts - - experts by experience, training and background - - to reach a conclusion that the drug is effective. And we are obliged to approve the drug unless we find that the labeling is false or misleading in some particular. . .
>
> So if we can come back to the regulatory flavor of the questions, I think it would be useful.

Id. at 66-67.

36. Dr. Leber further stated that "[w]e are always in a position of trying to make a fair judgment, knowing that we have to weigh the requirements of the law, the expectations of a public that wants freer access to new and effective drugs, even if they are not necessarily as potent on a milligram basis or even in terms of the size of the treatment effect as others." *Id.* at 98. He then explained that "[w]e take the data base as we have it . . . At the end of that, we have to go back to the regulatory charge that I raised. It is not that they are entitled to every claim, every superlative ever made, but is the application, as submitted, such that we have a right to conclude it does not have evidence of safety for use; it does not have evidence of efficacy or it is inadequately labeled ... If we cannot reach those conclusions, you have to approve the application[.]" *Id.* at 98-99. According to Dr. Leber, he had "no idea what constitutes proof of efficacy, except on the basis of what we, as a Committee, agree on an as *ad hoc* case as there needs to be. You can be guided by the past but the inference is an abstraction – what is an antidepressant?" *Id.* at 69.

37. Pfizer itself found it odd that the FDA did not question Pfizer about efficacy despite the fact that several European regulators were troubled by the drug's lack of efficacy. According to a February 25, 1991 internal Pfizer email between two of its employees: "There were no questions on efficacy . . . I find it odd that FDA not at all questioning efficacy and there are significant questions raised by several European companies."

38. In the end, Dr. Leber's machinations worked. The advisory committee members voted 6-3 that Pfizer had "provided evidence from more than one adequate and well-controlled clinical investigation that supports the conclusion that sertraline is effective for the treatment of depression?"

39. In an August 1991 FDA memorandum obtained through the Freedom of Information Act, Dr. Leber wrote about his recommendation that Zoloft be approved for marketing, stating that, "[i]n recommending this action, I have considered the fact that the evidence marshaled to support sertraline's efficacy as an antidepressant is not as consistent or robust as one might prefer it to be."

40. In another FDA memorandum, in December 1991, Dr. Leber acknowledged that other foreign regulatory agencies were not willing to allow Zoloft marketing in their countries due to Pfizer's inability to prove efficacy. Dr. Leber went on to state, "I do not believe we can successfully introduce similar, more demanding requirements domestically, at least until there is significant 'sea change' in our society's collective attitude towards Federal regulation of new drug approvals." Dr. Leber warned that the FDA's approval of Zoloft was likely to be challenged because the FDA is not "as demanding as it ought to be in regard to its standards for establishing the efficacy of antidepressant drug products."

Pfizer Deliberately Misled Consumers and Prescribing Healthcare Professionals about Zoloft's Efficacy

41. Pfizer has deliberately engaged in a comprehensive scheme to prevent consumers and doctors from knowing or appreciating Zoloft's true efficacy in treating depression.

The Drug label

42. Zoloft's drug label has never properly stated Zoloft's true efficacy or given consumers or prescribing healthcare professionals sufficient information to determine, for themselves, if purchasing or prescribing Zoloft is worth the risks. When Zoloft first entered the market, it's product label stated:

> ZOLOFT (sertraline hydrochloride) is indicated for the treatment of depression. The efficacy of ZOLOFT in the treatment of a major depressive episode was established in six to eight week controlled trials of outpatients whose diagnoses corresponded most closely to the DSM-III category of major depressive disorder.

43. In later years, Zoloft's label was amended several times. The most current version reads:

> The efficacy of ZOLOFT as a treatment for major depressive disorder was established in two placebo-controlled studies in adult outpatients meeting DSM-III criteria for major depressive disorder. Study 1 was an 8-week study with flexible dosing of ZOLOFT in a range of 50 to 200 mg/day; the mean dose for completers was 145 mg/day. Study 2 was a 6-week fixed-dose study, including ZOLOFT doses of 50, 100, and 200 mg/day. Overall, these studies demonstrated ZOLOFT to be superior to placebo on the Hamilton Depression Rating Scale and the Clinical Global Impression Severity and Improvement scales. Study 2 was not readily interpretable regarding a dose response relationship for effectiveness.

44. Zoloft's drug label, as it existed in 1991 and until the present, is inherently misleading because it does not mention or discuss the numerous clinical trials in which Zoloft was shown to be no more effective in treating depression than placebo. Moreover, the drug label fails to disclose that the two clinical trials that supposedly demonstrate Zoloft's efficacy showed only a marginal or slight effect on treating depression. Instead, Pfizer concocted a description which, through the artful omission of material facts, conveys the impression that Zoloft is a very effective treatment for depression.

45. This omitted information relating to Zoloft's efficacy should have been included in Zoloft's original drug label and those that followed, up to and including the current drug label. Doctors and consumers deserve to know what Zoloft's efficacy truly is and decide, in light of so many clinical trials demonstrating that Zoloft is no better than placebo, whether purchasing Zoloft is worth the risks. By omitting this material information, Pfizer has robbed consumers and prescribing healthcare professionals of having sufficient information to properly decide whether to purchase or prescribe Zoloft.

Selective Publication of Clinical Trial Data

46. Pfizer's deceptive drug label, however, is just one component of a larger marketing scheme designed to mislead consumers and healthcare professionals about Zoloft's efficacy. Specifically, Pfizer has engaged in selective and biased publication of Zoloft's clinical trials with the aim of promoting favorable studies and suppressing negative ones. Dr. Marcia Angell, the former editor of the New England Journal of Medicine and currently a senior lecturer in the department of social medicine at Harvard Medical School, has commented that "[m]any drugs that are assumed to be effective are probably little better than placebos, but there is no way to know because negative results are hidden." Marcia Angell, *Drug Companies & Doctors: A Story of Corruption*, N.Y. Rev. of Books, (January 15, 2009) *available at* http://www.nybooks.com/articles/archives/2009/jan/15/drug-companies-doctorsa-story-of-corruption/.

47. Pfizer was able to prevent the disclosure of unfavorable clinical results by making supposedly "un-biased" researchers agree to non-disclosure agreements and prevent the publication of any clinical data without first gaining express permission. In addition, Pfizer would expressly prohibit researchers from having access to underlying raw data to limit their ability to question, or challenge, the reported results. Then, if a researcher's clinical trial ultimately demonstrated a lack of efficacy, Pfizer would place the researcher on a "do-not-use-in-the-future" list.

48. Selective publication of clinical trial data gives the impression that Zoloft is more effective than it actually is. A recent study published in the New England Journal of Medicine exposed this practice. *See* Erick H. Turner, et al., Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy, 358 NEW ENG. J. MED. 252, 252-60 (2008). The study found "a bias toward the publication of positive results" and that a survey of published literature indicates that ninety-four (94) percent of clinical trial studies were positive, whereas only fifty-one (51) percent of the studies actually submitted to the FDA were positive. The authors state that "[s]elective reporting deprives researchers of the accurate data they need to estimate effect size realistically" and that, by "altering the apparent risk-benefit ratio of drugs, selective publication can lead doctors to make inappropriate prescribing decisions that may not be in the best interest of their patients and, thus, the public health." More importantly, an estimate of how much the impression of each drug's effectiveness was inflated by not publishing unfavorable studies revealed that Zoloft was the second to worst drug of those evaluated, with an estimated 64% inflated efficacy.

49. Several of the most prestigious medical journals in the world, including the New England Journal of Medicine, the Lancet, and the Journal of the American Medical Association, recognized the problem of pharmaceutical control over study design and publication:

> We are concerned that the current intellectual environment in which some clinical research is conceived, study subjects are recruited, and the data are analyzed and reported (or not reported) may threaten this precious objectivity.
>
> [C]orporate sponsors have been able to dictate the terms of participation in the trial – terms that are not always in the best interests of academic investigators, the study participants, or the advancement of science generally.
>
> Investigators may have little or no input into trial design, no access to the raw data, and limited participation in data interpretation. These terms are draconian for self-respecting scientists, but many have accepted them because they know that if they do not, the sponsor will find someone else who will.

> And, unfortunately, even when an investigator has had substantial input into trial design and data interpretation, the results of the finished trial may be buried rather than published if they are unfavorable to the sponsor's product. Such issues are not theoretical. There have been a number of recent public examples of such problems, and we suspect that many more go unreported.

Editorial, *Sponsorship, Authorship, and Accountability*, 345 NEW ENGL. J. MED. 825-27 (2001).

50. By selectively publishing clinical trial data, Pfizer has been able to convince the public and the medical community that Zoloft is more effective than clinical trials indicate.

Pfizer's Ghostwriting Operation

51. The clinical peer-review process is an integral component of the medical research field and pharmaceutical development. It allows new ideas and theories to be tested against the critical eye of fellow researchers and ferret out otherwise unfeasible approaches or products. Doctors rely heavily on published papers and the peer review process to gain insight into new and potentially life-saving advances in medicine, as well as to learn about potential dangers that were previously unknown. *See* Puneet Manchanda & Elizabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL'Y L. & ETHICS 785, 796 (2005). In addition, the FDA and other regulatory bodies rely on the intellectual rigor and transparency attendant to the peer review process to keep apprised of important issues that fall within their regulatory jurisdiction. The success of this system is predicated on integrity and transparency. Doctors, regulatory officials, researchers, and even consumers make important healthcare and research decisions based on the belief that these studies are unbiased and accurate.

52. Pfizer understood that the best way to ensure the success of Zoloft was to convince the scientific and medical community that Zoloft was safe and effective by cultivating a body of "peer-reviewed research" to enhance Zoloft's credibility. To that end, Pfizer created a large-scale ghostwriting program. Pfizer would author, or have a medical communications company author, a study specifically designed to promote a

marketing message, *i.e.*, Zoloft's efficacy. Then, Pfizer would pay "key opinion leaders" ("KOL's") to put their name on the article and get the article published in specifically targeted medical journals. When the article appeared in the journal, there would be no indication of Pfizer's involvement.

53. Pfizer had an entire team devoted to the publication of positive medical journal articles about Zoloft. In addition, Pfizer worked with outside medical ghostwriting vendors to create a steady stream of Zoloft-positive medical journal articles.

54. Dr. David Healy, a psychopharmacologist and professor at the University of Wales College of Medicine, and a colleague conducted an analysis of Zoloft articles that were "coordinated" by a medical communications company called Current Medical Direction ("CMD"). Pfizer had hired CMD to promote Zoloft in the 1990's. David Healy & Dinah Cattell, *Interface Between Authorship, Industry and Science in the Domain of Therapeutics*, 183 BRITISH J. OF PSYCH. 22-27 (2003). According to the study, CMD coordinated over 85 medical journal articles about Zoloft during a three-year period. By early 2001, 55 of these articles had been published in journals such as the *New England Journal of Medicine*, *Journal of the American Medical Association* (*JAMA*), *Archives of General Psychiatry* and the *American Journal of Psychiatry*. Interestingly, all of the clinical trial results were favorable to Zoloft. The analysis found that "the CMD-linked articles report[ed] universally positive results" and that there were "significant discrepancies between published data and the raw data from the actual clinical trials." Most of the 85 articles appeared to have been authored by CMD and, in a number of instances, the authors were listed in Pfizer internal memos as "TBD" (i.e., "to be determined"). The study concluded that:

> The combination of distinguished journal, distinguished author, an efficient distribution system and sponsored platforms appears to have led to an impact on the therapeutics domain greatly in excess of 50% of the impact of the rest of the literature on sertraline. The impact of this literature on third-party payers and other interested parties is at present unquantifiable. The question of literature impact would seem to be tied closely to the nature of ghostwriting. Authorship lines from perceived opinion-leaders with minimal company representation and non-declaration of other non-academic authorship inputs increase the

likelihood that these articles will be influential with prescribers and purchasers.

55. Corroborating the study's finding, an internal company document shows that CMD kept a "Zoloft publications scorecard" for Pfizer which contained a running list of in-progress medical journal articles with details of the status, the names of the designated authors ("KOLs" or "thought leaders" in their respective fields), and the ghostwriting vendor to be used.

56. An internal PowerPoint presentation prepared by Pfizer in 2000, states that the purpose of the publications program was to, among other things, "promote efficacy[,]" "[h]ighlight drug's superiority to a competitor(s)[,]" "[l]everage good will with academic investigators[,]" "[i]ncrease media and public perception of the drug and Pfizer[,]" and "[p]rovide tools for sales force to drive prescriptions based on data[.]" The PowerPoint explains that the "bottom line" in publication projects is to "optimize our ability to sell Zoloft[.]"

Paid-For Opinions and Conflicts of Interest

57. Studies have demonstrated that "[a]uthors who had financial relationships with pharmaceutical companies were significantly more likely to reach supportive conclusions than authors without such industry affiliations" and "reports suggest that industry may alter, obstruct, or even stop publication of negative studies." Scope and Impact of Financial Conflicts of Interest in Biomedical Research, 342 NEW ENGL. J. MED. 1539-44 (2000).

58. One of the most powerful methods employed by Pfizer to promote Zoloft's efficacy, was directly paying KOLs to declare their support for Zoloft and concealing Pfizer's financial relationship with KOLs. In one internal Pfizer memorandum from 1995, a Pfizer employee stated: "With regards to the authors, we want to avoid a list of Pfizer names. One is acceptable as a study coordinator, the rest should be investigators who will be of benefit to the launch of Zoloft[.]" Pfizer deliberately concealed various doctor's financial relationship with Pfizer so they would have more credibility in touting Zoloft when it went to market.

59. Dr. Marcia Angell, in reviewing a book about how conflicts of interest impact drug development, explains that "highly influential faculty physicians – referred to by the industry as 'thought-leaders' or 'key opinion leaders' (KOLs) . . . write textbooks and medical journal papers, issue practice guidelines (treatment recommendations), sit on FDA and other governmental advisory panels, head professional societies, and speak at the innumerable meetings and dinners that take place every year to teach clinicians about prescription drugs ..." Marcia Angell, *Drug Companies & Doctors: A Story of Corruption*, N.Y. REV. OF BOOKS, (January 15, 2009) *available at* http://www.nybooks.com/articles/archives/2009/jan/15/drug-companies-doctorsa-story-of-corruption/. Dr. Angell explains that "[c]onflicts of interest affect more than research. They also directly shape the way medicine is practiced, through their influence on practice guidelines issued by professional and governmental bodies, and through their effects on FDA decisions[.]"

60. Pfizer has employed through its ghostwriting and continuing education programs numerous KOLs in the medical profession. In so doing, Pfizer has found a way to insulate Zoloft and remain relatively unscathed by researchers in spite of its dismal, if not non-existent, efficacy.

Zoloft's Massive Efficacy Promotion Campaign

61. After Pfizer was approved in 1991, Pfizer embarked on a massive campaign to promote Zoloft as an effective and reliable treatment for depression.

62. The first arm of this campaign involved the "direct-to-prescriber" approach. Pfizer would "wine and dine" prescribing healthcare professionals to encourage them to prescribe Zoloft. Pfizer would pay prescribing healthcare professionals to attend various events, such as theater shows, sporting events, ski trips and pay for stays at luxurious hotels and meals at fancy restaurants.

63. Pfizer also used a large sales force, long recognized as the largest sales force in the industry, to visit prescribing healthcare professionals on a routine basis to promote Zoloft. These sales representatives, who were typically young attractive people,

would visit prescribing healthcare professionals and "brief" them on how effective Zoloft was at treating depression. The sales representatives would leave behind free samples and various forms of product literature, all designed to give prescribing healthcare professionals the impression that Zoloft was a reliable and effective medication for depression.[5]

64. The second arm of Pfizer's promotional campaign focused on media advertisements to prescribing healthcare professionals and consumers. These print and video advertisements gave the false and misleading impression that Zoloft was a tremendously effective drug for the treatment of depression.

65. For example, in a 2005 medical journal, Pfizer published an advertisement directed toward prescribing healthcare professionals which read:

> Zo effective
> Zo well tolerated
> Zo trusted
> Zoloft
> Choose the #1 prescribed SSRI

66. In another advertisement, Pfizer claims "Zoloft has helped millions with depression." In comic strip format, the advertisement tells a story about "Denise" who, depicted as a balloon-cartoon, is a music conductor that felt "an octave lower" because she "was depressed" and "had to do something about it." However, before she went to the doctor, she "did some homework" and discovered that "Zoloft is the number one prescribed brand for depression[.]" So, Denise went to her doctor and he told her "it's helped millions" just like Denise. In the next box, Denise "realize[s] that Zoloft was helping me at work and at home." Beneath the comic strip, the ad states: "Denise took comfort in the fact that Zoloft has helped so many people for so many years. Zoloft is

[5] Pfizer's willingness to engage in illegal conduct with regard to the promotion of drugs directly to prescribers is well documented. For instance, in 2009, Pfizer agreed to pay $2.3 billion dollars to settle government claims that the company aggressively promoted a number of its drugs, including Zoloft, for unapproved uses. *See* LeAnne Gendreau, *Pfizer to Announce Record $2.3 B Settlement*, Associated Press, Sept. 2, 2009 ("The company aggressively promoted drugs for unapproved, off label uses, bribed medical professionals with cash and gifts and used thinly disguised kickbacks to hawk its products.")

safe and effective. It has treated more people with more types of depression and anxiety than any brand of its kind. So she asked her doctor about Zoloft. Zoloft. #1 for millions of reasons." This advertisement, much like others, carefully misleads consumers into believing Zoloft is more effective for treating depression than clinical data would suggest. Pfizer stresses that Zoloft has "helped millions" but that inference presupposes that Zoloft is what is causing the perceived benefit in consumers, not the placebo effect—a fact that is simply not supported by Pfizer's own clinical research.

67. The combination of direct-to- prescriber and direct-to-consumer promotion convinced consumers and prescribing healthcare professionals that Zoloft was particularly effective at treating depression. Pfizer's promotion, however, never revealed that the majority of clinical trials showed that Zoloft was no better than placebo.

Plaintiff and Her Doctor Were Misled into Prescribing and Purchasing Zoloft

68. On or about March 18, 2005, Plaintiff Laura A. Plumlee was prescribed a fifty (50) mg daily dose of Zoloft by her psychiatrist to treat ongoing depression. In later years, because Zoloft was not effective at treating her depression, her dosage was increased to one hundred (100) mg, then two hundred (200) mg, and then to four-hundred (400) mg per day.

69. Upon information and belief, Plaintiff's physician was misled into prescribing Zoloft because he had been led to believe it was more effective in treating depression that it actually is. This deception occurred as a result of the same misleading conduct that was directed toward the Plaintiff—a misleading drug label and deceptive advertising.

70. Plaintiff continued to purchase and ingest Zoloft until shortly after Pfizer's patent over Zoloft expired in June 2006. Plaintiff last purchased brand name Zoloft on or about August 11, 2006. Thereafter, Plaintiff purchased the generic version of Zoloft, sertraline until on or about June 2008.

71. In total, between March 18, 2005 and August 11, 2006, Plaintiff spent approximately $162 of her own money to purchase Zoloft and, with insurance payments, Pfizer received approximately $3,315.

72. Prior to ingesting Zoloft, Plaintiff read over Zoloft's drug label. In addition, prior to purchasing the drug, Plaintiff had seen several commercials (described more fully below) which indicated that Zoloft was effective for treating depression. Relying on the representations about Zoloft's efficacy on both the drug label and through Pfizer's direct-to-consumer advertisements, Plaintiff was induced into purchasing and ingesting Zoloft.

73. During the period in which Plaintiff was purchasing and ingesting Zoloft, Plaintiff did not know that Zoloft's drug label and advertising were deceptive or that they lacked material information about the drug's efficacy.

74. In early 2012, Plaintiff discovered that Pfizer had misrepresented Zoloft's efficacy, stating that it was more effective that it actually was. Plaintiff learned that the majority of clinical trials related to Zoloft's efficacy had shown it is no better than placebo. Given the risk of the serious and well-documented side effects associated with Zoloft, Plaintiff would never have purchased or ingested Zoloft if this information had been made known to her. In other words, Plaintiff had relied on the sufficiency and accuracy of Pfizer's advertisements and Zoloft's drug label in making her decision to purchase and ingest Zoloft to treat her depression.

NATIONWIDE ISSUE AND INJUNCTIVE CLASS ALLEGATIONS

75. This matter is brought by Plaintiff on behalf of herself and those similarly situated. As discussed at length in this Complaint, Pfizer deliberately withheld from consumers that the majority of clinical trials designed to prove Zoloft's efficacy actually showed that it was no better than a placebo. Moreover, while Zoloft's drug label discuses the only two efficacy trials that show Zoloft was better than placebo at treating depression, it fails to include that the observed effect of Zoloft on depression was marginal at best. The Zoloft drug label fails to provide sufficient information to

consumers and prescribing healthcare professionals to make an informed decision about whether to purchase or prescribe Zoloft. Since Pfizer's misleading and deceptive drug label contains the core information that forms the basis for every Zoloft prescription written by a prescriber and filled by a consumer in the United States, consumers and prescribers were uniformly exposed to the same misconduct. Accordingly, this Complaint is uniquely suited for class-wide resolution, both in the context of an issue class and for injunctive relief.

76. The class is defined as follows:

> All persons within the United States of America who purchased and/or paid for Zoloft manufactured and/or distributed and/or marketed by Pfizer from December 30, 1991 (the launch date of Zoloft) until the present for the treatment of depression ("Nationwide Class")

The Nationwide Issue Class

77. Pfizer sold the same Zoloft with the same misleading drug label in every state. Moreover, Pfizer's advertising and medical literature manipulation was directed at all consumers and prescribing healthcare professionals within the United States. Through advertising and the drug label, Pfizer failed to represent Zoloft's true efficacy as demonstrated by its own clinical trials. Pfizer knew that Zoloft was marginally, if at all, effective and deliberately withheld this material fact from consumers and prescribing healthcare professionals in the United States.

78. Rule 23(c)(4) provides that an action may be brought or maintained as a class action with respect to particular issues when doing so would materially advance the litigation as a whole.

79. In an effort to materially advance the litigation as a whole, pursuant to Rule 23(c)(4), Plaintiff brings Count I of the Complaint, as alleged below, on behalf of herself and the Nationwide Class to resolve whether Zoloft's drug label is misleading or deceptive. Specifically, the issues applicable to the Nationwide Issue Class are:

a. Whether Zoloft's drug label was misleading or deceptive because it did not contain any information about the numerous clinical trials

demonstrating that Zoloft was no more effective than placebo in treating depression;

b. Whether Zoloft's drug label was misleading or deceptive because it mentioned only two clinical trials that showed Zoloft could treat depression but failed to mention the negative studies and that the observed benefit was marginal or very limited;

c. Whether Zoloft's omissions were material, *i.e.*, whether the information should have been made available to prescribing healthcare professionals and consumers in order to make an informed decision about whether to purchase Zoloft; and

d. Whether Pfizer's failure to include this information was deliberate, intentional, or done with reckless disregard.

80. Because Pfizer marketed and sold the same Zoloft with the same drug label in each state, resolution of these questions would materially advance the litigation as a whole. Resolution of these issues would dispose of factual issues that are central to any consumer protection claim brought against Pfizer regarding Zoloft, whether those claims are brought individually or in other consumer class actions. Resolution of these issues would also materially advance a nationwide injunctive action against Pfizer, as discussed below.

81. The Nationwide Issue Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the Nationwide Class members would be wholly impracticable. Zoloft has been purchased by millions of persons in the United States.

b. Commonality: Questions of law and fact are common to all members of the Nationwide Issue Class. Pfizer's misconduct was uniformly directed at all consumers and their prescribing healthcare professionals

in the United States. Since the issues presented by this Nationwide Issue Class deal exclusively with Pfizer's misconduct, resolution of these questions would be, by definition, common to the entire Nationwide Class.

c. Typicality: Plaintiff's claims are typical of the claims of the Nationwide Class, because her claims arise from the same course of conduct by Pfizer, *i.e.*, deceptive and unlawful marketing of Zoloft. Plaintiff is a typical class representative because, like all members of the Nationwide Class, she purchased Zoloft that was being deceptively and unlawfully marketed within the United States.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the Nationwide Class. Her consumer fraud claims are common to all members of the Class and she has a strong interest in vindicating her rights. In addition, Plaintiff, and the Nationwide Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

82. The Nationwide Issue Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Nationwide Class. The issues at stake here relate exclusively to Pfizer's conduct which was uniform across the entire class, *i.e.*, the misleading and deceptive marketing of Zoloft within the United States. Therefore, individual issues or defenses would be irrelevant for purposes of resolving the issues presented in the Nationwide Issue Class. The class issues fully predominate over any individual issues because no inquiry into individual conduct is necessary, just a narrow focus on Pfizer's deceptive and misleading marketing. In addition, this Nationwide Issue Class is superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*,:

a. Resolution of the issues presented on behalf of the Nationwide Class would materially advance the litigation of any individual consumer protection claim brought against Pfizer or any state-wide class action suits;

b. Resolving whether Zoloft's drug label was misleading or deceptive would allow individual claimants to bring claims with relative ease, as the individual claimants would only need to prove damages to recover for their consumer fraud claims;

c. Individual joinder of the individual members is wholly impracticable;

d. The economic damages suffered by the individual members is relatively modest compared to the expense and burden of individual litigation, thus consumers who have been otherwise harmed would be less likely to pursue claims against Pfizer;

e. The court system would benefit from a class action because individual litigation would overload court dockets and magnify the delay and expense to all parties;

f. The class action device presents far fewer management difficulties and provides the benefit of comprehensive supervision by a single court with economies of scale; and

g. Individual litigation by members would not be effective in stopping Pfizer's deceptive and unlawful conduct which will continue unless stopped through a class action lawsuit.

The Nationwide Injunctive Class

83. Rules 23(b)(1) and (2) contemplate a class action for purposes of seeking class-wide injunctive relief. Here, Pfizer has engaged in conduct that has resulted in misleading consumers and prescribing healthcare professionals about Zoloft's efficacy. Since Pfizer's conduct has been uniformly directed at all consumers and prescribing healthcare professionals in the United States, and the conduct continues presently,

injunctive relief on a class-wide basis is a viable and suitable solution to remedy Pfizer's continuing misconduct.[6]

84. The Injunctive Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the Injunctive Class members would be wholly impracticable. Zoloft has been purchased by millions of persons in the United States.

b. Commonality: Questions of law and fact are common to all members of the Nationwide Injunctive Class. Pfizer's misconduct was uniformly directed at all consumers and their prescribing healthcare professionals in the United States. Thus, all members of the Nationwide Class have a common cause against Pfizer to stop its unlawful conduct through an injunction. Since the issues presented by this Injunctive Class deal exclusively with Pfizer's misconduct, resolution of these questions would be, by definition, common to the entire Nationwide Injunctive Class. Moreover, there are common questions of law and fact inherent in the resolution of a Nationwide Injunctive Class, including, *inter alia*,:

i. Resolution of the issues presented in the Nationwide Issue Class;

ii. Whether members of the Nationwide Class will continue to suffer harm by virtue of Pfizer's unlawful and deceptive marketing of Zoloft and its impact on the labeling of the drug for generic manufacturers; and

[6] Since all generic manufacturers of drugs are required to replicate the label that exists on the brand name drug, enjoining Pfizer from continuing to use the misleading label on its brand name Zoloft will also force generic manufacturers to change their misleading label.

iii. Whether, on equitable grounds, Pfizer should be prevented from continuing to omit material information from Zoloft's drug label; and

c. Typicality: Plaintiff's claims are typical of the claims of the Nationwide Injunctive Class, because her claims arise from the same course of conduct by Pfizer, *i.e.*, deceptive and unlawful marketing practices, including the publication of misleading drug label, related to Zoloft. Plaintiff is a typical class representative because, like all members of the National Injunctive Class, she purchased Zoloft in the United States and Zoloft was sold unfairly, deceptively, and unlawfully to consumers within the United States.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the Nationwide Injunctive Class. Her consumer protection claims are common to all members of the Nationwide Injunctive Class and she has a strong interest in vindicating her rights. In addition, Plaintiff and the Nationwide Injunctive Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

85. The Nationwide Injunctive Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior.

a. With regard to Rule 23(b)(1)(A), resolution of the issues presented for the Nationwide Injunctive Class on an individual basis would pose a serious risk of requiring Pfizer to follow inconsistent courses of continuing conduct. One court could determine that the Zoloft drug label was partially misleading and order Pfizer to take specific action. Another court could also determine that Zoloft's drug label was defective but order a conflicting course of conduct. If the issues

presented for this Nationwide Injunctive Class are not dealt with by a single court, there is a very real possibility that Pfizer would be subjected to an inescapable legal quagmire of not being able to comply with one judgment without violating terms of another.

b. With regard to Rule 23(b)(2), Plaintiff seeks injunctive relief on behalf of the members on grounds generally applicable to the entire Nationwide Injunctive Class. Certification under Rule 23(b)(2) is appropriate because Pfizer has acted or refused to act on grounds that apply generally to the Nationwide Injunctive Class, *i.e.*, Pfizer has marketed the same Zoloft using the same misleading drug label and advertisements to all the class members. Any final injunctive or declaratory relief would benefit the entire Nationwide Injunctive Class as Pfizer would be prevented from continuing its unlawful and deceptive marketing practices and be required to honestly disclose to consumers and prescribing healthcare professionals the true efficacy of Zoloft in treating depression.

CALIFORNIA CONSUMER CLASS ALLEGATIONS

86. Pfizer's misleading and deceptive marketing of Zoloft was directed toward consumers and prescribing healthcare professionals in the State of California. Moreover, the deceptive conduct directed at California consumers and prescribing healthcare professionals was uniform—the same misleading drug label was directed at every California citizen who purchased Zoloft. Accordingly, in light of Pfizer's deceptive marketing / material omissions related to Zoloft's true efficacy, Plaintiff brings three consumer protection causes of action against Pfizer on behalf of herself and those similarly situated California Consumers.

87. The California Consumer Class is defined as follows:

All persons within the State of California who purchased and/or paid for Zoloft manufactured and/or distributed and/or marketed by Pfizer from December 30, 1991 (the launch date of Zoloft) until the present for the

treatment of depression, and who are not seeking a personal injury claim against Pfizer related to Zoloft ("California Consumer Class")

88. Pfizer's failure to include information about the numerous clinical trials showing that Zoloft was no more effective than placebo and failure to specify that, in the two trials in which Zoloft showed an effect, its effect was marginal or very limited, were material omissions. Accordingly, failure to properly represent these material facts to California consumers (the California Consumer Class), and prescribing healthcare professionals robbed them of being able to make an informed decision about purchasing or prescribing Zoloft.

89. Plaintiff brings Counts II, III, and IV against Pfizer, on behalf of herself, and all those similarly situated, pursuant to Federal Rule of Civil Procedure 23.

90. The California Consumer Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the California Consumer Class members would be wholly impracticable. Millions of Zoloft prescriptions have been filled in the State of California by millions of consumers.

b. Commonality: Questions of law and fact are common to all members of the California Consumer Class. Pfizer's misconduct was uniformly directed at all consumers and their prescribing healthcare professionals in California through the use of a misleading drug label. Thus, all members of the California Consumer Class have a common cause of action, here Counts II, III, and IV, against Pfizer, which involve common issues of fact and law applicable to all California Consumer Class members.

c. Typicality: Plaintiff's claims are typical of the claims of the California Consumer Class, because her claims arise from the same course of conduct by Pfizer, *i.e.*, deceptive and unlawful marketing

practices related to Zoloft. Plaintiff is a typical class representative because, like all members of the California Consumer Class, she purchased Zoloft in California and the Zoloft that was sold was unfairly, deceptively and unlawfully marketed to consumers within California.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the California Consumer Class. Her consumer protection claims are common to all members of the California Consumer Class and she has a strong interest in vindicating her rights. In addition, Plaintiff and the California Consumer Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

91. The California Consumer Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the California Consumer Class. Pfizer deliberately concealed material facts about Zoloft's efficacy, and in so doing, deprived all California consumers of making an informed decision to purchase a prescription drug. Under California law, individual reliance can be imputed on a class-wide basis when the company failed to disclose a material fact about the product, here the true efficacy data of Zoloft. The efficacy of a drug is, by definition, a material component of whether a consumer will purchase a drug—no consumer would knowingly purchase a side-effect-ridden sugar pill. Thus, under California's various consumer protection laws, the question of Pfizer's conduct, *i.e.*, whether the drug label was misleading, predominates over any individual issues. In addition, proceeding with a California Consumer Class action is superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*,:

a. Individual joinder of the individual members is wholly impracticable;

b. The economic damages suffered by the individual members may be relatively modest compared to the expense and burden of individual litigation;

c. The court system would benefit from a class action because individual litigation would overload court dockets and magnify the delay and expense to all parties;

d. The class action device presents far fewer management difficulties and provides the benefit of comprehensive supervision by a single court with economies of scale.

COUNT I
NATIONWIDE ISSUE / INJUNCTIVE CLASS
DECLARATORY / INJUNCTIVE RELIEF

92. Plaintiff incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

93. There is an actual controversy between Pfizer and the Nationwide Classes concerning whether Zoloft's drug label fails to adequately represent the efficacy of the drug. The specific issues relevant to this controversy are those issues relevant to the Nationwide Issue Class, which are restated here:

a. Whether Zoloft's drug label was misleading or deceptive because it did not contain any information about the numerous clinical trials demonstrating that Zoloft was no more effective than placebo in treating depression;

b. Whether Zoloft's drug label was misleading or deceptive because it mentioned only two clinical trials that showed Zoloft could treat depression but failed to mention that the observed benefit was marginal or very limited;

c. Whether Zoloft's omissions were material, *i.e.*, whether the information should have been made available to prescribing healthcare

professionals and consumers in order to make an informed decision about whether to purchase Zoloft; and

d. Whether Pfizer's failure to include this information was deliberate, intentional, or done with reckless disregard of the truth of its product's efficacy.

94. Pursuant to 28 U.S.C. § 2201, this Court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

95. Pfizer has failed to include material information regarding Zoloft's efficacy in its drug label by failing to properly disclose the numerous clinical trials showing that Zoloft is no more effective than placebo in the treatment of depression and failing to describe the marginal benefits in the treatment of depression observed in the two clinical trials purporting to show Zoloft's efficacy.

96. Resolution of these issues would materially advance individual claims for consumer fraud against Pfizer and materially advance the litigation on behalf of the California Consumer Class.

COUNT II
CALIFORNIA CONSUMERS CLASS
VIOLATIONS OF CAL. CIV. CODE §§ 1750, *ET SEQ.*

97. Plaintiff incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

98. California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* makes it unlawful to engage in unfair methods of competition and unfair or deceptive acts or practices intended to result, or which result, in the sale or lease of goods or services to any consumer.

99. Plaintiff and the California Consumer Class were, and continue to be, at all times material to the Complaint, "consumers" and "persons" as defined by the Cal. Civ. Code § 1761. Plaintiff and California Consumer Class purchased and/or paid for Zoloft for personal and/or family and/or household use during the relevant time period.

100. As alleged throughout this Complaint, Pfizer deliberately engaged in deceptive and unlawful marketing in violation of Civ. Code § 1770(a) by representing to the Plaintiff and California Consumer Class that Zoloft was more effective at treating depression than it actually was. Pfizer failed to adequately disclose material information about Zoloft's efficacy and, in so doing, deprived consumers of an ability to make an informed decision.

101. Specifically, Pfizer violated the following proscribed practices pursuant to Cal. Civ. Code § 1770(a) with the purpose of inducing Plaintiff and the California Consumer Class to purchase and ingest Zoloft:

a. § 1770(a)(2): Pfizer represented to Plaintiff and the California Consumer Class that Zoloft was proven to be superior to placebo in two clinical trials, however, failed to mention that a large percentage of the trial group quit the trial because it lacked efficacy and caused severe side-effects. This gave a false certification of Zoloft's efficacy because the clinical trial results, as represented by Pfizer, were skewed and Pfizer was aware of this problem. Moreover, omitting material information concerning to the actual results of those two clinical trials and concealing the results of numerous clinical trials showing that Zoloft was no more effective than placebo was a false certification of the drug's efficacy.

b. § 1770(a)(5): Pfizer represented to Plaintiff and the California Consumer Class that Zoloft has a specific use, benefit, or characteristic which it did not have, to wit, that Zoloft is more effective for the treatment of depression than it actually is. Omitting material information about the actual results of two clinical trials purporting to show Zoloft's efficacy and concealing the results of numerous clinical trials showing that Zoloft was no more effective than placebo

constituted a misrepresentation concerning a use, benefit, or characteristic.

c. § 1770(a)(7): Pfizer misrepresented to Plaintiff and the California Consumer Class that Zoloft was of a particular standard, quality, or grade., *i.e.*, substantially effective for the treatment of depression. In truth, Zoloft was not as effective as Zoloft's drug label represented, because there were numerous studies showing that Zoloft is no more effective at treating depression than placebo. Moreover, Pfizer's failure to properly disclose Zoloft's marginal benefit in treating depression, as observed in the two clinical trials purporting to show Zoloft's efficacy, constituted a misrepresentation of a material standard, quality, or grade.

d. § 1770(a)(9): Pfizer advertised to Plaintiff and the California Consumer Class that Zoloft was an effective and safe drug for the treatment of depression, when in truth, Pfizer knew that Zoloft was more than likely ineffective at treating depression. Pfizer concealed this information from Plaintiff and the California Consumer Class by omitting material information about the actual results of two clinical trials purporting to show Zoloft's efficacy and concealing the results of numerous clinical trials showing that Zoloft was no more effective than placebo.

102. Pfizer's concealment of numerous clinical studies showing that Zoloft was no better than placebo, and its failure to adequately describe Zoloft's marginal effect on depression, was a material omission that consumers and prescribing healthcare professionals should have known about prior to purchasing or prescribing Zoloft for the treatment of depression.

103. Plaintiff and the California Consumer Class lost money as a result of Pfizer's deceptive and unlawful marketing practices pursuant to Cal. Civ. Code §

1770(a), through the purchase of Zoloft that was illegally advertised and marketed in violation of Cal. Civ. Code § 1770(a).

104. As a result of Pfizer's violations of California's Consumer Legal Remedies Act, Plaintiff seeks an order of this Court permanently enjoining Pfizer from perpetrating its deceptive and unlawful marketing practices. Pursuant to Cal. Civ. Code § 1782(d), if Pfizer does not take action to cease its deceptive and unlawful marketing practices and amend the current drug label to accurate reflect the efficacy of Zoloft within thirty (30) days of being served with this Complaint, Plaintiff will amend this Complaint to seek, in addition to an order enjoining Pfizer from continuing its deceptive and unlawful practices, an order awarding, *inter alia*, Plaintiff and the California Consumer Class actual damages, restitution, punitive damages, attorneys' fees and costs, and for such other relief as set forth below.

COUNT III
CALIFORNIA CONSUMERS CLASS
VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.*

105. Plaintiff incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

106. California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*, protects both consumers and competitors by promoting fair competition in commercial markets for goods and services. California's Unfair Competition Law is interpreted broadly and provides a cause of action for any unlawful, unfair, or fraudulent business act or practice. Any unlawful, unfair, or fraudulent business practice that causes injury to consumers falls within the ambit of California's Unfair Competition Law.

107. Pfizer engaged in substantial advertising and marketing of Zoloft within the State of California.

108. Because of Pfizer's unlawful, fraudulent, and unfair business practices, Plaintiff and the California Consumer Class were misled into purchasing and using Zoloft.

Unlawful Business Practices

109. As set forth in the preceding paragraphs, Pfizer has engaged in the unlawful business practice of misleading Plaintiff and the California Consumer Class regarding Zoloft's true efficacy. Pfizer's deceptive and unlawful marketing practices have violated numerous California laws, including, *inter alia*: Cal. Civ. Code §§ 1709, *et seq.* (fraudulent deceit); Cal. Civ. Code §§ 1571, et seq. (fraud); Cal. U. Com. Code §§ 2313-15 (breach of express and implied warranty); Cal. Bus. & Prof. Code §§ 17500, *et seq.* (false advertising and marketing); and Cal. Civ. Code §§ 1750, *et seq.* (violations of California's Consumer Legal Remedies Act).

110. As a result of Pfizer's unlawful business practices, Plaintiff and the California Consumer Class purchased Zoloft without sufficient information regarding a material aspect of the drug. Specifically, Plaintiff and the California Consumer Class were misled into believing that Zoloft is more effective at treating depression than it actually is. Plaintiff and the California Consumer Class reasonably relied upon Pfizer's misrepresentations regarding Zoloft in deciding whether to purchase and use the drug.

111. In addition to engaging in unlawful marketing practices, Pfizer also engaged in an unlawful method of competition. Pfizer deliberately misled Plaintiff and the California Consumer Class about Zoloft's efficacy and thereby artificially inflated Zoloft's price on the open market. Because Plaintiff and the California Consumer Class were unaware of Zoloft's marginal-at-best ability to treat depression, they were more likely to purchase Zoloft as opposed to a competing antidepressant. The market was unable to correctly valuate Zoloft and, therefore, Pfizer gained an unlawful competitive advantage over competing antidepressant drugs. This unlawful method of competition resulted in Plaintiff and the California Consumer Class paying a substantially higher price for Zoloft than it was actually worth.

Fraudulent Business Practices

112. As set forth in the preceding paragraphs, Pfizer has engaged in the fraudulent business practice of misleading Plaintiff and the California Consumer Class regarding Zoloft's efficacy.

113. A business act or practice is "fraudulent" under California's Unfair Competition Law if it actually deceives or is likely to deceive members of the consuming public.

114. As set forth in the preceding paragraphs, Pfizer engaged in a comprehensive scheme to mislead consumers and prescribing healthcare professionals regarding Zoloft's ability to treat depression. Because of Pfizer's fraudulent business practices, Plaintiff and the California Consumer Class were misled about Zoloft's ability to treat depression and, accordingly, purchased Zoloft without knowing a material aspect of the drug.

Unfair Business Practices

115. As set forth in the preceding paragraphs, Pfizer has engaged in an unfair business practice of misleading Plaintiff and the California Consumer Class regarding Zoloft's ability to treat depression.

116. A business practice is unfair when it offends an established public policy or when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers.

117. Pfizer's deceptive and unlawful marketing practices offend public policy and are fundamentally immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. Pfizer's scheme was to mislead consumers about Zoloft's efficacy by hiding the majority of clinical trials showing Zoloft does not work while grossly over-stating its efficacy. This conduct offends any notion of public policy and is truly unethical. Moreover, since Zoloft is, at best, marginally effective at treating depression, consumers who were tricked into purchasing the drug will suffer the risk of

the many serious side-effects attendant to Zoloft and, in return, get little to no relief for their depression from the drug.

118. The harm to Plaintiff and the California Consumer Class caused by Pfizer's unfair business practices outweighs any countervailing benefits to consumers or competition, and could not reasonably have been known and avoided by consumers. Furthermore, Pfizer's unfair business practices cannot be excused for any business justification, motive, or rationale in light of the severity of Pfizer's misconduct and the harm caused to Plaintiff and the California Consumer Class.

119. As a result of Pfizer's violations of the UCL, Plaintiff seeks an order of this Court enjoining Pfizer from continuing this unlawful, fraudulent, and unfair practices and awarding Plaintiff and the California Consumer Class, *inter alia*, actual damages, restitution, a disgorgement of Pfizer's profits, and for such other relief set forth below.

COUNT IV
CALIFORNIA CONSUMER CLASS
VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17500, *ET SEQ.*

120. Plaintiff incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

121. Plaintiff and the California Consumer Class bring a cause of action against Pfizer pursuant to Cal. Bus. & Prof. Code §§ 17500, *et seq.* ("California's False Advertising Law").

122. The purpose of California's False Advertising Law is to protect consumers from false or misleading advertising and promotions. California's False Advertising Law prohibits the false or deceptive advertising of products to consumers in any form of media, when the company placing the advertisement knows, or should have known, that the advertisement would be likely to mislead consumers about a material aspect of a product.

123. Pfizer has used advertising on its packaging and through various media outlets to sell and market Zoloft directly to consumers. The advertisements and labeling

are deceptive, untrue, or misleading within the meaning of the California's False Advertising Law because they misstate observed efficacy of Zoloft in treating depression.

124. In making and disseminating the statements alleged herein, Pfizer knew or should have known that the statements were untrue or misleading, and that it acted in violation of California's False Advertising Law. Pfizer knew or should have known the true efficacy of Zoloft in treating depression as the data was compiled in Pfizer's own clinical trials of Zoloft. Pfizer, however, deliberately chose to engage in false advertising by using a misleading and deceptive drug label which had the effect of inducing Plaintiff and the California Consumer Class into purchasing and ingesting Zoloft.

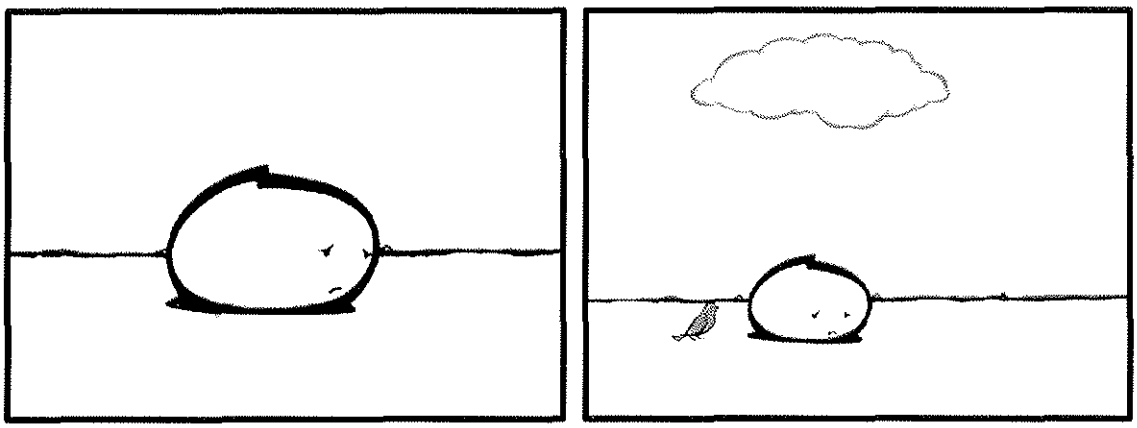
125. Pfizer's misrepresentations of material facts related to Zoloft, as detailed above, constitute false and misleading advertising in violation of California's False Advertising Law.

126. In addition, Pfizer has directly advertised to Plaintiff and the California Consumer Class by representing that Zoloft is very effective at treating depression. The volume of advertisements directed at California consumers between 1991 and 2012 is substantial.

127. Many advertisements directed toward Plaintiff and the California Consumer Class involved a little balloon-shaped cartoon character who would bounce around feeling either depressed or happy depending on whether it had recently taken Zoloft. Pfizer broadly released commercials depicting the balloon-cartoon after 2001.

128. One commercial, which Plaintiff saw and relied on prior to taking Zoloft, was one of Pfizer's most successful advertisements.[7] The commercial was designed to convince consumers that Zoloft was very effective at treating depression. The commercial is depicted below. It begins with the balloon-cartoon looking sad under a rain cloud.

[7] Full commercial available at http://www.youtube.com/watch?v=6vfSFXKlnO0, last accessed on January 29, 2013 at 3:25 p.m.

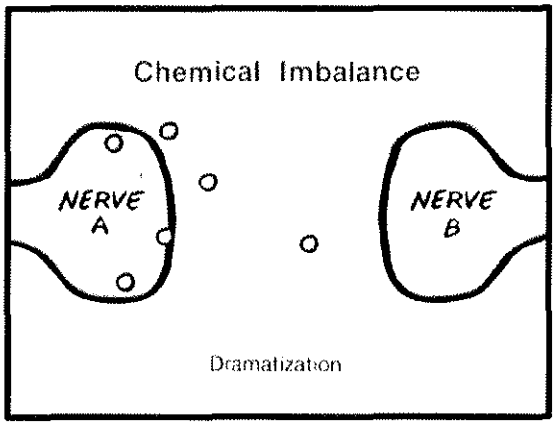


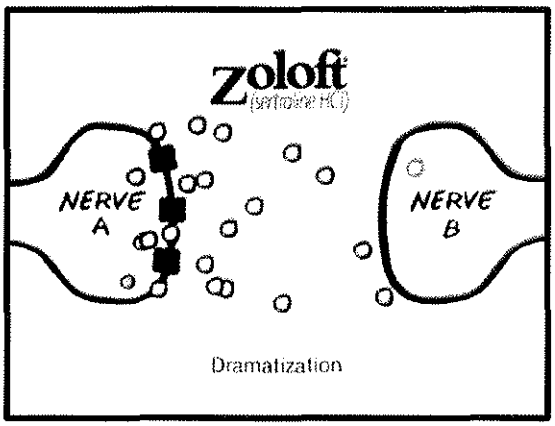
A voice over states:

> You know when you feel the weight of sadness.
>
> [sound of rain]
>
> You may feel exhausted, hopeless, and anxious.
>
> [whimper]
>
> Whatever you do, you feel lonely and don't enjoy the things you once loved.
>
> [sad moan]
>
> Things just don't feel like they used to.
>
> These are some symptoms of depression: a serious medical condition affecting over 20 million Americans.

The commercial then goes into a description of how depression works, relying on the chemical imbalance theory that has been rejected by scientists.[8]

[8] *See, e.g.*, Ronald Pies, *Psychiatry's New Brain-Mind and the Legend of the 'Chemical Imbalance*, Psychiatric Times, July 11, 2011("[T]he 'chemical imbalance' image has been vigorously promoted by some pharmaceutical companies, often to the detriment of our patients' understanding. . . In truth, the chemical imbalance notion was always a kind of urban legend – never a theory seriously propounded by well-informed psychiatrists."); Jeffrey R. Lacasse and Jonathan Leo, *Serotonin and Depression: A Disconnect between the Advertisements*, 2 PLoS MEDICINE 1211-16 (December 2005) ("Contemporary neuroscience research has failed to confirm any serotonergic lesion in any mental disorder, and has in fact provided significant counterevidence to the explanation of a simple neurotransmitter deficiency.") .

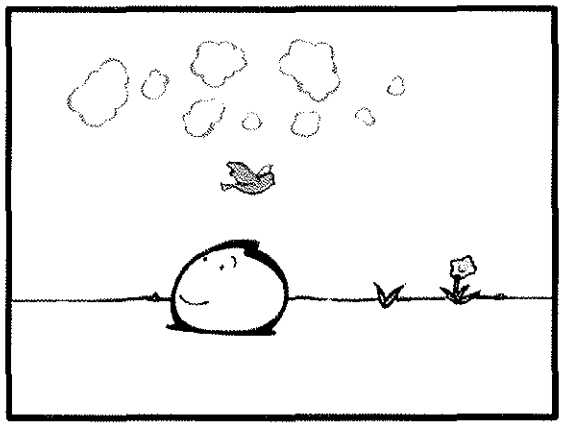




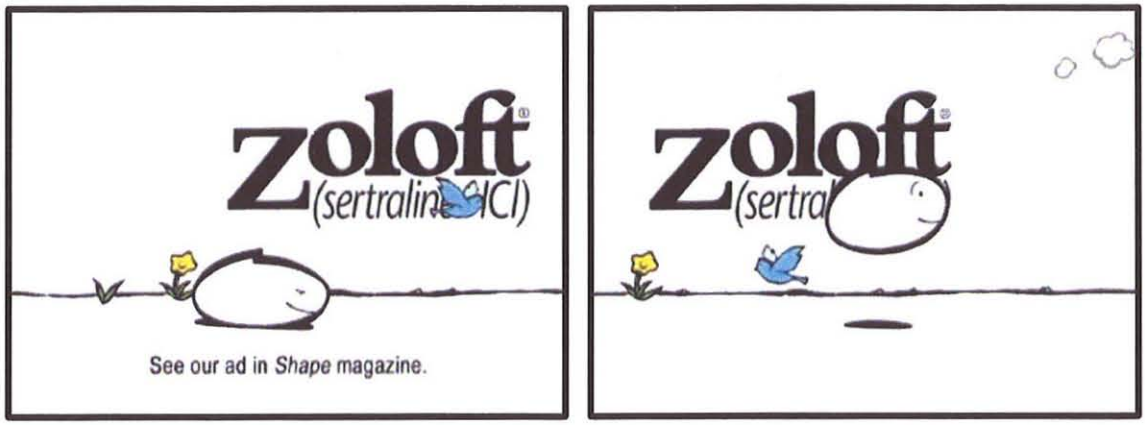
A voice over states:

> [happy music starts]
>
> While the cause is unknown, depression may be related to an imbalance of natural chemicals between nerve cells in the brain.
>
> Prescription Zoloft works to correct this imbalance.
>
> You just shouldn't have to feel this way anymore.

The commercial then cuts to the cartoon-character, smiling, with birds chirping.



The commercial then begins to list the various potential side-effects of taking Zoloft while the balloon-cartoon proceeds to bounce along the Zoloft logo.



A voice over states:

Only your doctor can diagnose depression.

Zoloft is not for everyone.

People taking MAOI's or pimozides shouldn't take Zoloft.

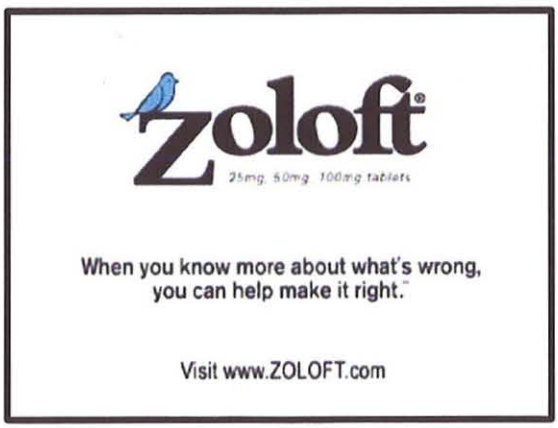
Side effects may include dry mouth, insomnia, sexual side effects, diarrhea, nausea, and sleepiness.

Zoloft is not habit forming.

Talk to your doctor about Zoloft.

The number one prescribed brand of its kind.

The commercial finally settles on the Zoloft Logo, and touts Zoloft's efficacy in treating depression.



The voice over:

Zoloft, "When you know more about what's wrong, you can help make it right."

129. After seeing this commercial, the Plaintiff, like numerous consumers within California, was excited about purchasing and ingesting Zoloft. She specifically relied on this advertisement in making her decision to purchase and ingest Zoloft. Plaintiff and the California Consumer Class were misled into believing that Zoloft would be an effective and reliable drug for the treatment of their depression.

130. Many of the California Consumer Class members saw this famous Zoloft commercial, and Pfizer directed numerous commercials which expressed the materially same message to consumers within California.

131. The above described commercial and magazine ads (described in paragraphs 63-65 above) are just a few of the thousands of advertisements Pfizer directed toward the California Consumer Class designed to mislead consumers about Zoloft's efficacy.

132. As a result of Pfizer's deceptive and unlawful marketing of Zoloft, Pfizer has improperly and illegally obtained money from Plaintiff and the California Consumer Class.

133. Accordingly, pursuant to California's False Advertising Law, specifically Cal. Bus. & Prof. Code § 17535, Plaintiff and the California Consumer Class seek an order of this Court requiring Pfizer to fully disclose the true nature of its misrepresentations to consumers and healthcare professionals, disgorging Pfizer's ill-gotten gains and/or award full restitution of all monies wrongfully acquired by means of its false advertising in California, enjoining Pfizer from continuing to violate California's False Advertising Law in its sale and marketing of Zoloft, awarding those damages available under California law, and for such other relief as set forth below.

EXEMPLARY DAMAGES ALLEGATIONS

134. Plaintiff incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

135. Pfizer's conduct as alleged herein was done with oppression, fraud, and malice. Pfizer was fully aware of Zoloft's true efficacy as documented in its own clinical

trials and internal company documents. Nonetheless, Pfizer deliberately crafted its drug label to mislead consumers and prescribing healthcare professionals into believing that Zoloft is more effective at treating depression than it actually is. This was not done by accident or through some justifiable negligence. Rather, Pfizer knew that it could turn a profit by convincing consumers and prescribing healthcare professionals that Zoloft was very effective at treating depression. This was accomplished not only through its misleading drug label, but through a comprehensive scheme of selective publishing, ghostwriting, paying KOLs, and misleading advertising as more fully alleged throughout this Complaint. Such conduct was done with a conscious disregard of the Plaintiff's, the Nationwide Class Members', and the California Consumer Class members' consumer rights.

136. There is no indication that Pfizer will stop its deceptive and unlawful marketing practices unless it is punished and deterred.

DEMAND FOR JURY TRIAL

137. Plaintiff respectfully requests a trial by jury on all claims triable as a matter of right.

PRAYER FOR RELIEF

138. WHEREFORE, Plaintiff, individually and on behalf of the Nationwide Class described herein, prays for the following relief:

a. Find that this action satisfies the prerequisites for maintenance of a class action pursuant to Federal Rules of Evidence 23(a), (b)(1), (b)(2), and (c)(4), and certify a Nationwide Issue and Injunctive Class described more fully herein.

b. Designate Plaintiff as a representative for the Nationwide Issue and Injunctive Class and her counsel as Class counsel.

c. Issue a judgment against Pfizer that:

i. Declares the following:

1. Zoloft's drug label, between 1991 to the present, was misleading or deceptive because it did not contain material information about Zoloft's efficacy, to wit, the drug label failed to provide information about the majority of clinical trials demonstrating that Zoloft was no more effective than placebo in treating depression and specify the marginal benefit to treating depression observed in the two clinical trials purporting to show Zoloft's efficacy;
2. Pfizer intentionally, deliberately, or recklessly created and distributed Zoloft's misleading drug label with regard to its efficacy description for depression.

ii. Permanently enjoins Pfizer from continuing to sell or market Zoloft with its current drug label and directing Pfizer to seek FDA approval of a new label that properly discloses Zoloft's efficacy.

iii. Grants Plaintiff and the Nationwide Issue and Injunctive Class reasonable attorneys' fees and costs of suit; and

iv. Grants Plaintiff and the Nationwide Issue and Injunctive Class such other and further relief as the Court deems just and proper under the circumstances.

139. WHEREFORE, Plaintiff, individually and on behalf of the California Consumer Class described herein, prays for the following relief:

a. Find that this action satisfies the prerequisites for maintenance of a class action pursuant to Federal Rules of Evidence 23(a) and (b)(3), and certify a California Consumer Class described more fully herein.

b. Designate Plaintiff as a representative for the California Consumer Class and her counsel as Class counsel.

c. Issue a judgment against Pfizer that:

i. Permanently enjoins Pfizer from performing further acts in violation of the various California Consumer Protection Statutes, alleged in Counts II, III, and IV.

ii. Grants Plaintiff and the California Consumer Class a refund of all moneys acquired by Pfizer by means of its deceptive and unlawful marketing of Zoloft in California;

iii. Grants Plaintiff and the California Consumer Class an award of restitution and/or disgorgement of Pfizer's profits from its deceptive and unlawful marketing of Zoloft in violation of the California Consumer Protection Statutes, alleged in Counts II, III, and IV;

iv. Grants Plaintiff and the California Consumer Class any actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

v. Grants Plaintiff and the California Consumer Class exemplary and punitive damages sufficient to punish and deter Pfizer and others from future deceptive and unlawful marketing practices;

vi. Grants Plaintiff and California Consumer Class pre-judgment and post-judgment interest;

vii. Grants Plaintiff and California Consumer Class reasonable attorneys' fees and costs of suit; and

viii. Grants Plaintiff and California Consumer Class such other and further relief as the Court deems just and proper under the circumstances.

Dated: January 30, 2013

Respectfully Submitted,

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