Michael L. Baum, Esq. (SBN: 119511)
mbaum@baumhedlundlaw.com
R. Brent Wisner, Esq. (SBN: 276023)
rbwisner@baumhedlundlaw.com
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Telephone: (310) 207-3233
Fax: (310) 820-7444

Christopher L. Coffin, Esq.
ccoffin@pbclawfirm.com
Nicholas R. Rockforte, Esq.
nrockforte@pbclawfirm.com
David M. Hundley, Esq.
dhundley@pbclawfirm.com
PENDLEY, BAUDIN & COFFIN, L.L.P.
1515 Poydras St., Suite 1400
New Orleans, LA 70112
Telephone: (225) 687-6396
Fax: (225) 687-6398

Attorneys for Plaintiffs and the California Consumer Class.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

T/S
2/1

RANDY and BONNIE MARCUS, on behalf of themselves and all other persons similarly situated,

Plaintiffs,

vs.

FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC.,

Defendants.

Case No. SACV13-714 - AG (JPRx)

COMPLAINT

CLASS ACTION

DEMAND FOR JURY TRIAL

For the Complaint, Plaintiffs Randy and Bonnie Marcus ("Plaintiffs"), upon information and belief, allege as follows:

1. This matter arises out of Defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc.'s ("Forest") deceptive and unlawful marketing of the "blockbuster" antidepressant Lexapro (generically known as escitalopram) for adolescent depression. The clinical trials examining whether Lexapro is effective at treating adolescent major depressive disorder ("MDD") indicate that Lexapro is not clinically effective. The clinical trials demonstrate that any perceived benefit adolescents receive from taking Lexapro to treat MDD is primarily explained by the placebo effect—the perceived efficacy of a drug based upon one's belief that the drug works. Despite knowing that Lexapro was clinically ineffective at treating adolescent depression, Forest has aggressively marketed Lexapro to adolescent patients in violation of California consumer protection law. Specifically, Lexapro's drug label contains materially false and misleading information about clinical trial data and omits information that would be required by physicians and patients to make an informed decision about whether to prescribe and purchase Lexapro to treat adolescent MDD. By publishing and promoting a misleading and deceptive drug label and indicating that Lexapro is effective in treating adolescent MDD when it is not, Forest has violated California consumer protection law. This class action, brought on behalf of consumers and third-party payers in California, seeks to hold Forest accountable for its unlawful and deceptive marketing.

PARTIES

2. Plaintiffs Randy and Bonnie Marcus are, and were at all material times herein, citizens and residents of the State of California, County of Orange.

3. Defendant Forest Laboratories, Inc., is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York. Forest Laboratories, Inc. 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 Lexapro. Forest Laboratories, Inc. regularly conducts business, including the sale and marketing of Lexapro, within the State of California and the United States of America.

4. Defendant Forest Pharmaceuticals, Inc. is a wholly owned subsidiary of Forest Laboratories Inc. and is organized under the laws of Delaware with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals, Inc. 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 Lexapro. Forest Pharmaceuticals, Inc. regularly conducts business, including the sale and marketing of Lexapro, within the State of California and the United States of America.

5. For the purposes of this Complaint, "Forest" refers collectively to Defendants Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc.

JURISDICTION AND VENUE

6. 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 Forest. Furthermore, the aggregate amount in controversy exceeds

$5,000,000, exclusive of interests and costs.

7. This Court has personal jurisdiction over Forest because Forest has purposefully directed its marketing and sales of numerous pharmaceutical products to the State of California. Forest 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.

8. 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 Central District of California.

FACTUAL BACKGROUND

9. This matter arises out of Defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc.'s ("Forest") deceptive and unlawful marketing of the "blockbuster" antidepressant Lexapro (generically known as escitalopram) for adolescent depression.

The Antidepressant Marketplace

10. The market for antidepressants is large and competitive. Since the emergence of "blockbuster" antidepressants in the 1980'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.

11. Forest is one of the largest pharmaceutical companies in the United States with annual revenue exceeding $4 billion. Forest is also a leader in the antidepressant industry and has enjoyed considerable financial success from the manufacture and sale of Celexa and Lexapro, as well as other more recent psychotropic drugs.

12. Lexapro (generically known as escitalopram) is a selective serotonin reuptake inhibitor ("SSRI") antidepressant, in the same class of drugs as Prozac (fluoxetine) and Paxil (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 Lexapro, 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, Forest has successfully used the theory to promote the use of Lexapro.

13. 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 is 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"). The NDA specifically requests that the FDA approve the drug for a specific indication, *i.e.*, the treatment of a specific condition. 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.

14. 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.[1] FDA approval of a medication for a specific indication does not mean that the drug is necessarily safe and effective, or in compliance with potentially more demanding state law requirements. FDA approval merely means the drug satisfied the baseline regulatory threshold. The FDA sets the floor, not the ceiling of drug regulation.

15. Once a drug is approved by the FDA, a pharmaceutical company is allowed to market and sell the drug *only* for the approved indication. If the drug manufacturer would like to add an additional indication for the drug, it must

[1] *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).

submit a separate supplemental NDA to the FDA for approval.

16. Historically, drug companies have been reluctant to engage in pediatric safety and efficacy studies for drugs already approved for adult populations. Drug manufacturers understood that, absent some information to the contrary, prescribing healthcare professionals would assume that drugs proven effective for adults could, at a reduced dosage, be effective in pediatric populations. Conducting a study that could potentially indicate otherwise was not in the manufacturer's interest. However, in the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105–15, § 111, 111 Stat. 2296 (Nov. 21, 1997), Congress recognized the lack of pediatric safety and efficacy studies being conducted and created a powerful incentive to encourage pharmaceutical companies to engage in more robust pediatric research. Specifically, Congress amended the Food, Drug, and Cosmetic Act ("FDCA") to allow drug manufacturers to get an additional six months of patent exclusivity on drugs if they agreed to conduct and submit pediatric safety and efficacy studies to the FDA. *See* 21 U.S.C.A. § 355a.

17. Patent exclusivity is an integral aspect of the pharmaceutical industry. The developer of a pharmaceutical product invests heavily in research and development. In recognition of that substantial investment, the drug manufacturer can exclusively market and sell that drug for a specific indication (assuming it is approved by the FDA). This drug is sold under the "brand name." Once the patent on the drug expires, however, other drug manufacturers are allowed to market and sell generic versions of the drug. Once the drug goes off-patent or "goes generic"

the profits from selling the brand name drug plummet. Thus, maintenance of patient exclusivity is important to brand name drug manufacturers.

The Placebo Effect

18. Before the FDA will approve a drug for a particular indication, the drug manufacturer must prove that the drug is effective. To that end, the drug manufacturer must prove that the benefit created by a drug is not caused by the act of taking the drug itself, *i.e.*, the placebo effect.

19. 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).[2] 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

[2] The history of placebo control groups in drug trials can be traced to a lie told by an Army nurse during World War II. The nurse was assisting an anesthetist named Henry Beecher, who was tending to US troops under heavy German bombardment. When the morphine supply ran low, the nurse assured a wounded soldier that he was getting a shot of potent painkiller, though her syringe contained only salt water. Amazingly, the bogus injection relieved the soldier's agony and prevented the onset of shock. Returning to his post at Harvard after the war, Dr. Beecher became one of the nation's leading medical reformers. He launched a crusade to promote a method of testing new medicines to find out whether they were truly effective. Dr. Beecher proposed that if test subjects could be compared to a group that received a placebo, health officials would finally have an impartial way to determine whether a medicine was actually responsible for making a patient better. He published his findings in a 1955 paper titled, "The Powerful Placebo," in *The Journal of the American Medical Association*, and described how the placebo effect had undermined the results of more than a dozen trials by causing improvement that was mistakenly attributed to the drugs being tested. The article caused a sensation. By 1962, reeling from news of birth defects caused by a drug called thalidomide, Congress amended the FDCA (the Kefauver Harris Amendment, Pub. L. No. 87-781, 76 Stat. 780 (1962)) requiring trials to include placebo control groups.

both groups receive essentially the same benefit, then the drug at issue is considered no more effective than a sugar pill.

20. Because Lexapro is an antidepressant, the issue 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. This is generally done using questionnaires designed to measure the severity of a person's depression. If a person believes they are feeling better because they believe they are taking a drug that cures their depression, then they will answer the subjective questions in a way that shows an improvement of depression. Thus, the potential for the placebo effect to drive the actual effectiveness of an antidepressant is very high.

21. The vulnerability of antidepressants being susceptible to the placebo effect is well documented. For instance, 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.

22. The vulnerability of antidepressant's benefits to be driven by the placebo effect is also applicable in treating pediatric populations. In an analysis of four SSRIs, which consisted of 477 patients on antidepressants and 464 on placebo, and a review of a report by the U.S. Food and Drug Administration (FDA) of a number of antidepressants, the authors concluded that the drugs cannot confidently be recommended as a treatment option for childhood depression. The authors found that clinical investigators' conclusions on efficacy of antidepressants in childhood depression exaggerated their benefits and adverse effects were downplayed. Jureidini et al., *Efficacy and Safety of Antidepressants for Children and Adolescents*, 328 BRITISH MED. J. 879 (2004). In a separate editorial, published in the *British Journal of Psychiatry* in 2005, titled "Wishful thinking:

antidepressant drugs in childhood depression," the authors point out that: a) the use of selective serotonin reuptake inhibitors (SSRIs) in children under 18 years old increased ten-fold in the UK from 1992 to 2001 and usage rates in the United States are even higher; b) reasons for the increasing rates of use are likely due to heavy promotion of both medication and illness, distortions of the published data related to safety and efficacy, and underestimation by clinicians of the importance of the placebo response; and c) continued endorsements of the use of antidepressants in children and adolescents despite lack of efficacy is probably the result of how guidelines are developed and by whom, and potential conflicts of interest due to pharmaceutical industry influence. In conclusion, the authors argue that the "perceived need to 'do something' and the wishful thinking that the drugs may actually be better than the trial evidence indicates, the injunction to 'first do no harm' has been forgotten."

23. Under federal law, the FDA cannot approve a drug for a specific indication unless the drug manufacturer submits at least two placebo-controlled clinical trials showing that the benefit observed in the treatment group was statistically superior to the benefit observed in the control (placebo) group. These "positive" studies, however, are evaluated in a vacuum. Even if there are twenty clinical trials indicating that a drug is not statistically superior to a placebo (negative studies), so long as two studies show some statistical superiority, it is sufficient to meet the regulatory threshold.

24. In addition, federal law requires that the two positive studies show a statistically significant superiority over placebo. This, however, is different than

clinical significance (or clinical importance). Statistical significance is a statistical term of art that means that the difference between the benefit observed in the treatment group and the control group was not the result of chance. Clinical significance, however, examines whether the observed benefit of a drug is enough to outweigh the risks associated with the drug, particularly when compared to alternative, less risky treatments. If, for example, a drug is proven to be statistically superior to placebo, it may still not be clinically significant because the additional benefit is so marginal that alternative treatments would be preferable. The question of clinical significance is not part of the regulatory framework of the FDCA and drug manufacturers are not required to demonstrate the clinical significance of a drug before gaining premarket approval.

Lexapro's Mirror-Image Counterpart: Celexa

25. Lexapro is closely related to the antidepressant Celexa (generically known as citalopram). Lexapro is a stereoisomer of Celexa, which means they contain the same molecular formula, *i.e.*, atomic composition, and the same sequence of bonded atoms, *i.e.*, atomic constitution, but differ in the way they occupy space. In the case of Celexa and Lexapro, they are a special form of stereoisomer called an enantiomer, which means the molecules are mirror image reflections of one another.

26. Forest and Danish pharmaceutical manufacturer H. Lundbeck *A/S* ("Lundbeck") began development of Lexapro in the summer of 1997. Lexapro was created in response to the anticipated loss of patent exclusivity on a very similar antidepressant Celexa in 2002. Forest hoped that the revenues generated by

new Lexapro sales could replace the anticipated lost revenue from Celexa going generic.

27. Forest submitted a NDA to the FDA for Lexapro in March 2001. On August 14, 2002, the FDA approved Lexapro for the treatment of adult MDD. On December 18, 2003, the FDA approved Lexapro for the treatment of adult generalized anxiety disorder.

Celexa's Pediatric Efficacy Problem

28. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa" to the FDA. Forest wanted a get a six month extension of patent exclusivity for Celexa pursuant to 21 U.S.C.A. § 355a (worth an estimated $485 million to Forest in revenue). On April 28, 1999, the FDA issued a Written Request to Forest to conduct "two independent, adequate and well-controlled clinical trials in pediatric depression" for Celexa.

29. On September 24, 1999, Forest submitted protocols to the FDA describing two clinical trials designed to test the efficacy and safety of Celexa in treating pediatric depression. The first study, Study 94404, was to be conducted by Lundbeck and was designed to test the safety and efficacy of Celexa in treating adolescents for depression ("Celexa Study 94404"). The second study, Study 18, was to be conducted by Dr. Karen D. Wagner of the University of Texas at Galveston, and would test the safety and efficacy of Celexa in treating children and adolescents for depression ("Celexa Study 18").

30. The first study, Celexa Study 94404, evaluated 233 adolescents, between the ages of thirteen (13) and eighteen (18) who had been diagnosed with

MDD lasting longer than four (4) weeks. The trial lasted twelve (12) weeks for each participant and the study was completed in March 2001. Half of the participants were given Celexa and half were given placebo. At the beginning of the twelve week trial, participants were tested with the Schedule for Affective Disorders and Schizophrenia for School Aged Children ("Kiddie-SADS-P") which yielded a numeric baseline score.[3] Then, after the twelve (12) week trial, the participants were tested again using the Kiddie-SADS-P scale. The overall reduction of the Kiddie-SADS-P score was the measure of efficacy.

31. Celexa Study 94404 was negative for pediatric efficacy. Participants taking Celexa experienced an average 12.4 point improvement of their Kiddie-SADS-P score and the placebo group received a 12.7 point improvement. Although the placebo group outperformed Celexa in treating depression, that difference was not statistically significant. The results of Celexa Study 94404 were sent in an email on July 16, 2001 to Forest executives which read "citalopram vs placebo in the treatment of adolescent depression have been unblinded and unfortunately with a negative result. It was not possible to detect a significant difference between the two treatment groups."

32. The second study, Celexa Study 18, evaluated 178 children and adolescents, between the ages of 7-11 and 12-17 respectively, to determine whether the use of Celexa to treat depression was safe and effective. To qualify for the study, the participant had to have been suffering from MDD for at least four

[3] In addition, participants were tested using several other depression metrics, but the results of these tests were considered secondary endpoints.

(4) weeks and all participants had to have a Children's Depression Rating Scale—Revised ("CDRS-R") score greater than or equal to forty (40). However, after initially qualifying, participants were put on a placebo for one week. Only if, after the week on placebo, the participant's CDRS-R remained above forty (40) would they be allowed to participate in the trial.[4] Celexa Study 18 consisted of eight (8) weeks of treatment with either Celexa or placebo. At the end of the eight (8) weeks, the participant's CDRS-R score was taken again. Celexa Study 18 was completed in April 2001 and was subsequently distributed to Forest Executives in mid-2001.

33. Celexa Study 18 purported to be a positive study. According to the report, participants taking Celexa had an average 21.7 point improvement of their CDRS-R score, whereas participants taking placebo had an average 16.5 point improvement of their CDRS-R score. This difference in point averages, according to statistical modeling, resulted in a 4.6 point difference between Celexa and placebo in treating pediatric MDD. This 4.6 point difference was, according to the

[4] Using a one week placebo lead-in period in an efficacy study leaves the door wide open for companies and their paid researchers to influence the outcome of the study. If the purpose of conducting an efficacy trial is to determine whether the subject drug is superior to placebo, then "washing out" those participants who respond significantly to the placebo effect before the study begins creates a bias in the sample. Those people who respond the most to the placebo effect are categorically removed from the sample thus bolstering the "effect" seen in the treatment group relative to the control group. This aspect of Celexa Study 18 was pointed out by doctors reviewing the published version of the study, with one doctor noting that "a placebo run-in period might help to 'wash out' nonspecific responders, allowing sharper evaluation of treatment-specific effects as shown in some pharmacotherapy studies." Remy P. Barbel, Letters to Editor, *Child Psychopharmacology, Effect Sizes and the Big Bang*, 162 AM. J. PSYCHIATRY 4, 817-18 (April 2005).

study, statistically significant.[5] When Celexa Study 18 was publicly published, the "authors" chose to represent the difference in effect between Celexa and placebo as a response rate. The response rate was calculated by determining whether the participant's CDRS-R score was lower than or equal to twenty-eight (28). In the published Celexa Study 18, the response rate for Celexa was 36% whereas the response rate for placebo was 24%.

34. On its face, this variation in response, a 4.6 point improvement on the CDRS-R scale (or 12% response rate difference) is not clinically significant. As Doctor Maju Mathews stated in a Letter to the Editor criticizing the published version of Celexa Study 18:

> Our greatest concern is with the results and conclusions drawn. There is no table showing the results in detail. The authors have only stated that 36% of [Celexa]-treated patients met the criteria for response, compared to 24% of patients receiving placebo. This response rate, while in itself marginal compared to other studies of antidepressants, does not in itself show that [Celexa] is better than placebo.

35. Maju Mathews, M.D., Letters to Editor, *Child Psychopharmacology, Effect Sizes and the Big Bang*, 162 AM. J. PSYCHIATRY 4, 818 (April 2005). After conducting a basic evaluation of the data presented in the published Celexa Study 18, Dr. Mathews noted that "the number of children who need to be treated with [Celexa] for one additional positive outcome was eight." *Id.* He concluded that in

[5] To gain some perspective on whether a 4.6 point difference is clinically significant, studies show that requiring children and adolescents to exercise twice a week results, on average, in a 20.4 point improvement of their CDRS-R score in patients whose baseline CDRS-R was on average 48.9 points, *i.e.*, clinically depressed. Notably absent from an exercise treatment regimen are many of the risks associated with taking an antidepressant—as well as any potential profit for a drug manufacturer.

light of such a marginal benefit "[n]one of these shows that [Celexa] is any better than placebo." *Id.*

36. As it turns out, Dr. Mathews' criticism of Celexa Study 18 was well founded. A close evaluation of the unpublished version of Celexa Study 18 reveals that data was manipulated to create the appearance of statistical significance. In other words, the purported results of Celexa Study 18 are fraudulent and misleading. During the study, the first nine (9) participants were given "1 week of medication with potentially unblinding information (tablets had an incorrect color coating)." When the data for Celexa Study 18 was first analyzed, the researchers correctly excluded the data from the unblinded participants, realizing it was unreliable. The results of the initial statistical analysis showed that CDRS-R score difference was *not statistically significant*. Thus, the unbiased and unadulterated data of Celexa Study 18 was negative for efficacy. However, faced with having a clinical trial show that Celexa failed to significantly outperform placebo for treating pediatric depression, the researchers decided to *include* the data from the unblinded participants. By adding the unblinded patients' data, Celexa Study 18 was able to find statistical significance between the treatment and placebo-control group—even if only marginal. Use of unblinded patients is inconsistent with the whole point of a double blinded placebo controlled trial – using them meant it was not a double blinded placebo controlled trial, and promoting Celexa Study 18's results as if they were a fully randomized, double blinded placebo controlled trial was extremely misleading.

37. Forest also misrepresented the authorship of Celexa Study 18. In fact,

the manuscript was written by a "medical communications" (ghostwriting) company in coordination with Forest's marketing department. The purported author, Karen Wagner, did not see a draft of the paper until quite late in its development. According to email correspondence between Forest and the medical communications company: "I've heard through the grapevine that not all the data look as great as the primary outcome data. For these reasons (speed and greater control) I think it makes sense to prepare a draft in-house that can then be provided to Karen Wagner (or whomever) for review and comments." Another email notes: "I don't know that any decision has been made about who is going to write the manuscript (not to be confused with who is going to be the author(s) of the manuscript, which also isn't decided, as far as I know). But, for reasons I'll list below, I think it would make sense to have a first draft prepared in-house." Another email exchange states: "Given what I have seen of the data, I believe we should maintain control, which means either writing in-house or having an outside group [medical communications companies] draft the manuscript."

38. The published version of Celexa Study 18 had numerous other flaws, including but not limited to the fact that Forest presented the effect size in an incorrect and misleading manner and intentionally decided not to report pre-determined secondary outcomes, all of which proved unfavorable to Celexa. In an internal Forest email exchange, employees discussed ways to "avoid mentioning the lack of statistically significant positive effects at week 8 or study termination for secondary endpoints."

39. On April 18, 2002, Forest submitted the results of Celexa Study

94404 and Celexa Study 18 to the FDA. Forest submitted these studies as part of a request to extend its patent exclusivity on Celexa, which was set to expire at the end of 2002, pursuant to 21 U.S.C.A. § 355a. In addition, Forest submitted a supplemental NDA to the FDA requesting a pediatric indication for Celexa.

40. On July 15, 2002, the FDA granted Forest six additional months of patent exclusivity for the use of Celexa in the treatment of adult MDD.

41. On September 23, 2002, the FDA denied Forest's supplemental NDA requesting a pediatric indication for Celexa. The FDA concluded that Forest had failed to meet the regulatory threshold of providing two well-controlled clinical studies showing that Celexa was superior to placebo. Specifically, the FDA stated that Celexa Study 94404 "is a clearly negative study that provides no support for the efficacy of [Celexa] in pediatric patients with [MDD]."

Lexapro's Pediatric Efficacy Problem

42. Recognizing the revenue potential of having a pediatric indication, Forest began testing whether Lexapro was safe and effective in children and adult in December 2002.

43. The first study, Lexapro Study 15, was conducted by Dr. Wagner. It was started in December 2002 and was completed in December 2004. The trial evaluated 264 children and adolescents (only 217 completed the trial), between the ages of 6-17 to determine whether the use of Celexa to treat depression was safe and effective. Lexapro Study 15 mirrored Celexa Study 18. For instance, to qualify for the study, the participant had to have been suffering from MDD for at least four (4) weeks and all participants had to have a CDRS-R score greater than

or equal to forty (40). In addition, all participants were screened during a one-week placebo trial and only those participants whose CDRS-R remained above forty (40) after taking placebo for a week would be allowed to participate. Lexapro Study 15 consisted of eight (8) weeks of treatment with either Lexapro or placebo. At the end of the eight (8) weeks, the participant's CDRS-R score was taken again. The difference of the patient's CDRS-R score from the beginning to the end served as the metric for efficacy.

44. Lexapro Study 15 was negative for efficacy. Participants taking Lexapro experienced an average 20.3 point improvement of their CDRS-R score, whereas participants taking placebo received an average 20.9 point improvement of their CDRS-R score. Although the placebo group outperformed Lexapro in treating depression, that difference was not statistically significant.

45. Although Lexapro Study 15 showed that Lexapro was no more effective than placebo in treating pediatric MDD, Forest commissioned a second pediatric study involving Lexapro—Lexapro Study 32. Forest was very concerned with being able to legally promote Lexapo for pediatric use, particularly in light of recent competition. In January 2003, competitor Eli Lilly and Company received approval for its blockbuster drug Prozac in treating pediatric depression. Forest knew that there were billions to be made by securing a pediatric indication for Lexapro. As one Forest executive stated, "I understand that everything hinges on [Lexapro Study] 32."

46. Lexapro Study 32 was started in February 2005 and was completed in May 2007. The trial evaluated 316 adolescents (only 260 completed the trial),

between the ages of 12-17 to determine whether the use of Lexapro to treat depression was safe and effective. The study consisted of a two-week screening period, including single-blind placebo lead-in during the second week, followed by eight (8) weeks of double-blind treatment. Much like Celexa Study 18 and Lexapro Study 15, the study tracked changes in the participants CDRS-R score at week one and their CDRS-R score at week eight (8). The average baseline CDRS-R score of participants in the Lexapro control group was 57.6 and the average CDRS-R score of the placebo group was 56.[6]

47. Lexapro Study 32 purports to be positive for efficacy. Participants taking Lexapro experienced an average 22.4 point improvement of their CDRS-R score, whereas participants taking placebo received an average 18.4 point improvement of their CDRS-R score. This difference in point averages, according to statistical modeling, resulted in a 3.4 point difference between Lexapro and placebo in treating adolescent MDD.

48. On its face, Lexapro Study 32 has several problems. First, the fact that the Lexapro group started with a baseline CDRS-R score that was significantly higher than the placebo group, indicates that there was selection bias (not true randomization into the Lexapro and placebo groups). When the difference in baseline CDRS-R score is 1.7 points, there is a substantial likelihood that it will affect the final results, particularly when the difference between Lexapro and

[6] The difference in baseline scores between the Lexapro and placebo groups was statistically significant, which means that on average the participants who received Lexapro were more severely depressed than the group receiving placebo.

placebo is only 3.4 points. Second, Lexapro Study 32 had a two-week screening period which creates, from the beginning, selection bias against people who are susceptible to the placebo effect—effectively making Lexapro seem more effective than it is. Third, and most importantly, the 3.4 point difference of CDRS-R scores between Lexapro and placebo participants is not clinically significant. Other, less risky treatments have been shown to be more effective, and they do not involve the serious potential side-effects of using Lexapro.

49. Lexapro Study 32 was submitted to the Journal of the American Academy of Child and Adolescent Psychiatry for publication. As is customary for peer reviewed medical journals, the manuscript was submitted by the journal to a number of peer reviewers for comment. One reviewer made the following comments:

> [Comment 6.] The effect size (ES) reported as 0.27 may be comparable to prior reports, however, it should be noted that according to Chen this is a relatively small ES. Given this small ES, there were no data to see if this level of change had any quality of life meaning.
>
> [Comment 7.] It was not clear why the authors consider the baseline difference in the CDRS-R (~2 points) between the two treatment groups as not clinically significant even though it was statistically significant. This is confusing as the authors' then note that a CDRS-R treatment difference between the groups of ~2pts, which is statistically significant, shows efficacy. It was clear the authors controlled for these baseline severity scores but then what does a 2-point difference really mean for the adolescent? Is this a quality of life difference? *The primary outcome (CDRS-R) was significant but there was little discussion of why most of the secondary outcome measures were not significant.
>
> [Comment 8.] Finally, one has to wonder whether the restrictive entry criteria in conjunction with the small effect size limit the utility of [Lexapro] in the real world of adolescent MDD. Are these results

statistically significant but clinically not meaningful?[7]

50. Even though Forest had only one clinical trial that was allegedly positive for efficacy in adolescents, it still decided to "roll the dice" and apply to get Lexapro approved for adolescent populations. In May 2008, Forest submitted a supplemental NDA to the FDA requesting an indication for Lexapro in the treatment of adolescent MDD. As part of the application, Forest submitted Celexa Study 94404, the results of Celexa Study 18, Lexapro Study 15, and Lexapro Study 32.[8] The following chart reflects the clinical trials submitted in support of Lexapro's efficacy:

Study	*Stat. Efficacy*	*Clinical Efficacy*	*Placebo Effect*	*Drug Effect*	*Difference*
Celexa Study 94404	Negative	Negative	12.7 pts[9]	12.4 pts	(-0.3 pts)
Celexa Study 18	Positive[10]	Negative	16.5 pts	21.7 pts	4.6 pts
Lexapro Study 15	Negative	Negative	20.9 pts	20.3 pts	(-0.6 pts)
Lexapro Study 32	Positive	Negative	18.4 pts	22.4 pts	3.4 pts

51. Forest's supplemental NDA, therefore, did not provide two well-controlled studies demonstrating that Lexapro was statistically more effective than placebo in treating adolescents for MDD. Nonetheless, the FDA agreed "that it

[7] Notably, in response to Comment 8 above, Forest stated "clearly further research to address some of these issues is warranted." This statement was made in December 2008. However, between May 22, 2008 and March 6, 2009, while Forest was communicating with the FDA in an attempt to get a pediatric indication for Lexapro, Forest failed to conduct any further placebo-controlled pediatric studies of Lexapro.

[8] Forest also submitted Lexpapro Study 32A, which was a study conducted on the participants in the treatment group of Lexapro Study 32 after Lexapro Study 32 was completed to test whether the use of Lexapro was effective at maintenance in adolescent MDD. Since this study was not relevant to the issue of efficacy and used Study 32, it is not included here.

[9] Using the Kiddie-SADS-P scale.

[10] Based on corrupted unblinded data.

would be sufficient to provide data from 1 positive study with Lexapro" because the FDA "agreed to extrapolate on the basis of a previously reviewed positive study with [Celexa]."

52. Thus, the FDA accepted the questionable data from Lexapro Study 32 and the flawed data from Celexa Study 18 to conclude that Forest met its regulatory requirement of providing two well-controlled studies showing that Lexapro was effective for the treatment of adolescent MDD.[11] On March 20, 2009, Lexapro was approved by the FDA for use in adolescent MDD.

53. After receiving FDA approval, Forest issued a press release in which it's CEO, Howard Solomon, stated:

> We have long believed that Lexapro would be of benefit for the treatment of depression in adolescents and that is why we undertook the several studies described in the package insert. We are enormously gratified that Lexapro will be available for depressed adolescents who so much require the benefits which Lexapro has made available for depressed adults for the past seven years.

54. In a November 2011 article appearing in the Journal of the Canadian Academy of Child and Adolescent Psychiatry titled "A Review of Escitalopram and Citalopram in Child and Adolescent Depression," the authors criticize the FDA's approval of Lexapro (escitalopram) and point out that:

> While only one RCT for escitalopram was statistically superior to placebo on the primary outcome measure, according to Forest Laboratories, Inc. … the FDA decision to approve escitalopram was based on two RCTs [randomly controlled trials] – the escitalopram

[11] To be clear, Plaintiffs' claims herein are predicated on violations of state law and do not seek, in any way, to enforce FDA regulation or hold Forest accountable for committing fraud on the FDA.

> RCT with positive results [Lexapro Study 32] and an earlier trial with citalopram [Celexa Study 18].
>
> The citalopram trial [Celexa Study 18] that formed part of the basis for escitalopram FDA approval was alleged to have been written and submitted by a medical "ghost-writer" on behalf of Forest Laboratories, Inc. [citation omitted] In April 2009, one month after the FDA approval for escitalopram in adolescents was granted, Forest Laboratories admitted that a medical communication company, Prescott Medical Communications Group was not acknowledged as a contributor to the article at the time of publication.
> . . .
>
> The research groups that have studied citalopram and escitalopram for pediatric depression in RCTs are not independent groups, with the exception of the von Knorring group from Sweden [citation omitted]. However, the RCT by this group was a negative trial. [Celexa Study 94404].
> . . .
>
> From these data, escitalopram and citalopram should not be considered for first-line treatment of adolescent depression, given the lack of replication of positive studies by independent groups. . . . the US FDA approval of escitalopram was premature, given the available evidence.

55. The FDA's approval of Lexapro for adolescent MDD is not the first time the FDA has approved a drug of questionable efficacy. FDA officials and advisors have commented since the beginning of the modern antidepressant era that the agency's standards for approving antidepressants are minimal according to the law. For instance, during an FDA advisory committee meeting related to one of the SSRI antidepressants, Dr. Paul Leber, the Division Director of the FDA at the time explained that "the law, as far as I know, never discussed multiplicity," *i.e.*, the law does not address drugs where multiple clinical trials failed to show efficacy. Dr. Leber pointed out that the FDA does "not have a systematic program" to analyze multiple studies not submitted for an efficacy determination,

but admitted "[m]aybe there ought to be." He explained that: "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. . . [W]e have to look at the application submitted to us and recognize, in a way, that we can exhort people to do more. But the law did not set out a very Draconian or Procrustean set of standards that have to be met." Dr. Leber admitted "I have 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?" He explained that "over the past 27 years or so since people have been looking at that question, we have taken changes on the HAM-D, the Clinical Global Impression of severity, POMS [Profile of Mood States] factors and a variety of other things and taken those as testimony or indicators of efficacy. But that is tradition. That is not truth." Dr. Leber told the advisory committee members that they could tell the FDA "look, we think the standards in this field are terrible. People have been getting away with non-substantive efficacy for years. We'd like you to change your standards." Unfortunately, those minimal standards did not subsequently change.

Lexapro's Misleading Drug Label

56. The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, provides that a drug is misbranded when its label is false or misleading in any particular, or if any required information appears on the label in such terms as to render it unlikely to be read and understood by the ordinary individual under customary conditions of purchase and use. The FDA has passed many regulations

effectuating the FDCA and specifying, in detail, the labeling requirements of prescription drugs. Specifically, 21 C.F.R. § 201.56(a)(1) provides that "[t]he labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug." In addition, 21 C.F.R. § 201.56(a)(2) provides that "[t]he labeling must be informative and accurate and neither promotional in tone or false or misleading in any particular."

57. The drug label for Lexapro is misleading and inadequate. Specifically, the drug label states materially false statements about Celexa Study 18, omits material information about Lexapro Study 32 and does not present the totality of the essential scientific information in a way that would allow for the safe and effective use of the drug. Lexapro's drug label was changed following its approval for adolescent MDD in March 2009. Under the Section "Pediatric Use" the label stated:

> Safety and effectiveness of Lexapro has not been established in pediatric patients (less than 12 years of age) with Major Depressive Disorder. Safety and effectiveness of Lexapro has been established in adolescents (12 to 17 years of age) for the treatment of major depressive disorder [see Clinical Studies (14.1)].

Under the Section "Clinical Studies" the label stated (emphasis added):

> Adolescents
>
> The efficacy of Lexapro as an acute treatment for major depressive disorder in adolescent patients was established in an 8-week, flexible-dose, placebo-controlled study that compared Lexapro 10-20 mg/day to placebo in outpatients 12 to 17 years of age inclusive who met DSM-IV criteria for major depressive disorder [*i.e.*, Lexapro Study 32]. The primary outcome was change from baseline to endpoint in the Children's Depression Rating Scale - Revised (CDRS-R). **In this study, Lexapro showed statistically significant greater mean**

improvement compared to placebo on the CDRS-R.

The efficacy of Lexapro in the acute treatment of major depressive disorder in adolescents was established, in part, on the basis of extrapolation from the 8-week, flexible-dose, placebo-controlled study with racemic citalopram 20-40 mg/day [*i.e.*, Celexa Study 18]. **In this outpatient study in children and adolescents 7 to 17 years of age who met DSM-IV criteria for major depressive disorder, citalopram treatment showed statistically significant greater mean improvement from baseline, compared to placebo, on the CDRS-R**; the positive results for this trial largely came from the adolescent subgroup.

Two additional flexible-dose, placebo-controlled MDD studies (one Lexapro study in patients ages 7 to 17 and one citalopram study in adolescents) did not demonstrate efficacy.

58. This label is fundamentally misleading for a variety of reasons. First, the label states that Celexa Study 18 "showed statistically significant greater mean improvement from baseline, compared to placebo, on the CDRS-R[.]" This statement is materially false since, as described above, the statistical significance of Celexa Study 18 is predicated on a manipulation of data. The actual results of Celexa Study 18 indicate that Celexa was not superior to Lexapro in treating pediatric depression. By including this information on Lexapro's drug label as justification for Forest's claim that Lexapro is effective for adolescent MDD, Forest blatantly misled consumers and prescribing healthcare professionals in violation of consumer protection law.

59. Second, the label states that the data in Lexapro Study 32 demonstrated that "Lexapro showed statistically significant greater mean improvement compared to placebo on the CDRS-R." This statement is misleading because it does not provide any indication that the difference between Lexapro and placebo as seen in Lexapro Study 32 was statistically marginal, and not clinically

meaningful. Without some indication of how much Lexapro outperformed placebo, consumers and prescribing healthcare professionals cannot properly weigh the risks versus benefits of using Lexapro to treat adolescent MDD.

60. Moreover, while Forest mentions that "[t]wo additional flexible-dose, placebo-controlled MDD studies (one Lexapro study in patients ages 7 to 17 and one citalopram study in adolescents) did not demonstrate efficacy" (Lexapro Study 15 and Celexa Study 94404), the totality of the data, examined from every perspective, illustrates that Forest's representation that Lexapro is an effective treatment for adolescent depression is unsupported.[12]

61. Forest had a duty to fairly and honestly deal with consumers and prescribing healthcare professionals, and by artfully omitting this material information, Forest misled consumers and prescribing healthcare professionals in violation of consumer protection law.

62. In sum, the Lexapro label as it existed from 2009 until the present was, and continues to be, fundamentally misleading because it suggests, despite clinical data to the contrary, that Lexapro is more effective at treating adolescent MDD than it actually is. Consumers and prescribing healthcare professionals deserve to know what Lexapro's efficacy truly is in treating adolescent MDD and

[12] Analyzing the four clinical trials of Celexa and Lexapro together shows that the drugs are not more likely than placebo to bring about a meaningful improvement. Analyzing the two Celexa studies combined shows there is no convincing evidence that treatment produced a clinically meaningful benefit. Likewise, the two Lexapro trials, combined, do not provide convincing evidence of efficacy. *See also* Carandang et al.,"A Review of Escitalopram and Citalopram in Child and Adolescent Depression," Journal of the Canadian Academy of Child and Adolescent Psychiatry, November 2011 ("From these data, escitalopram and citalopram should not be considered for first-line treatment of adolescent depression, given the lack of replication of positive studies by independent groups. . . . the US FDA approval of escitalopram was premature, given the available evidence.").

decide, in light of accurate and complete clinical trial data, whether purchasing Lexapro is worth the risks. By omitting this material information and misrepresenting the actual results of Celexa Study 18, Forest robbed consumers and prescribing healthcare professionals of having sufficient information to properly decide whether to purchase or prescribe Lexapro for adolescent use.

Plaintiffs Were Misled into Purchasing Lexapro

63. On or about April 21, 2009, Plaintiffs Randy and Bonnie Marcus's son, aged seventeen, was prescribed a twenty (20) mg daily dose of Lexapro by his physician to treat his ongoing depression. This prescription was issued approximately one month after Lexapro had been approved for adolescent MDD.

64. Based upon the representations made by Forest regarding Lexapro's efficacy in treating adolescent MDD, Plaintiffs began purchasing Lexapro for their son. Plaintiffs, however, were misled by Forest's deceptive representations about Lexapro's efficacy.

65. Upon information and belief, the physician who prescribed Lexapro to Plaintiffs' son was also misled into prescribing Lexapro because the physician was led to believe, based on Forest's deceptive and unlawful marketing, that Lexapro was more effective in treating adolescent MDD than it actually was. This deception occurred as a result of the same misleading conduct that was directed toward the Plaintiffs—a misleading drug label and deceptive marketing.

66. Plaintiffs continued to purchase Lexapro for their son until April 2011.

67. In total, between April 2009 and April 2011, Plaintiffs spent

approximately $495.00 of their own money to purchase Lexapro to treat their son's depression. $175.00 of that money was spent while their son was an adolescent, *i.e.*, under eighteen years of age. In total, with insurance payments, Forest received approximately $1,250.04 .

68. Prior to purchasing Lexapro for their son, Plaintiffs read over Lexapro's drug label. Relying on the representations about Lexapro's adolescent efficacy, Plaintiffs were induced into purchasing Lexapro for their son.

69. During the period in which Plaintiffs were purchasing Lexapro for their minor child, Plaintiffs did not know that Lexapro's drug label and advertising were deceptive or that they lacked material information about the drug's efficacy in treating adolescent depression.

70. In early 2013, Plaintiffs discovered that Forest had misrepresented Lexapro's efficacy, and that the company had been stating the drug was more effective than it actually was. Plaintiffs learned that the clinical trials related to adolescent efficacy showed Lexapro is not clinically more effective than placebo. Plaintiffs would never have purchased Lexapro for their son if this information had been made known to them. In other words, Plaintiffs relied on the sufficiency and accuracy of Forest's representations about Lexapro's efficacy in adolescents in making their decision to purchase Lexapro.

CASS ALLEGATIONS

71. Plaintiffs bring Counts I and II against Forest on behalf of themselves and those similarly situated. As discussed at length in this Complaint, Forest deliberately withheld from consumers that the clinical trials designed to prove

Lexapro's adolescent efficacy actually showed that it was no better than a placebo. Specifically, the Lexapro drug label misrepresented the results of Celexa Study 18 as demonstrating adolescent efficacy when it did not. In addition, the Lexapro drug label omits material information about the actual results of the one clinical trial purporting to demonstrate that Lexapro is effective for adolescent MDD. Moreover, the label does not present the totality of the essential scientific information in a way that would allow for the safe and effective use of the drug.

72. These false statements and material omissions were directed at every consumer and their prescribing healthcare professionals. Moreover, since the false and misleading representations pertain to the issue of efficacy, they are material—no consumer or prescribing healthcare professional would purchase or prescribe a side-effect ridden sugar pill. Because of this uniformity of deceptive and unlawful marketing, this matter is uniquely suitable for a consumer class action.

73. The class is defined as follows:

> All consumers and entities (other than governmental entities) who paid for Lexapro, purchased in the State of California, for use by an adolescent, between March 2009 and the present. This class does not include those individuals who are seeking personal injury claims arising out of their purchase of Lexapro. ("California Consumer Class")

74. 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. Hundreds of thousands if not millions of Lexapro prescriptions have been filled in the State of California for use in treating adolescent MDD.

b. Commonality: Questions of law and fact are common to all members of the California Consumer Class. Forest'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 I and II, against Forest, which involve common issues of fact and law applicable to all California Consumer Class members.

c. Typicality: Plaintiffs' claims are typical of the claims of the California Consumer Class, because their claims arise from the same course of conduct by Forest, *i.e.*, deceptive and unlawful marketing practices related to Lexapro. Plaintiffs are typical class representatives because, like all members of the California Consumer Class, they purchased Lexapro in California that was unfairly, deceptively and unlawfully marketed to consumers within California.

d. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the California Consumer Class. Their consumer protection claims are common to all members of the California Consumer Class and they have a strong interest in vindicating their consumer rights. In addition, Plaintiffs and the California Consumer

Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

75. 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. Forest deliberately concealed material facts about Lexapro's adolescent 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 and there is similar exposure to the misleading conduct. Here, the efficacy of Lexapro in treating adolescent MDD was uniformly expressed to all consumers in California. Moreover, the efficacy of a drug is, by definition, a material component of whether a consumer will purchase a drug. Thus, under California's various consumer protection laws, the question of Forest'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
CALIFORNIA CONSUMERS CLASS
VIOLATIONS OF CAL. CIV. CODE §§ 1750, *ET SEQ.*

76. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

77. 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.

78. Plaintiffs 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. Plaintiffs and California Consumer Class purchased and/or paid for Lexapro for personal and/or family and/or household use during the relevant time period.

79. As alleged throughout this Complaint, Forest deliberately engaged in deceptive and unlawful marketing in violation of Civ. Code § 1770(a) by representing to the Plaintiffs and California Consumer Class that Lexapro was more effective at treating adolescent MDD than it actually was. Forest failed to

adequately disclose material information about Lexapro's efficacy in treating adolescent depression and, in so doing, deprived Plaintiffs and the California Consumer Class of an ability to make an informed decision.

80. Specifically, Forest violated the following proscribed practices pursuant to Cal. Civ. Code § 1770(a) with the purpose of inducing Plaintiffs and the California Consumer Class to purchase Lexapro for adolescent use:

a. § 1770(a)(2): Forest represented to Plaintiffs and the California Consumer Class that Lexapro was proven to be superior to placebo in treating adolescent MDD, when in fact the clinical data did not support this claim. This gave a false certification of Lexapro's efficacy because the clinical trial results, as represented by Forest, were skewed and Forest was aware of this problem.

b. § 1770(a)(5): Forest represented to Plaintiffs and the California Consumer Class that Lexapro has a specific use, benefit, or characteristic which it did not have, to wit, that Lexapro is more effective for the treatment of adolescent MDD than it actually is. Making false representations and omitting material information about the results of clinical trials purporting to show Lexapro's efficacy constituted a misrepresentation concerning a use, benefit, or characteristic.

c. § 1770(a)(7): Forest misrepresented to Plaintiffs and the California Consumer Class that Lexapro was of a particular standard, quality, or grade., *i.e.*, substantially more effective for the treatment of adolescent

MDD than it was. In truth, Lexapro was not as effective as Lexapro's drug label represented. Forest's failure to properly disclose Lexapro's true efficacy in treating adolescent MDD, as observed in the clinical data purporting to show Lexapro's efficacy, constituted a misrepresentation of a material standard, quality, or grade.

d. § 1770(a)(9): Forest advertised to Plaintiffs and the California Consumer Class that Lexapro was an effective and safe drug for the treatment of adolescent MDD, when in truth, Forest knew that Lexapro was clinically ineffective. Forest concealed this information from Plaintiffs and the California Consumer Class by making false statements and omitting material information about the actual results of clinical trials purporting to show Lexapro's efficacy.

81. Forest's misrepresentation and omission of clinical data on Lexapro's drug label was material because consumers and prescribing healthcare professionals should have known about this information prior to purchasing or prescribing Lexapro for the treatment of adolescent MDD.

82. Plaintiffs and the California Consumer Class lost money as a result of Forest's deceptive and unlawful marketing practices pursuant to Cal. Civ. Code § 1770(a), through the purchase of Lexapro that was illegally advertised and marketed in violation of Cal. Civ. Code § 1770(a).

83. As a result of Forest's violations of California's Consumer Legal Remedies Act, Plaintiffs seek an order of this Court permanently enjoining Forest from perpetrating its deceptive and unlawful marketing practices. Pursuant to Cal.

Civ. Code § 1782(d), if Forest does not take action to cease its deceptive and unlawful marketing practices and amend the current drug label to accurately reflect the efficacy of Lexapro within thirty (30) days of being served with this Complaint, Plaintiffs will amend this Complaint to seek, in addition to an order enjoining Forest from continuing its deceptive and unlawful practices, an order awarding, *inter alia*, Plaintiffs and the California Consumer Class actual damages, restitution, punitive damages, attorneys' fees and costs, and for such other relief as set forth below.

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

84. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

85. 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.

86. Forest engaged in substantial advertising and marketing of Lexapro within the State of California.

87. Because of Forest's unlawful, fraudulent, and unfair business practices, Plaintiffs and the California Consumer Class were misled into

purchasing Lexapro.

Unlawful Business Practices

88. As set forth in the preceding paragraphs, Forest has engaged in the unlawful business practice of misleading Plaintiffs and the California Consumer Class regarding Lexapro's true efficacy. Forest'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).

89. As a result of Forest's unlawful business practices, Plaintiffs and the California Consumer Class purchased Lexapro without sufficient information regarding a material aspect of the drug. Specifically, Plaintiffs and the California Consumer Class were misled into believing that Lexapro is more effective at treating adolecent MDD than it actually is. Plaintiffs and the California Consumer Class reasonably relied upon Forest's misrepresentations regarding Lexapro in deciding whether to purchase the drug.

90. In addition to engaging in unlawful marketing practices, Forest also engaged in an unlawful method of competition. Forest deliberately misled Plaintiffs and the California Consumer Class about Lexapro's efficacy and thereby artificially inflated Lexapro's price on the open market. Because Plaintiffs and the California Consumer Class were unaware of Lexapro's marginal-at-best ability to

treat adolescent MDD, they were more likely to purchase Lexapro as opposed to a competing antidepressant. The market was unable to correctly valuate Lexapro and, therefore, Forest gained an unlawful competitive advantage over competing antidepressant drugs. This unlawful method of competition resulted in Plaintiffs and the California Consumer Class paying a substantially higher price for Lexapro than it was actually worth.

Fraudulent Business Practices

91. As set forth in the preceding paragraphs, Forest has engaged in the fraudulent business practice of misleading Plaintiffs and the California Consumer Class regarding Lexapro's efficacy.

92. 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.

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

Unfair Business Practices

94. As set forth in the preceding paragraphs, Forest has engaged in an unfair business practice of misleading Plaintiffs and the California Consumer Class regarding Lexapro's ability to treat depression.

95. 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.

96. Forest's deceptive and unlawful marketing practices offend public policy and are fundamentally immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. Forest's scheme was to mislead consumers about Lexapro's efficacy by misrepresenting and suppressing material information about Lexapro efficacy in treating adolescent MDD. This conduct offends any notion of public policy and is truly unethical. Moreover, consumers who were tricked into purchasing the drug will suffer the risk of the many serious side-effects attendant to Lexapro.

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

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

EXEMPLARY DAMAGES ALLEGATIONS

99. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

100. Forest's conduct as alleged herein was done with oppression, fraud, and malice. Forest was fully aware of Celexa's and Lexapro's true efficacy as documented in its own clinical trials and internal company documents. Nonetheless, Forest deliberately crafted its drug label to mislead consumers and prescribing healthcare professionals into believing that Lexapro is more effective at treating pediatric and adolescent depression than it actually is. Moreover, Forest's comprehensive program of deceptive marketing was done in willful violation of federal and state law and with complete disregard for the safety and well being of Plaintiffs and the members of the class. Forest's conduct was not done by accident or through some justifiable negligence. Rather, Forest knew that it could turn a profit by convincing consumers and prescribing healthcare professionals that Lexapro is safe and effective at treating pediatric and adolescent depression. Such conduct was done with a conscious disregard of consumer rights.

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

DEMAND FOR JURY TRIAL

102. Plaintiffs respectfully requests a trial by jury on all claims triable as a matter of right.

PRAYER FOR RELIEF

103. WHEREFORE, Plaintiffs, individually and on behalf of the various

classes described herein, pray 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 the California Consumer Class;

b. Designate Plaintiffs as representatives for the California Consumer Class;

c. Issue a judgment against Forest that:

i. Permanently enjoins Forest from continuing to sell or market Lexapro with its current drug label and directing Forest to seek FDA approval of a new label that properly discloses Lexapro's efficacy in treating adolescent MDD;

ii. Grants Plaintiffs and the California Consumer Class a refund of all moneys acquired by Forest by means of its deceptive and unlawful marketing of Lexapro in Califorina;

iii. Grants Plaintiffs and the California Consumer Class an award of restitution and/or disgorgement of Forest's profits from its deceptive and unlawful marketing of Lexapro in violation of the consumer protection claims alleged in Counts I and II;

iv. Grants Plaintiffs 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 Plaintiffs and the California Consumer Class exemplary and punitive damages sufficient to punish and deter Forest and

others from future deceptive and unlawful marketing practices;

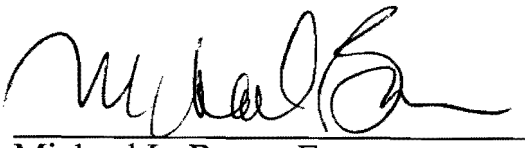
vi. Grants Plaintiffs and California Consumer Class pre-judgment and post-judgment interest

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

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

Dated: May 3, 2013

Respectfully Submitted,



Michael L. Baum, Esq.

R. Brent Wisner, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Telephone: (310) 207-3233
Fax: (310) 820-7444

Christopher L. Coffin, Esq.
Nicholas R. Rockforte, Esq.
David M. Hundley, Esq.
PENDLEY, BAUDIN & COFFIN, L.L.P.
1515 Poydras St., Suite 1400
New Orleans, LA 70112
Telephone: (225) 687-6396
Fax: (225) 687-6398

Attorneys for Plaintiffs and the California Consumer Class.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA

CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)

RANDY and BONNIE MARCUS, on behalf of themselves and all other persons similarly situated

DEFENDANTS

FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC.

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)

Michael L. Baum, Esq.
BAUM HEDLUND ARISTEI & GOLDMAN, PC
12100 Wilshire Boulevard
Suite 950
Los Angeles, California 90025
(310) 207-3233

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☒ Yes ☐ No ☒ **MONEY DEMANDED IN COMPLAINT: $** TBD

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

1) VIOLATIONS OF CAL. CIV. CODE §§ 1750, ET SEQ.;
2) VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17200, ET SEQ.

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Act
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Info. Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☒ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpractice
- ☐ 365 Personal Injury-Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus-Alien Detainee
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 444 Welfare
- ☐ 445 American with Disabilities - Employment
- ☐ 446 American with Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence Habeas Corpus
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus/ Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/ PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: SACV13-714

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? [X] No [ ] Yes

If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? [X] No [ ] Yes

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)
- [ ] A. Arise from the same or closely related transactions, happenings, or events; or
- [ ] B. Call for determination of the same or substantially related or similar questions of law and fact; or
- [ ] C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- [ ] D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.

[ ] Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.

[ ] Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	Forest Laboratories, Inc. - New York Forest Pharmaceuticals, Inc. - Missouri

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.

Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ **Date** May 3, 2013

Michael L. Baum, Esq.

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))