UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION ANGELA JAECKEL, RUTH DUNHAM, TANYA SHIPPY, and MARTHA and PETER PALUMBO, on behalf of themselves and all others similarly situated, Plaintiffs, v. FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC. Defendants.	MDL No. 2067 Master Docket No. 09-MD-2067-(NMG) Judge Nathaniel M. Gorton Magistrate Judge Marianne B. Bowler SECOND AMENDED COMPLAINT CONSUMER CLASS ACTION JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT

This case is involves a sophisticated program of deceptive conduct, carefully crafted around a nuanced regulatory scheme.[1] Using a fundamentally misleading drug label, the "endorsements" of paid opinion leaders, gerrymandered clinical trials, and a legion of specially trained sales personnel, Defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc. (collectively, "Forest") misled consumers and the medical community about Celexa's and Lexapro's efficacy in treating pediatric depression. By misrepresenting Celexa's and Lexapro's efficacy, Forest violated the consumer protection statutes of the States of Illinois, Missouri, and New York. This class action, brought on behalf of consumers and third-party payers in Illinois, Missouri, and New York, seeks to hold Forest accountable for its deceptive marketing.

[1] In Plaintiffs' original complaint, the allegations primarily focused on Forest's off-label promotion of Celexa and Lexapro. While Plaintiffs maintain that Forest's off-label promotion activity is illegal, and relevant to the unethical pattern of conduct giving rise to this class action, it is not the focus of Plaintiffs' claims.

TABLE OF CONTENTS

NATURE OF ACTION

1. The clinical trials that examined whether the antidepressants Celexa and Lexapro are effective at treating pediatric major depressive disorder ("MDD") indicate that Celexa and Lexapro are no more effective clinically than a sugar pill. The clinical trials show that any perceived benefit pediatric patients receive from taking Celexa or Lexapro 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. Starting in 2001, when the first two clinical trials of Celexa in pediatric patients indicated it was not superior to placebo in treating MDD, Defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc. ("Forest") definitively learned that Celexa lacked efficacy in pediatric patients. However, instead of limiting marketing efforts to promote Celexa and Lexapro to adult populations, Forest concocted a comprehensive and aggressive program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's pediatric efficacy.

3. The program started with Celexa's and Lexapro's drug label[2], which was and continues to be directed at every consumer and prescribing healthcare professional in the United States. Following the completion of Celexa's pediatric efficacy trials in mid-2001, Forest was under an obligation to update Celexa's existing drug label to reflect the results of the negative pediatric studies. Similarly, when Lexapro entered the market in early 2002, Forest was under an obligation to include the negative Celexa trial data on its label. However, instead of disclosing the results of the negative studies on the label, Forest decided to manipulate the situation so as to convey Celexa and Lexapro as effective treatments for pediatric MDD. Forest suppressed the dissemination of one of the negative trials and doctored the data of the other to make the study

[2] 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.

appear "positive." Using the fraudulently "positive" study, Forest began a widespread campaign to promote the "positive" results to the medical community. At that time, there was a vacuum of information about Celexa's pediatric efficacy, the aggressive dissemination of the fraudulent "positive" study led to a widespread belief within the medical community that Celexa was, in fact, an effective treatment for pediatric MDD. This widespread deception was also attributed to Lexapro, which is generally believed to be the same as Celexa.[3] Forest finally corrected the Celexa label in 2005, although it never fixed the Lexapro label, to include the results of the negative trials. But, by then, the damage was done.

4. In addition to a misleading and deceptive label, Forest also directly misled prescribing doctors about Celexa's and Lexapro's efficacy in treating pediatric MDD. This program of deception included:

a. Crafting a company-wide marketing plan to specifically increase pediatric use of the Celexa and Lexpro;

b. Training an aggressive sales force to tell prescribing healthcare professionals that Celexa and Lexapro were effective treatments for children and adolescents, using fraudulent clinical data and paid-for endorsements from leaders in the medical profession;

c. Paying millions to medical professionals to "present" the use of Celexa and Lexapro in pediatric populations as an effective treatment for pediatric MDD, despite lacking proper scientific support;

d. Paying physicians directly to participate in "advisory boards" wherein Forest was able to convey marketing messages, which included pediatric use;

e. Paying physicians directed to participate in a bogus "clinical trial" designed to get

[3] A fact that was endorsed by the FDA when it approved Lexapro for use in adolescents in 2009 based, in part, on a Celexa trial. As discussed later on in this Second Amended Complaint, the Celexa study used by the FDA was fraudulent.

physicians experience prescribing a Celexa and Lexapro; and

f. Paying physicians with money and lavish gifts to continue prescribing Celexa and Lexapro.

5. Forest knew that disclosing Celexa and Lexapro's true pediatric efficacy to consumers and prescribing healthcare professionals would have drastically reduced the drugs' revenue potential. So, instead of being honest and straightforward with consumers and prescribing healthcare professionals and allowing them to decide, for themselves, if Celexa and Lexapro were worth the risk, Forest hid the efficacy data, mislead consumers and prescribing healthcare professionals, and positioned Celexa and Lexapro as effective pediatric medications in the medical community.

6. Each Plaintiff, representative of the putative class members within the States of Illinois, Missouri, and New York, purchased Celexa and Lexapro for use in their children believing, because of Forest's comprehensive program of deceptive promotion, that Celexa and Lexapro were effective treatments for their child's depression. They were misled. Accordingly, Plaintiffs bring this class action on behalf of consumers and third-party payors in Illinois, Missouri, and New York, seeking to hold Forest accountable for its unlawful and deceptive marketing.

PARTIES

7. Plaintiff Angela Jaeckel is currently a citizen of the State of Illinois, domiciled in the city of Mundelein located in Lake County. Plaintiff Jaekel paid, in whole or in part, for Celexa and/or Lexapro for use by her minor child. The events giving rise to Plaintiff Jaeckel's claims, as alleged in this Second Amended Complaint, occurred in the State of Illinois.

8. Plaintiff Ruth Dunham is currently a citizen of the State of Missouri, domiciled in the city of St. Charles located in St. Charles County. Plaintiff Dunham paid, in whole or in part, for Celexa and/or Lexapro for use by her minor child. The events giving rise to Plaintiff Dunham's claims, as alleged in this Second Amended Complaint, occurred in State of Missouri.

9. Plaintiff Tanya Shippy is currently a citizen of the State of Missouri, domiciled in the city of Odessa located in Lafayette County. Plaintiff Shippy paid, in whole or in part, for Celexa and/or Lexapro for use by her minor child. The events giving rise to Plaintiff Shippy's claims, as alleged in this Second Amended Complaint, occurred in State of Missouri.

10. Plaintiffs Martha and Peter Palumbo are currently citizens of the Commonwealth of Pennsylvania, domiciled in the city of Bradford located in McKean County. The Palumbo Plaintiffs paid, in whole or in part, for Celexa and/or Lexapro for use by their minor child. The events giving rise to the Palumbo Plaintiffs' claims, as alleged in this Second Amended Complaint, occurred in the State of New York.

11. 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 regularly conducts business within all states in the United States, and derives substantial revenues from goods consumed in the United States. Forest Laboratories has a license from H. Lundbeck *A/S* ("Lundbeck"), a Danish pharmaceutical company, to promote and sell Celexa and Lexapro in the United States.

12. Defendant Forest Pharmaceuticals, Inc. is a wholly owned subsidiary of Forest Laboratories and is organized under the laws of Delaware with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals manufacturers, distributes, and sells prescription products, including Celexa and Lexapro, in the United States.

JURISDICTION AND VENUE

13. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(d). At least one member of the class is a citizen of a different state than Defendants Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. and the aggregate amount in controversy exceeds $5,000,000, exclusive of interests and costs.

14. The actions were originally filed in the United States District Court for the Eastern District of Missouri (Jaeckel) and the United States District Court for the Southern

District of New York (Palumbo), where the Courts had personal jurisdiction over Forest.

15. Before the Judicial Panel on Multidistrict Litigation transferred these actions from the United States District Court for the Eastern District of Missouri and the United States District Court for the Southern District of New York to the *In re Celexa and Lexapro Marketing and Sales Practices Litigation* in the United States District Court for the District of Massachusetts, venue was proper pursuant to 28 U.S.C. § 1391(b).

PEDIATRIC EFFICACY: CELEXA AND LEXAPRO

16. 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.

17. Forest is one of the largest pharmaceutical companies in the United States with annual revenues 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.

18. Celexa (citalopram) and Lexapro (escitalopram) are selective serotonin reuptake inhibitor ("SSRI") antidepressants 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 Celexa or 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 Celexa and Lexapro.

19. 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"). 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.

20. 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.[4] 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.

21. Once a drug is approved by the FDA, a pharmaceutical company is allowed to

[4] *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).

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 submit a separate supplemental NDA to the FDA for approval.

22. 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.

23. 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 and Efficacy

24. To obtain FDA approval, a 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.

25. The placebo effect is the effect that a drug has on a patient that has nothing to do with the ingredients in the drug, but is simply caused by the patient's *belief* that the drug 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).[5] 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 considered no more effective than a sugar pill.

26. Because Celexa and Lexapro are antidepressants, 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

[5] 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.

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. 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.

27. In an analysis of four selective serotonin reuptake inhibitor antidepressants (in the same class as escitalopram and citalopram), 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, including Celexa, 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., *British Medical Journal*, "Efficacy and safety of antidepressants for children and adolescents," November 2, 2005. In a separate editorial by Tonkin and Jureidini, 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." *See also* Whittington and Kendall, "Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data," *The Lancet*, April 24, 2004.

28. 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.

29. 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.

Forest Knew Celexa Was Not Effective at Treating Pediatric Depression

30. Celexa was originally developed and patented by the Danish pharmaceutical company H. Lundbeck A/S in 1989. The drug was initially marketed and sold in Europe, but in the early 1990's, Forest began working with Lundbeck to get Celexa approved for use in the United States.

31. In May 1997, Forest Laboratories submitted an NDA to the FDA for Celexa in the treatment of adult major depressive disorder ("MDD"). On August 17, 1998, the FDA approved the Celexa NDA to treat adult MDD. A year later, on December 22, 1999, the FDA approved Celexa for use as an oral liquid solution in treating adult MDD. Celexa was never approved by the FDA for use in pediatric populations.

32. Commercially, Celexa was an enormous success. In Forest's brochure to investors in 1999, it stated that, in "[j]ust eight months after launch, Celexa has captured more than a seven percent share of new prescriptions that are written for antidepressants." In fact, following Celexa's launch, sales of Celexa comprised 17% of all of Forest's revenue in 1999,

49% in 2000, 61% in 2001, 69% in 2002, and 77% in 2003. During that same period, Forest's annual revenue increased from $527 million in 1998 to $2.25 billion in 2003. This expansion of revenue was directly caused by Forest's success in marketing and selling Celexa which, according to Forest's annual report, "has come at the expense of the market leaders."

33. 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.

34. 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 Austin, and would test the safety and efficacy of Celexa in treating children and adolescents for depression ("Celexa Study 18").

Celexa Study 94404

35. In July 2001, Celexa Study 94404 and Celexa Study 18 were unblinded and their results were disseminated to senior Forest executives.

36. 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.[6] 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.

37. Celexa Study 94404 was negative for 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. [redacted]

Celexa Study 18

38. 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 (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.[7] Celexa Study 18 consisted of eight (8) weeks of treatment with either Celexa or placebo.

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

[7] 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 *cont'd . . .*

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.

39. 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 study, statistically significant.[8] 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%.

40. 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]-

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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).

[8] 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.

> 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.

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

41. 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.

42. Forest also misrepresented the authorship of Celexa Study 18. [redacted]

43. 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

FDA Denies Celexa Pediatric Indication

44. 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.

45. 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.

46. 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]."

Forest Knew Lexapro Was Not Effective at Treating Pediatric Depression

47. Forest knew that the patent exclusivity on Celexa was set to expire in late 2002. So, even before Celexa was approved for use in the United States, Forest and Lundbeck began development of a "new" antidepressant—one that could replace the anticipated revenue lost from Celexa going generic. This was how Lexapro was conceived.

48. Forest and Lundbeck began development of Lexapro in the summer of 1997 and submitted an NDA to the FDA in March of 2001. This short development period (3.5 years) is attributed to Lexapro's similarity to Celexa. 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.

49. On August 14, 2002, the FDA approved Lexapro for the treatment of adult MDD. On December 18, 2004, the FDA approved Lexapro for the treatment of adult generalized anxiety disorder. Lexapro was a consummate success. By the end of 2003, Lexapro had done its intended job and effectively replaced the revenues lost from Celexa going generic in 2003.

50. Forest, however, wanted to get Lexapro approved for pediatric populations. Accordingly, in anticipation of submitting a supplemental NDA for a pediatric indication, Forest began conducting pediatric studies with Lexapro.

Lexapro Study 15

51. The first study, Lexapro Study 15, which was conducted by Dr. Wagner, 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.

52. 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.

Lexapro Study 32

53. 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 Lexapro 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."

54. 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.[9]

55. 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.

56. 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 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

[9] 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.

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.

57. 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?[10]

FDA Approves Lexapro Pediatric Indication

58. 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

[10] 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.

Study 32.[11] 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[12]	12.4 pts	(-0.3 pts)
Celexa Study 18	Positive[13]	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

59. 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 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]."

60. 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.[14] On March 20, 2009, Lexapro was approved by the FDA for use in adolescent MDD.

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

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[11] 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.

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

[13] Based on fraudulent data.

[14] To be clear, Plaintiff's 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.

> We have long believed that Lexaporo 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.

62. The FDA's approval of Lexapro for adolescents has received considerable criticism. For instance, the website Psychcentral run by Dr. John M. Grohol pointed out:

> Lexapro … has been approved by the U.S. Food and Drug Administration (FDA) to treat depression in children ages 12 to 17 . . . Digging into the studies that resulted in the FDA's approval demonstrates a clearly mixed picture of Lexapro's effectiveness in children . . . [Y]ou have 2 studies that show effectiveness and 2 that do not, and you still approve because, according to Forest, 'it's very difficult to do depression studies'?! That's the strangest rationale I've ever heard from a pharmaceutical company defending its product's less-than-stellar data.

63. 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 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.

64. 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.

CONSUMER PROTECTION VIOLATIONS

65. Knowing full well that Celexa and Lexapro were not clinically effective for the treatment of pediatric MDD, Forest engaged in a comprehensive program to mislead and deceive consumers and prescribing healthcare professionals into believing that Celexa and Lexapro were clinically effective in treating pediatric MDD. Forest's program of deception included:

a. Crafting a misleading and deceptive drug label that omitted important information effectively depriving consumers and healthcare professionals of the ability to make an informed decision about whether to purchase Celexa or Lexapro for pediatric MDD; and

b. Developing and executing a company-wide marketing plan to promote the use of Celexa and Lexapro in pediatric patients in a false and misleading manner. This plan included:

i. Training an aggressive sales force to tell prescribing healthcare professionals that Celexa and Lexapro were effective treatments for children and adolescents, using fraudulent clinical data and paid-for endorsements from leaders in the medical profession;

ii. Paying millions to medical professionals to "present" the use of Celexa and Lexapro in pediatric populations as an effective treatment for pediatric MDD, despite lacking proper scientific support;

iii. Paying physicians directly to participate in "advisory boards" wherein Forest was able to convey marketing messages, which included pediatric use;

iv. Paying physicians directed to participate in a bogus "clinical trial" designed to get physicians experience prescribing a Celexa and Lexapro; and

v. Paying physicians with money and lavish gifts to continue prescribing Celexa and Lexapro.

Forest Published Misleading and Inadequate Labeling

66. The drug labels for Celexa and Lexapro were misleading and inadequate. Specifically, the drug labels for Celexa and Lexapro omitted material information about pediatric efficacy that would be required before a patient or prescribing physician could make an informed decision about whether to purchase or prescribe Celexa and Lexapro for pediatric use.

67. 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, to 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."

Celexa's Misleading Label from July 2001 – February 2005

68. When Celexa was first approved by the FDA to treat adult MDD in 1998, the drug label indicated under the section "Pediatric Use" that "[s]afety and effectiveness in pediatric patients have not been established." In 1998, when no pediatric studies had been completed, this representation on the label was not misleading or inaccurate.

69. In July-2001, however, when Celexa Study 94404 and Celexa Study 18 were unblinded and made available to Forest executives, Forest had an obligation to update the Celexa label to reflect that that two clinical trials had been conducted to evaluate the safety and efficacy of Celexa in pediatric populations and that they were both negative. Forest, however, did not take any action to update the Celexa label.

70. Then, in September 2002, when the FDA rejected Forest's supplemental NDA to

get a pediatric indication for Celexa, Forest again did not update its label to reflect that the FDA had expressly rejected a pediatric indication for Celexa.

71. It was not until Forest was required to update Celexa's label to provide FDA-mandated warnings about the increased risk of pediatric suicidality in 2005 that Forest finally added the relevant information about the failed pediatric efficacy studies. Specifically, in February 2005, Forest changed the Celexa label to read:

> Safety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS—Clinical Worsening and Suicide Risk). **Two placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients.** Anyone considering the use of Celexa in a child or adolescent must balance the potential risks with the clinical need.

This label was the first label since Celexa Study 94404 and Celexa Study 18 were unblinded that acknowledged, in carefully chosen words, Celexa's inability to effectively treat pediatric depression.

72. Accordingly, between mid-2001 and February 2005, the Celexa drug label was fundamentally misleading and materially deficient because it failed to provide material information that was available to Forest regarding whether Celexa was effective for pediatric depression. Forest had an obligation to provide this material information to consumers and prescribing healthcare professionals and breached that duty by failing to take any action to update or correct Celexa's label.

Lexapro's Misleading Label from July 2001 – February 2005

73. When Lexapro was first approved by the FDA to treat adult MDD in 2002, the drug label indicated under the section "Pediatric Use" that "[s]afety and effectiveness in pediatric patients have not been established." This description, however, was fundamentally misleading and deceptive because it omitted material information.

74. In July-2001, when Celexa Study 94404 and Celexa Study 18 were unblinded and made available to Forest executives. Forest had an obligation to ensure that the Lexapro label,

which was first issued in 2002, reflected that that two clinical trials had been conducted to evaluate the safety and efficacy of Celexa in pediatric populations and that they were both negative. Forest had consistently represented Lexapro as being nearly identical to Celexa and, thus, clinical trials relating to Celexa's efficacy in treating pediatric depression were essential in understanding Lexapro's pediatric efficacy. Forest's failure to include Celexa's negative data in the Lexapro label was misleading and deceptive.

Forest Crafted and Executed a Company-Wide Marketing Plan to Promote the Use of Celexa and Lexapro to Treat Pediatric MDD That Was Deceptive and Misleading

Company Policy and Practice of Deceptive Promotion

One-Sided Publications—Cultivating Misleading "Science" to Encourage Pediatric Use

76. Although Forest submitted Celexa Study 94404 to the FDA in 2002, Forest failed otherwise to disclose the negative study beyond a small group of its senior executives. At the same time, Forest aggressively promoted Celexa Study 18 as a "positive" study even though it was based on a fraudulent manipulation of data. This one-sided publication strategy relayed the false impression that pediatric use of Celexa was safe and effective, even though the clinical data

indicated otherwise.

77. Forest took aggressive steps to publicize the deceptively presented results of Celexa Study 18. On August 27, 2001, Forest presented Celexa Study 18 results to its Executive Advisory Board without making any mention of the contemporaneous negative Lundbeck results or the negative data and flaws in Celexa Study 18, including how statistical significance was achieved by including unblinded patients. Forest thereafter arranged for Dr. Wagner, the study's ostensible leader, to present a poster summary of the results of Celexa Study 18 to various professional groups, including the American Psychiatric Association, the American College of Neuropsychopharmacology, and the Collegium Internationale Neuro- PsychopharrnaIogicum. In these presentations, Dr. Wagner presented false, misleading and deceptive information concerning the efficacy of Celexa from Study 18 to those in attendance at the conferences. . In conjunction with these presentations, Forest coordinated the "placement" of news stories about Celexa Study 18's "positive" results in numerous national and local media outlets.

78. Over the course of 2002, Forest arranged for Dr. Wagner to give promotional presentations on the pediatric use of Celexa and to serve as the chair of a seven-city Continuing Medical Education ("CME") program on treating pediatric depression. Forest also sponsored twenty (20) CME teleconferences that addressed Celexa Study 18's results, providing false and misleading information to physicians about the efficacy of Celexa based on Celexa Study 18.

79. In all of these meetings, the improperly-included data used to find statistical significance in Celexa Study 18 was never disclosed, nor were the negative results of Celexa Study 94404.

80. This carefully orchestrated, early dissemination of false information created a domino effect within the medical community. By broadly disseminating the results of Celexa Study 18 in a highly misleading and deceptive way while simultaneously suppressing the negative results of Celexa Study 94404, Forest created a perception within the medical community that Celexa was safe and effective for pediatric MDD. Pointing to the seemingly

positive results of Celexa Study 18 and the lack of any negative studies, prescribers were easily convinced, through Forest's false, misleading and deceptive marketing and the resulting indirect statements that spread within the medical community, that Celexa was effective in treating pediatric MDD.

81. On June 21, 2004, the New York Times published a news story entitled "Medicine's Data Gap — Journals in a Quandry; How to Report on Drug Trials." The story featured The American Journal of Psychiatry article on Celexa Study 18, revealing the negative results of Celexa Study 94404. Three days after the story ran, Forest issued a press release acknowledging the existence of Celexa Study 94404 and its finding that Celexa "did not show efficacy versus placebo." That same day, Forest also disclosed the results of an earlier double-blind placebo-controlled study of Lexapro in children and adolescents—Lexapro Study 15, which was also negative.

82. After promoting the supposedly positive results of Celexa Study 18 for over three years, , and suppressing the results of Celexa Study 94404, the "cat was finally out of the bag." However, the damage caused by Forest's pervasive and one-sided promotion of manipulated "science" designed to legitimize the use of Celexa in pediatric populations had already taken a strong hold in the medical community. By July 2004, the proliferation of Celexa and Lexapro use in the pediatric population constituted a substantial percentage of Celexa and Lexapro sales.

Forest Sales Representatives Specifically Pushed Pediatric Use While Lacking of Scientific Support

83. Forest utilized numerous schemes to help further its mission to increase pediatric use (and sales) of Celexa and Lexapro, including paying pediatric specialists to give promotional speeches to other physicians on pediatric use; selectively distributing publications on pediatric uses to pediatric specialists; misrepresenting the safety and effectiveness of the drugs; and making extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses. But, of all these schemes, the most powerful and pervasive push came from the

massive and well-trained sales representative force whose sole objective was to get prescribing healthcare professionals to prescribe more Celexa and Lexapro.

84. Forest assigned its sales representatives to specific geographic regions across the United States. Within each region, sales representatives encouraged specific doctors to increase their prescriptions of Celexa and Lexapro. These sales representatives were specifically trained to represent Celexa and Lexapro as being an effective SSRI for children and adolescents. Pushing the pediatric use of Celexa and Lexapro despite the lack of scientific support for such use was a systematic duty of a Forest sales representative.

85. From 1998 through the end of 2004, the lists of physicians to whom Forest directed its sales representatives, also known as "call panels," included thousands of child psychiatrists, pediatricians, and other physicians who specialized in treating children. Forest had more than 500,000 promotional sales calls or "details" with these pediatric specialists. The sales representatives documented these details through "call notes." Forest recorded thousands of call notes evidencing its false and misleading pediatric promotion. Examples of such notes include the following:

- discussed cx [Celexa] use in children . . . and results of dr. karen wagner study [Celexa Study 18] regarding cx use for children and adolescents.
- went over peds use, 0 drug interactions, less ae [adverse events], less compliance issues for children, he is sold on that. closed on keeping cx first choice.
- went over Celexa children, the invitation to the winery.
- [doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!
- discuss lx [Lexapro] brief and what he [is] using dosing w children . . .reinforce safety for children.
- Let him know some child psychs are using LX for children.
- Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat

the anxiety and depression and OCD.

- dinner program [with child psychiatrist as speaker] at amato's with yale child study center.
- focus on Lexapro efficacy at just 10mg..great choice for child/adolescents.
- mainly sees children but always felt comfortable with CX & children -got his commitment to give [Lexapro] a fair clinical trial. went over lxp use on children and efficacy.

Call notes such as these represent only a small fraction of the instances in which sales representatives memorialized their promotion of Celexa and Lexapro.

Paid Presenters Push the Pediatric Efficacy Message

86. In addition to a large well-trained sales force, Forest also employed numerous physicians whose sole purpose was to puppet marketing messages designed by Forest to disseminate false and misleading Celexa and Lexapro efficacy data in order to get doctors to prescribe the drugs to their pediatric patients. Forest maintained a list of "approved" promotional speakers, many of which were pediatric specialists. Forest sales representatives and managers would organize promotional lunches and dinners on Celexa and Lexapro with these paid speakers to deliver a sales pitch to fellow doctors. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on pediatric use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment Options in Depressive Disorders in Adolescents," "Use of Antidepressants in Adolescents," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children," "Adolescents, and Adults," "Celexa in CHP/Ped Practice," "Treating Difficult Younger Patients," "Assessment and Treatment of Suicidal Adolescents," and "Treating Pediatric Depression."

[redacted]

[redacted]

"Advisory Boards"— a Pretext for Buying Goodwill (and Prescriptions)

88. In yet another component of Forest's company-wide program to push the use of Celexa and Lexapro for pediatric use by deceptive means, between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro which involved over 19,000 advisory board attendees that Forest called "consultants." As a "consultant" Forest paid each attendee an honorarium of $500. Ostensibly, Forest paid physicians to attend these advisory boards to get their feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal company documents, Forest intended that the advisory boards would induce the attendees to prescribe more Celexa and Lexapro. Many of these advisory boards involved the deceptive promotion of Celexa and Lexapro for use in pediatric populations.

[redacted]

The Exceed Study—A Pretext to Push Lexapro

96. In addition to the advisory board scheme, Forest used fake "clinical trials" as a ruse to pay prescribers to start prescribing Celexa and Lexapro. In 1998, Forest successfully used a so-called "seeding study"—a clinical study intended to induce participating physicians to prescribe the drug under study—as part of the promotional strategy for the launch of Celexa. With the launch of Lexapro in 2002, Forest sought to replicate the success of the Celexa seeding study. Forest called the Lexapro seeding study EXCEED (Examining Clinical Experience with Escitalopram in Depression).

97. In the planning stages for EXCEED, a senior Forest marketing executive wrote that the purpose of the study was to ensure a "fast uptake" for Lexapro. The overall Lexapro marketing plan, which was reviewed by the company's most senior executives, stated:

> Another component of the rapid uptake of Lexapro will be to encourage trial. The experience trial for Lexapro (EXCEED) will follow approval and will be larger in scope than the Celexa experience trial (EASE). More prescribers will have the ability to trial Lexapro on several patients to gain experience. Trial leads to adoption and continued usage of a product if a prescriber has successful results.

[redacted]To the extent the EXCEED trial had a scientific purpose, it was secondary to the purpose of inducing participating physicians to prescribe Lexapro [redacted]

99. Forest aimed the EXCEED study at 2,000 physicians, many of whom were specialists in pediatric care. Under the study protocol, each participating physician could enroll up to five (5) patients in the study, which would last eight (8) weeks and involve three (3) patient visits. After the first visit, the physician would fill out a one-page form with the patient's age,

race, gender, and basic medical history, and Forest would pay the physician $50. After each of the next two (2) visits, the physician would fill out an additional page requiring the physician to write the date of the visit and to check one of seven (7) boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two (2) other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten (10) patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference.

100. By the time the EXCEED study was completed, Forest had made study participation payments to 1,053 physicians, who in turn put 5,703 patients on Lexapro during the course of the study.

Preceptorships—Another Pretext to Buy Goodwill (and Prescriptions)

101. Between 1999 and 2003, Forest paid millions of dollars to physicians who participated in so-called "preceptorships." Each physician who participated in a preceptorship received a "grant" of as much as $1,000 per preceptorship. Ostensibly, preceptorships were a training opportunity where Forest sales representatives would spend a half-day or full day with a physician and learn about how Celexa and Lexapro were used in practice. In reality, Forest sales representatives used the preceptorships to induce physicians to prescribe Celexa and Lexapro.

102. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out ROI forms to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify

the cost to Forest. Senior Forest sales managers and headquarters staff reviewed and approved the completed preceptorship ROI forms. Many of these preceptorship payments were directed at pediatric specialists.

103. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments, included the following:

- Dr. ___ is the managing partner of the ___ Psychiatric Group and is very influential among his colleagues in the ___ Hospital network. He currently averages @ 12 per week on 1" RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. ___.
- Dr. ___ is the largest prescriber of SSRI's in a 3 state area. . . . We are currently her first line SSRI. We must, however, continue to support her monetarily or this will not continue to be the case. . . . We have to keep the pressure on to continue to receive the growth we are getting with Dr ___.
- Dr. ___ is my largest prescribing Celexa physician. He is a high maintenance target and doing round tables and preceptorships will help me to keep his business and to continue to grow his business.
- 2 different preceptorhsips. Doc is 3rd ranked phys. in SSRI potential + bus had dropped. Needed his full attention.
- Dr. ___ is my fourth largest SSRI writer. . . A preceptorship will provide opportunity for rapport and for future detail time and sales.
- # 1 physician in Territory. . . . Dr. ___ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship.
- This full day preceptorship will give me the opportunity to sell Celexa as a first-line choice in doctor's practice.
- To influence doctor to Rx Celexa.

Lavish Entertainment and Gifts—Forget Pretext

[redacted]

105. Prior to 2003, Forest sales representatives commonly spent their marketing money on fishing, golf, and spa outings for physicians, and on buying tickets to sporting events and the theater for physicians. Many of these physicians were pediatric specialists who exclusively or primarily treated pediatric populations. Both prior to and after 2003, Forest sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."
- In September 2002, a sales representative gave a high-prescribing child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.
- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.
- In June 2002, a sales representative arranged a salmon fishing charter cruise for

four physicians in his territory.

- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.
- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."
- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.
- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would "always rxlex [i. e. , prescribe Lexapro] 141 aslong [sic] as we have fun and take care of him."

106. These illegal kickbacks are yet another example of the lengths to which Forest was willing to go in order to entice doctors to prescribe Celexa and Lexapro for pediatric use despite a lack of scientific support to do so.

CLASS ALLEGATIONS

107. This matter is brought as a class action pursuant to Federal Rule of Civil Procedure 23, on behalf of consumers and entities within the States of Illinois, Missouri, and New York.[15] As discussed at length in this Second Amended Complaint, Forest has engaged in a comprehensive program to mislead consumers and prescribing healthcare professionals about

[15] Plaintiffs' Counsel is currently collecting records for additional class representatives for other states whose consumer protection rights have been violated by Forest's conduct. Once these cases are fully vetted, Plaintiffs' Counsel intends to file those cases in the relevant courts and move to transfer them into this MDL.

Celexa's and Lexapro's efficacy in treating pediatric MDD. Forest's conduct has been directed at consumers in all states in a uniform manner—using the same misleading and deceptive drug labels and same misleading and deceptive promotional practices. Class action law has long recognized that, when a company engages in misconduct that has uniformly harmed a large number of people, class resolution can be an effective tool to redress the harm. This is particularly true when the alleged misconduct was directed categorically at a class of people and that class of people is directly harmed by that conduct. Accordingly, this Second Amended Complaint is uniquely suited for class-wide resolution.

108. There are three classes of consumers that are contemplated as part of the Second Amended Complaint which arise under the various consumer protection statues in Illinois, Missouri, and New York. The classes are defined as follows:

Illinois Class

All consumers and entities (other than governmental entities) that paid for Celexa or Lexapro prescribed or purchased in the State of Illinois for use by a minor between July 1998 (for Celexa) and August 2002 (for Lexapro) through the present. This class does not include those individuals who are seeking personal injury claims arising out of their purchase of Celexa and/or Lexapro.

Missouri Class

All consumers and entities (other than governmental entities) that paid for Celexa or Lexapro prescribed or purchased in the State of Missouri for use by a minor between July 1998 (for Celexa) and August 2002 (for Lexapro) through the present. This class does not include those individuals who are seeking personal injury claims arising out of their purchase of Celexa and/or Lexapro.

New York Class

All consumers and entities (other than governmental entities) that paid for Celexa or Lexapro prescribed or purchased in the State of New York for use by a minor between July 1998 (for Celexa) and August 2002 (for Lexapro) through the present. This class does not include those individuals who are seeking personal injury claims arising out of their purchase of Celexa and/or Lexapro.

109. The Illinois, Missouri, and New York Classes (the "Classes") are properly brought and should be maintained as class actions under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, adequacy because:

a. Numerosity: Hundreds of thousands of Celexa and Lexapro prescriptions were written and/or purchased in Illinois, Missouri, and New York for use by a minor.

b. Commonality: Questions of law and fact are common to all members of the Classes. Specifically, Forest's misconduct was directed at all members of this Class and their respective prescribing healthcare professionals in Illinois, Missouri, and New York. Thus, all members of the Classes have common questions of fact and law, *i.e.*, whether Forest engaged in a comprehensive program of deceptive marketing in promoting the pediatric use of Celexa and Lexapro.

c. Typicality: Plaintiffs' claims are typical of the claims of the classes because their claims arise from the same course of conduct by Forest, *i.e.*, false, misleading and deceptive marketing. All Plaintiffs purchased Celexa and/or Lexapro for use by a minor, expecting it to be effective. Accordingly, their claims are typical of the Classes.

d. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the Classes. Their interests in vindicating their consumer protection claims are shared with all members of the Classes. In addition, Plaintiffs are represented by counsel who are competent and experienced in both consumer protection and class action litigation.

110. The Classes are 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 Classes. Forest deliberately engaged in a widespread program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's efficacy in treating pediatric MDD. Under the consumer protection laws of Illinois, Missouri, and New York, reliance is not an element of a consumer protection claim, so common questions of fact and law predominate

over any questions that may affect individual members of the classes. In addition, proceeding with these class actions 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; and

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
VIOLATIONS OF ILLINOIS' CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILL. COMP. STAT. 505/1, *ET SEQ.*

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

112. This Count is brought pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*

113. This claim is asserted by Plaintiff Jaeckel on her own behalf and on behalf of all others similarly situated.

114. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 501/1, *et seq.*, makes it unlawful to engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact.

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

116. Forest's deceptive and unlawful marketing practices with the State of Illinois offend public policy and are fundamentally immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. Forest's comprehensive deceptive marketing program for Celexa and Lexapro, combined with its misleading drug labels, misled consumers about Celexa's and Lexapro's efficacy in treating pediatric depression. This conduct offends any notion of public policy and is truly unethical because it effectively promotes the use of a drug with known side-effects but whose efficacy is lacking. Such conduct is particularly egregious when it is directed at a class of people who, by virtue of their age, are particularly vulnerable to malicious and predatory marketing schemes.

117. As alleged throughout this Second Amended Complaint, Forest deliberately engaged in deceptive and unlawful marketing in violation of 815 Ill. Comp. Stat. 501/2 by representing to Illinois consumers, through deceptive promotion and the misleading drug labels, that Celexa and Lexapro were safe and effective in treating pediatric and adolescent MDD. These representations were materially false and misleading.

118. In addition, Forest has committed, *inter alia*, the following unlawful and deceptive marketing practices pursuant to 815 Ill. Comp. Stat. 510/2:

- 510/2(5): Forest knowingly represented, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that it did not have, *i.e.*, that Celexa and Lexapro was effective for the treatment of pediatric and adolescent MDD.

a. 510/2(7): Forest knowingly represented, through deceptive promotion and misleading drug labels, that Celexa and Lexapro were of a particular quality or standard, *i.e.*, capable of effectively treating pediatric and adolescent MDD, when,

in truth, Forest knew or should have known that neither Celexa or Lexapro were clinically effective at treating pediatric or adolescent MDD.

b. 510/2(9): Forest advertised and sold Celexa and Lexapro indicating through deceptive promotion and misleading drug labels, that Celexa and Lexapro would effectively treated pediatric and adolescent MDD when Forest never intended to provide a product that would perform as advertised.

c. § 48-603(12): Forest, through deceptive promotion and misleading drug labels, engaged in a practice that was misleading, false, or deceptive when it represented to Plaintiff and Illinois consumers and prescribing healthcare professionals that Celexa and Lexapro were clinically effective for pediatric and adolescent depression. These deceptive acts had a likelihood of confusing or misleading Illinois consumers and prescribing healthcare professionals.

119. The facts Forest misrepresented as alleged in this Second Amended Complaint were material to Plaintiffs' and Class Members' decisions about whether to purchase Celexa or Lexapro, in that they concerned facts that would have been important to a reasonable consumer in making a decision whether to purchase Celexa or Lexapro.

120. Forest's misrepresentations and deceptive acts and omissions were likely to mislead reasonable consumers acting reasonably under the circumstances such as Plaintiffs.

121. Plaintiff and Illinois consumers lost money as a result of Forest's deceptive and unlawful marketing practices by purchasing Celexa and Lexapro that was deceptively advertised and marketed in violation of 815 Ill. Comp. Stat. 501/2 and 510/2.

COUNT II
VIOLATIONS OF MISSOURI'S MERCHANDISING PRACTICES ACT MO. REV. STAT. §§ 407.010, ET SEQ.

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

123. This Count is brought pursuant to the Missouri Merchandising Practices Act, §

407.010, *et seq.*

124. This claim is asserted by Plaintiffs Dunham and Shippy, on their own behalf and on behalf of all other similarly situated.

125. At all times relevant hereto, Plaintiffs and members of the various classes and Forest were persons within the meaning of § 407.010(5) RSMo.

126. At all times relevant hereto, Plaintiffs and members of the various classes were purchasers within the meaning of § 407.025.1 RSMo.

127. At all times material hereto, Defendants conducted trade or commerce within the meaning of § 407.010(7) RSMo.

128. The Missouri Merchandising Practices Act, § 407.020.1, provides in pertinent part:

> The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce … in or from the state of Missouri, is declared to be an unlawful practice. … Any act, use or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation.

129. Forest engaged in misrepresentations, unlawful schemes and courses of conduct that induced Plaintiffs and members of the various classes to purchase Celexa or Lexapro through one or more unfair and/or deceptive acts and/or practices alleged in this Second Amended Complaint.

130. The facts Forest misrepresented as alleged in this Second Amended Complaint were material to Plaintiffs' and the various class members' decisions about whether to purchase Celexa or Lexapro, in that they concerned facts that would have been important to a reasonable consumer in making a decision whether to purchase Celexa or Lexapro.

131. Forest's misrepresentations and deceptive acts and omissions were likely to mislead reasonable consumers acting reasonably under the circumstances such as Plaintiffs.

132. Forest's conduct as alleged herein was unfair in that: (1) it offended public policy;

(2) it was immoral, unethical, oppressive, or unscrupulous; and/or (3) it caused substantial economic injury to consumers, namely Plaintiffs and members of the various classes.

133. Forest's unfair and/or deceptive acts and/or practices alleged in the preceding paragraphs occurred in connection with Forest's conduct of trade and commerce in Missouri.

134. Forests' unfair and/or deceptive acts and/or practices violate the Missouri Merchandising Practices Act. § 407.020.1 RSMo.

135. As a direct and proximate result of Forest's violation of the Missouri Merchandising Practices Act § 407.020.1 RSMo, Plaintiffs and members of the Class were damaged in an amount to be proven at trial.

COUNT III
VIOLATIONS OF NEW YORK'S CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, N.Y. GEN. BUS. LAW § 349, ET SEQ.

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

137. This Count is brought pursuant to the New York General Business Law § 349, *et seq.*

138. This claim is asserted by Plaintiffs Martha and Peter Palumbo on their behalf and on behalf of all others similarly situated.

139. The New York General Business Law § 349, *et seq*., makes it unlawful to engage in deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in the state of New York.

140. Forest unfairly, unconscionably, and deceptively advertised, labeled, marketed, represented and sold Celexa and Lexapro without disclosing their efficacy in treating pediatric depression to Plaintiffs and Plaintiffs' physicians, through its comprehensive deceptive promotion program for Celexa and Lexapro combined with its misleading drug labels.

141. Because Forest unfairly, unconscionably, and deceptively advertised, labeled,

marketed, represented and sold Celexa and Lexapro, Forest knew that Celexa and Lexapro had a specific characteristic, use or benefit that it did not have, *i.e.*, that Celexa and Lexapro were effective for the treatment of pediatric and adolescent MDD.

142. Forest violated New York's State Consumer Protection Act, N.Y. Gen. Bus. Law § 349 *et seq.* by falsely misrepresenting deceptive material to pediatric consumers, such as Plaintiffs, concerning the efficacy and commercial value of Celexa and Lexapro, thereby inducing and misleading physicians to prescribe Celexa and/or Lexapro and Plaintiffs and Class Members to purchase Celexa and/or Lexapro for pediatric use, and Plaintiffs and the class members to refrain from taking steps to seek alternative treatment options with a more favorable risk-benefit profile.

143. As a result of such violations, Plaintiffs and the class members were caused to purchase Celexa and/or Lexapro for pediatric use, resulting in economic harm and forgoing safe and effective alternative treatment options in reliance upon Forest's misrepresentations that Celexa and Lexapro for pediatric use was effective and had a positive risk-benefit profile.

144. The facts which Forest misrepresented as alleged in this Second Amended Complaint were material to Plaintiffs' and the class members' decisions about whether to purchase Celexa and/or Lexapro, in that they concerned facts that would have been important to a reasonable consumer in making a decision whether to purchase Celexa, and therefore, Plaintiffs and the class members were materially mislead.

145. Forest's misrepresentations and deceptive acts and omissions were likely to mislead reasonable consumers acting reasonably under the circumstances such as Plaintiffs.

146. Plaintiffs purchased and used Celexa and/or Lexapro for use and thereby suffered ascertainable losses a result of Forest's actions in violation of N.Y. Gen. Bus. Law § 349 *et seq*.

147. Had Forest not engaged in deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for Celexa and/or Lexapro, and would have not incurred related costs and expenses.

148. Forest engaged in wrongful conduct while at same time obtaining, under false pretenses, moneys from Plaintiffs for Celexa and/or Lexapro that would not have been paid had Forest not engaged in unfair and deceptive conduct.

149. Unfair methods of deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristic, ingredients, uses, benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

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

151. Plaintiffs were injured by Forest's deceptive, fraudulent, and unlawful conduct and omissions. The cumulative effect of Forest's conduct and omissions directed at parties, physicians, consumers, including Plaintiffs and the class members, was to create demand for and sell Celexa and Lexapro. Each aspect of Forest's conduct combined to artificially create sales of Celexa and Lexapro.

152. Forest had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, labeling and sale of Celexa and Lexapro.

153. Had Forest not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for Celexa and/or Lexapro, and would not have incurred unnecessary expenses and costs associated with those purchases.

154. Forest's deceptive, unconscionable, or fraudulent misrepresentations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the N.Y. Gen. Bus. Law § 349 *et seq*.

155. Forest's actions, as complained of herein, constitute unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes listed herein.

156. Forest has engaged in unfair or deceptive acts or trade practices or consumer oriented conduct or has made false representations in violation of N.Y. Gen. Bus. Law § 349 *et seq*.

157. Under the statute listed herein to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices, Forest is the supplier, manufacturer, advertiser, and seller, who are subject to liability for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

158. Forest had actual knowledge of the lack of efficacy of Celexa and Lexapro in the pediatric and adolescent populations but failed to take any action to properly to cure such condition or to adequately warn consumers, such as Plaintiffs and the class members and their physicians.

159. Forest's deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

160. By reason of the unlawful acts engaged in by Forest, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

161. As a direct and proximate result of Forest's deceptive conduct and practices, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in amount to be proven at trial.

EXEMPLARY DAMAGES ALLEGATIONS

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

163. 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 these drugs are more effective at treating pediatric and adolescent depression than they actually are. 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 Plaintiff and the members of the various classes. 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 Celexa and Lexapro were safe and effective at treating pediatric and adolescent depression. Such conduct was done with a conscious disregard of consumer rights.

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

DEMAND FOR JURY TRIAL

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

PRAYER FOR RELIEF

166. 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 respective Deceptive Marketing and Label Classes;

b. Designate Plaintiffs as representatives for the respective classes;

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 various classes alleged herein a refund of all moneys acquired by Forest by means of its deceptive and unlawful marketing of Celexa and Lexapro in Illinois and Missouri;

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

iv. Grants Plaintiff and the various classes alleged herein any actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

v. Grants Plaintiff and the various classes alleged herein exemplary and punitive damages sufficient to punish and deter Forest and others from future deceptive and unlawful marketing practices;

vi. Grants Plaintiff and the various classes alleged herein pre-judgment and post-judgment interest

vii. Grants Plaintiff and the various classes alleged herein reasonable attorneys' fees and costs of suit; and

viii. Grants Plaintiff and the various classes alleged herein such other and further relief as the Court deems just and proper under the circumstances.

Dated: April 30, 2013

Respectfully submitted by,

/s/ Christopher L. Coffin
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Counsel for MDL Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 30, 2013.

Dated: April 30, 2013

Respectfully submitted,

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