UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION This document relates to: DELANA S. KIOSSOVSKI and RENEE RAMIREZ, on behalf of themselves and all others similarly situated,[1] Plaintiffs, v. FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC. Defendants.	MDL No. 2067 Master Docket No. 09-MD-2067-(NMG) Judge Nathaniel M. Gorton Case No. 14-CV-13848 (NMG) (Leave to file granted 1/14/16) REDACTED DOCUMENT

FIRST AMENDED COMPLAINT

PRELIMINARY STATEMENT

This case is about Defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc. (collectively "Forest") leading illegal and fraudulent Enterprises to sell the antidepressants Celexa and Lexapro for use in the pediatric and adolescent populations throughout the United States. Using the Enterprise and Sub-Enterprises described in detail below, Forest conspired with various medical communications companies, consultants and researchers, to promote the off-label use of Celexa and Lexapro in pediatric and adolescent patients, despite knowing that their own clinical trial data establishes that Celexa and Lexapro do not provide any clinically significant benefit over placebo in treating pediatric depression. Through a calculated and orchestrated deceptive marketing scheme, Forest robbed parents of being able to make an

[1] Plaintiff Marlene T. LoConte has been removed pursuant to the Court's June 16, 2015 Order dismissing her claims. By filing this Amended Complaint, however, Plaintiffs do not waive their right to appeal the Court's June 16, 2015 ruling following the entry of a final judgment on all claims.

informed decision about treating their children and adolescents with Celexa or Lexapro. This lawsuit seeks to hold Forest accountable for its leading role in these corrupt and fraudulent Enterprises, and obtain a refund for consumers that paid money for Celexa and Lexapro for pediatric use because of the Enterprise participants' fraudulent activity.

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NATURE OF ACTION

1. Clinical trials examining whether the antidepressants Celexa (generically known as citalopram) and Lexapro (generically known as escitalopram) are effective at treating pediatric major depressive disorder ("MDD") indicate that the drugs are not clinically superior to placebo (a sugar pill). [redacted] In addition, both drugs pose serious safety concerns when used in pediatric populations, such as significant increased risk of suicidality.

2. Since the drugs first entered the market, Forest knew that clinical trial data did not support the use of Celexa and Lexapro in pediatric populations. [redacted] However, instead of limiting marketing efforts to promote Celexa and Lexapro to the adult populations, Forest and the other Enterprise participants/co-conspirators concocted a comprehensive and aggressive program to mislead consumers and prescribing healthcare professionals into using Celexa and Lexapro in pediatric populations.

3. This carefully-orchestrated scheme involved both material omissions, i.e., deliberate concealment of material information and carefully crafted promotional programs, both of which were designed to induce prescribers and consumers to prescribe and purchase Celexa and Lexapro for pediatric use. Forest engaged in these activities despite Forest and the Enterprise participants knowing that these drugs posed serious health risks to children and adolescents and that these drugs did not clinically outperform placebo.

4. Forest suppressed the dissemination of one of the negative Celexa trials and manipulated the data of the other to make the study appear "positive." Using the false "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,

and 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 eventually attributed to Lexapro, which is generally believed to be, essentially, the same compound as Celexa. Due to years of off-label pediatric promotion of Celexa, by the time Lexapro was launched by Forest, the damage was done, and consumer and prescribers were convinced that the drug was clinically superior to placebo.

5. Forest's scheme was designed to and in fact directly misled prescribing doctors about Celexa's and Lexapro's efficacy in treating pediatric MDD. This program of deception included:

[redacted]

f. Paying physicians with money and lavish gifts to encourage them to begin or continue

prescribing Celexa and Lexapro to all age groups, with a particular focus on children and adolescents markets.

6. Forest knew that disclosing Celexa's and Lexapro's true pediatric efficacy and safety risks 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 their children, whether Celexa and Lexapro were worth the risks, Forest hid the efficacy and safety data and misled consumers and prescribing healthcare professionals.

7. Plaintiffs seek to serve as representatives of the putative Classes of consumers outlined herein who paid for Celexa and Lexapro used by their children and adolescents because Plaintiffs were misled to believe, because of Forest's comprehensive program of deceptive promotion through the Enterprises, that Celexa and Lexapro were safe and effective treatments for pediatric depression.

8. Forest and the Enterprise participants knew that Plaintiffs and members of the putative Classes would be injured by this fraudulent and deceptive marketing campaign because Plaintiffs and members of the Classes were required to pay for Celexa and Lexapro used by their children. Plaintiffs and members of the Classes were denied the opportunity to make fully informed decisions about whether to purchase Celexa and Lexapro and were injured by paying for prescriptions of those drugs that no reasonable consumer would have purchased had they known the true facts—facts that Forest and the co-conspirators hid from the public.

THE PARTIES AND UNNAMED CO-CONSPIRATORS

I. Named Parties

9. Plaintiff Delana S. Kiossovski (hereafter "Kiossovski" and "Plaintiff") is a citizen of the State of Washington, domiciled in Mountlake Terrace, Washington. During the class period, Mrs. Kiossovski paid, in whole or in part, for Celexa prescribed to her minor daughter for the treatment of pediatric depression. Kiossovski was injured by the conduct alleged herein by

paying for a drug while being misled about a material aspect of the product and for purchasing a product that no reasonable consumer would have purchased knowing all the facts.

10. Plaintiff Renee Ramirez (hereafter "Ramirez" and "Plaintiff") is a citizen of the State of California, domiciled in Chino Hills, California. During the class period, Mrs. Ramirez paid, in whole or in part, for Lexapro and Celexa prescribed to her minor son while he was under the age of 12 for the treatment of pediatric depression. Ramirez was injured by the conduct alleged herein by paying for a drug that was ineffective for her son while being misled about a material aspect of the product and for purchasing a product that no reasonable consumer would have purchased knowing all of the facts.

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. Forest Laboratories, Inc. manufactures, distributes, and sells prescription products, including 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 manufactures, distributes, and sells prescription products, including Celexa and Lexapro, in the United States.

13. The Defendants identified herein as well as the Unnamed Co-Conspirators discussed below are "Enterprise participants" in the Celexa and Lexapro Deceptive Off-Label Promotion Enterprise (the "Enterprise" or "Celexa and Lexapro Enterprise") and the various sub-enterprises.

II. Unnamed Co-conspirators

14. Although not named as parties, the following co-conspirators violated 18 U.S.C.

§§ 1962 (c) and (d) by actively participating in Forest's scheme to market Celexa and Lexapro for use in children and adolescents for depression and to fraudulently conceal Forest's participating in this scheme, which had the intended result of and did defraud Plaintiffs and the members of the putative Classes:

[redacted]

[redacted]

[redacted]

[redacted]

JURISDICTION AND VENUE

15. This United States District Court for the Western District of Washington, Seattle Division 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 interest and costs.[2]

16. The United States District Court for the Western District of Washington, Seattle Division also has federal question jurisdiction pursuant to 28 U.S.C. § 1331. The causes of action alleged herein arise under the laws of the United States.

17. Venue is proper before the United States District Court for the Western District of Washington, Seattle Division pursuant to 28 U.S.C. § 1391(b). A substantial portion of the events giving rise to the claims alleged took place within the Western District of Washington and, at all relevant times, Forest transacted business, marketed and made material omissions and misrepresentations in this District. Additionally, Plaintiff Delana S. Kiossovski resides and is domiciled in this District.

FACTUAL BACKGROUND

18. 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

[2] This matter was originally filed in Western District of Washington, Seattle Division and was transferred to this multidistrict proceeding *In re: Celexa and Lexapro Marketing and Sales Practices Litigation*, 09-MD-2067-(NMG) (D. Mass) for pretrial coordination.

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.

19. 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. A significant amount of this financial success has come from sales of Celexa and Lexapro for us in children and adolescents.

20. Celexa (citalopram) and Lexapro (escitalopram) are selective serotonin reuptake inhibitor ("SSRI") antidepressants in the same class of drugs as Prozac (fluoxetine) and Paxil (paroxetine). Celexa and Lexapro are closely-related SSRI drugs in terms of chemical composition. 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 in all populations, including children and adolescents.

I. FDA Approval Process

21. The FDA approval process for a new drug involves several steps. First, the company must conduct laboratory testing in animals to determine whether the drug will be relatively safe and, to some extent, effective. If animal testing indicates that the drug or compound is relatively safe, the company then submits an investigational new drug ("IND") application to the FDA to gain approval to test the product with human subjects. These tests are called clinical trials and are carried out sequentially in three phases—Phase I, II, and III studies. Each phase increases the number of subjects and is designed to test for safety and efficacy of the drug for specific indications and patient populations. After the clinical trials are completed, the

company then compiles the data and analysis in a new drug application ("NDA"). FDA reviews the NDA with three major concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's strength, quality, and identity. Although the FDA evaluates the NDA to determine whether the drug will be salable to the public, the company manufacturing the drug always bears the responsibility of ensuring that the drug is manufactured, promoted, and labeled correctly. Indeed, the United States Supreme Court and numerous other federal courts have held that the FDA's regulation and approval of drugs sets the floor, not the ceiling, of drug regulation.

22. When a drug is approved by the FDA, it means the drug manufacturer satisfied the regulatory requirements set forth in the Food Drug and Cosmetic Act ("FDCA"). It does not mean that the drug meets all state law requirements or that it can be promoted for all uses in all populations. In getting FDA approval, a drug manufacturer submits a NDA which contains, among other things, "full reports of investigations which have been made to show whether or not … such drug is effective in use" and "the labeling proposed to be used for such drug[.]" 21 U.S.C. § 355 (b)(1)(A) and (b)(1)(F). Once the NDA is complete, the FDA has six months to review the application. *Id.* at § 355(c)(1). The FDA must either "[a]pprove the application" *or* "[g]ive the applicant notice of an opportunity for a hearing" to determine "whether such application is approvable." *Id.* at § 355(c)(1)(A)-(B). At the hearing, the FDA can deny an application *only if* it makes one of seven enumerated findings. *Id.* at § 355(d)(1)-(7). In the context of efficacy, since the FDA does not conduct its own clinical trials, its role is circumscribed. The FDA can only deny an application if it finds the application lacks "substantial evidence that the drug will have the effect it purports or is represented to have[.]" *Id.* at § 355(d)(5). The FDCA mandates that the FDA approve an application *unless* it finds the application lacks substantial evidence of efficacy. "Substantial evidence" is defined under 21 U.S.C. § 355(d) as:

> [E]vidence consisting of adequate and well-controlled investigations … on the basis of which it could fairly and responsibly be concluded by such experts that

> the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from *one adequate and well-controlled clinical investigation and confirmatory evidenc*e (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence[.]

23. Thus, any "positive" studies of a drug are viewed in a vacuum. Even if there are twenty clinical trials indicating that a drug is not statistically superior to a placebo (negative / failed studies), so long as one study shows some statistical superiority and there is some other confirmatory evidence, it is sufficient to meet the regulatory threshold of "substantial evidence" and the FDA is obligated to approve the drug. The FDA is not permitted to conduct a meta-review of the data and reject a NDA on those grounds.

24. In addition, the FDA does not draft the drug label. The drug manufacturer submits proposed labeling and, unless the FDA finds, under FDCA standards, that the label is misleading, it *must* approve it. 21 U.S.C. § 355(d). This does not mean the label meets disclosure requirements created by state law. It means the FDA did not find the label to be misleading under the FDCA. *See, e.g.*, *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 776 F. Supp. 2d 907, 915 (D. Minn. 2011) (FDA's approval of a label "creates a floor below which no label in the class can fall, but does not preclude a manufacturer from including more information in its label.").

25. 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.

26. 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.

II. The Placebo Effect and Clinical Trials

27. The placebo effect is the perceived or actual improvement in a medical condition that a patient receives from a medically ineffective treatment that the patient *believes* to be effective. It has been demonstrated that the simple belief that one is possibly experiencing medical treatment is, alone, sufficient to create significant improvement in a patient for many conditions. The exact cause of the placebo effect is a matter of academic and scientific debate, but its effect on medical treatment is well established and documented.

28. Because of the placebo effect, before a drug is considered effective, it must demonstrate that it is superior to placebo. Since all drugs contain side-effects, a physician must be sure that the potential benefits of a drug outweigh its risks. If a drug is not able to outperform placebo (a sugar pill without any relevant side effects) in any meaningful way, then the drug should not be prescribed. Indeed, the central precept of medical ethics is that the physician should *primum non nocere* (first, do no harm). This is why researchers must control for the placebo effect when evaluating the efficacy of a drug. This is done using double-blind placebo-

controlled clinical trials.[3] Trial participants are divided (unbeknownst to them) into a treatment group, where the participants receive the drug, or a control group, where they receive a placebo. Researchers then observe the results of the drug on the participants to see if the participants in the treatment group responded better than those taking a placebo.

29. 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, a physiological, objective test does not exist for determining the extent of a person's depression. Rather, researchers must rely exclusively on the subjective articulations of the patient concerning their depression. This is done using questionnaires completed by patients or their doctors designed to measure the severity of a patient's depression. However, this subjective measurement increases the potential for the placebo effect to drive the perceived efficacy of an antidepressant in a clinical trial. Specifically, if a patient believes she is feeling better because she is taking a drug that "cures" depression, unrelated to whether she is taking a particular antidepressant or not, she will be more inclined to respond positively to questions about her symptoms and appear better to the doctor observing the patient in a way that shows an improvement. For example, an analysis of efficacy

[3] 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 U.S. 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 a saline solution. Amazingly, the 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 investigating different conditions by consistently causing improvement that was mistakenly attributed to the drugs being tested. By 1962, reeling from news of birth defects caused by a drug called thalidomide, Congress amended the Food, Drug, and Cosmetic Act (the Kefauver Harris Amendment, Pub. L. No. 87-781, 76 Stat. 780 (1962)) requiring trials to include placebo control groups.

data submitted to the FDA between 1987 and 1999 for six of the most popular new generation antidepressants indicate that more than 80% of the response to medication observed in clinical trials testing antidepressant efficacy was duplicated by placebo. *See* 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), and 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, 0260-68 (2008); *see* 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).

30. Researchers use two metrics to determine whether the difference seen between a treatment group and a control group in a placebo-controlled clinical trial is sufficient to consider the drug "effective" for the purposes for which it was tested.

31. The first determinant is whether the difference seen between the treatment and control group was *statistically significant*. Statistical significance is a term used in statistics. It means that the observed effect in a population, here the difference between the treatment and control group, was not the result of chance. It suggests, based on probability, that there is, on average, an *actual difference* between the observed results.

32. The second determinant is whether the difference seen between the treatment and control group was *clinically* significant. As the name suggests, clinical significance deals with whether the use of the drug, based on how it performs against placebo, is sufficient to make a meaningful difference in a person's life. Estimates of clinical significance are needed to establish whether the observed benefit of a drug in the treatment group over the control group is sufficient to outweigh the risks associated with the drug, particularly when compared to alternative, less risky treatments. If a drug is shown to be statistically superior to placebo, it may not be clinically significant because the additional benefit may be so marginal that alternative treatments would be preferable. This is particularly important when weighing the observed benefits against the

known risks of treatment.

33. The use of placebo-controlled clinical trials to ascertain a drug's efficacy is the only reliable way to determine the efficacy of a drug. Indeed, one of the biggest reforms of the FDCA came in 1962, when Congress amended the FDCA to require all new drugs to have efficacy established by placebo-controlled trials. In the 1970's, several drug companies (including Pfizer), *see, e.g.*, *Pfizer, Inc. v. Richardson*, 434 F.2d 536, 540 (2d Cir. 1970), sought to oppose this new requirement by arguing that testimonials, clinical impression, and practical experience were sufficient to establish efficacy. *See Pharm. Mfrs. Ass'n v. Richardson*, 318 F. Supp. 301, 309-10 (D. Del. 1970) (providing an in-depth account). Drug companies asserted that subjective accounts by prescribers and patients were enough to show that a drug was effective and suitable for sale. The courts, however, rejected this self-serving view:

> In a great many instances during the past, drug companies have relied upon testimonials, clinical impressions, practical experience, and unsubstantiated subjective views of medical practitioners as evidence supporting their claims of efficacy for pre-1962 drugs. . . . such medical experience derived from random observations, isolated case reports and subjective impressions standing alone cannot [satisfy] the objective test of scientifically controlled investigations which Congress intended.

Id.

34. This view was further expressed by the United States Supreme Court, which noted that the 1962 amendments and subsequent regulations "express well-established principles of scientific investigation" and that "their strict and demanding standards, barring anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug, are amply justified by the legislative history." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973). The Court explained that "[t]he hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous." *Id.* Whether a drug is effective is not a question of individual belief, but of well-controlled observation.

III. Celexa's Lackluster Pediatric Efficacy Data

35. 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.

36. In May 1997, Forest Laboratories submitted an NDA to the FDA for Celexa for the treatment of adult major depressive disorder ("MDD"). On August 17, 1998, the FDA approved the Celexa NDA to treat adult MDD.

[redacted]

38. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa" to the FDA. Forest wanted to obtain 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.

39. 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" or "the Lundbeck Study"). The second study, Study 18, was to be conducted by Dr. Karen D. Wagner of the University of Texas, and would test the safety and efficacy of Celexa in treating

children and adolescents for depression ("Celexa Study 18" or "the Wagner Study").

a. Celexa Study 94404

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

41. 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 evaluated with the Schedule for Affective Disorders and Schizophrenia for School Aged Children ("Kiddie-SADS-P") which yielded a numeric baseline score.[4] 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.

42. 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.

43. A 2006 publication purporting to present the results of Celexa Study 94404, known to Forest in 2001, noted: "suicide attempts, including suicidal thoughts and tendencies, were reported by 5 patients in the placebo group and by 14 patients in the citalopram group (not significant) with no pattern with respect to duration of treatment, time of onset, or dosage." Anne-Liis von Knorring *et al., A Randomized, Double-blind, Placebo-controlled Study of Citalopram in Adolescents with Major Depressive Disorder*, Journal of Clinical Psychopharmacology, 26:311-315 (2006) (parenthetical in original).

44. Thus, Celexa Study 94404 demonstrated two things: 1) Celexa was no better than

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

placebo as a treatment for major depression in adolescents and 2) Celexa was associated with a borderline statistically significant relative risk of approximately 2.6-2.7 (which was actually statistically significant under certain statistical tests) for suicide-related adverse events (SREs) including suicide attempts, thoughts and tendencies compared to placebo. This data demonstrated that the risk could actually be as much as 7 times greater with Celexa. The fact that the incidence of SREs was borderline significant in a study with only approximately 240 patients is alarming. It should have signaled to Forest that its drug was not only ineffective as a treatment for major depression in adolescents, but could also be dangerous, as the evidence indicated an association between its drug and a tragic consequence of the very disease it claimed to treat. At the absolute minimum, this information would have been material to any physician's or parent's decision to prescribe or pay for Celexa respectively.

b. Celexa Study 18

45. 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.[5] Celexa Study 18 consisted of eight (8) weeks of treatment with either Celexa or placebo.

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

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 and several co-conspirators in mid-2001.

46. 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.[6] 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%.

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

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

48. Maju Mathews, M.D., Letters to Editor, *Child Psychopharmacology, Effect Sizes*

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to Editor, *Child Psychopharmacology, Effect Sizes and the Big Bang*, 162 AM. J. PSYCHIATRY 4, 817-18 (April 2005).

[6] 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.

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.*

[redacted]

51. The published version of Celexa Study 18 had numerous other flaws, including

but not limited to the fact that Forest and the co-conspirators presented the effect size in an incorrect and misleading manner and intentionally decided not to report predetermined secondary outcomes, all of which proved unfavorable to Celexa. In addition, the published version of Study 18 did not disclose the results of Study 94404, which were known to Forest, that Celexa was no better than placebo and that the rate of suicidality with Celexa was dramatically higher.

c. The FDA Denies Celexa Pediatric Indication

52. 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.

53. 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.

54. 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 at least one well-controlled clinical study showing that Celexa was superior to placebo with some confirmatory evidence. 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]."

IV. Lexapro's Lackluster Pediatric Efficacy Data

55. 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 why Lexapro was conceived.

56. 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.

57. 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 sales and marketing success. By the end of 2003, Lexapro had done its intended job and effectively replaced the revenues lost from Celexa going generic in 2003.

58. Forest, however, wanted to have Lexapro approved for pediatric populations. Thus, in anticipation of submitting a supplemental NDA for a pediatric indication, Forest began conducting pediatric studies with Lexapro.

a. Lexapro Study 15

59. 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 Lexapro 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.

60. 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.

b. Lexapro Study 32

61. 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. This study, however, would use a study design specifically "gerrymandered" to improve the chances of yielding a positive result. Indeed, there was tremendous pressure on Forest scientists to ensure that Lexapro Study 32 was successful. 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, "everything hinges on [Lexapro Study] 32."

62. 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.[7]

[7] The difference in baseline scores between the Lexapro and placebo groups was statistically significant, which means that on average the participants in the treatment ground, *i.e.*, received

63. 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. Even though eighty-two percent (82%) of Lexapro's observed efficacy was duplicated in the placebo group, this difference in point averages, according to statistical modeling, resulted in a statistically significant 3.4 point difference between Lexapro and placebo in treating *adolescent* MDD.

64. 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 statistically 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. This is particularly true since the difference between the Lexapro and placebo groups was only 3.4 points. Here, the Lexapro treatment group had a baseline that was "worse" than the placebo group, thus, there was substantially more room for improvement in the treatment group. Since the success of a clinical trial involves comparing the relative improvements of each group, *i.e.*, the delta, having a dissimilar baseline skews the results in favor of efficacy—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 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.

Lexapro, were more depressed on average than the group receiving placebo. This variance can be important because research has shown that any efficacy observed in antidepressants generally is observed in the most severely depressed.

[redacted]

c. FDA Approves Lexapro Adolescent Indication

66. In May 2008, Forest submitted a supplemental NDA to the FDA requesting an indication for Lexapro in the treatment of adolescent MDD. As part of the application, Forest submitted Celexa Study 94404, the results of Celexa Study 18, Lexapro Study 15, and Lexapro Study 32.[9] The following chart reflects the clinical trials submitted in support of Lexapro's efficacy:

Study	*Stat. Efficacy*	*Clin. Efficacy*	*Plac. Effect*	*Drug Effect*	*Delta*

[redacted]

[9] Forest also submitted Lexapro 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.

Celexa Study 94404	Negative	Negative	12.7 pts[10]	12.4 pts	(-0.3 pts)
Celexa Study 18	Positive[11]	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

67. 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 decided that, for purposes of evaluating the "substantial evidence" requirement, the FDA would consider the "data from 1 positive study with Lexapro" (Lexapro Study 32) and "extrapolate on the basis of a previously reviewed positive study with [Celexa]" (Celexa Study 18). Thus, the FDA accepted the questionable data from Lexapro Study 32 and the flawed data from Celexa Study 18[12] to conclude that Forest met its regulatory requirement of providing more than one well-controlled study showing that Lexapro was effective for the treatment of adolescent MDD.[13] On March 20, 2009, Lexapro was approved by the FDA for use in adolescent MDD.

68. After receiving FDA approval, Forest issued a press release in which its CEO, Howard Solomon, stated:

> We have long believed that Lexapro would be of benefit for the treatment of depression in adolescents and that is why we undertook the several studies described in the package insert.[14] 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.

69. 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:

[10] Using the Kiddie-SADS-P scale.
[11] Based on fraudulent data.
[12] Celexa Study 18, which tested Celexa in a range of pediatric patients, was never meant to be used to determine the efficacy of Lexapro or to be used to isolate efficacy for adolescents. Indeed, Dr. Wagner, the author and researcher for Celexa Study 18, testified that using her pediatric data from Celexa Study 18 to support adolescent efficacy for Lexapro is completely improper.
[13] To be clear, Plaintiffs' claims herein do not seek, in any way, to enforce FDA regulation or hold Forest accountable for committing fraud on the FDA.
[14] There were, in fact, only two studies performed on Lexapro, and only one of them purported to be positive.

> 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.

70. 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.

71. 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. Indeed, as described above, the standard of

establishing efficacy turns on whether a drug sponsor has submitted "substantial evidence" of efficacy, which only requires one positive study and some confirmatory evidence—and expressly ignores whether there is substantial evidence to the contrary. The FDA can only reject an application if it finds that the application lacks "substantial evidence." Otherwise, it *must* approve it. For example, during an FDA advisory committee meeting related to another SSRI antidepressant, 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." Thus, despite Lexapro being approved for an adolescent indication, it does not mean, as Dr. Leber once explained, that the drug company is "entitled to every claim, every superlative ever made," but only means that "the application, as submitted," was "such that we have a right to conclude . . . it does not have

evidence of efficacy[.]"

d. There is No Evidence Demonstrating That Lexapro is Effective for Children with MDD Under the Age of 12

72. Although the FDA approved Lexapro for adolescents (ages 12 to 17 years old) for MDD, Lexapro has never been approved for use in children under 12 years of age.

73. The only studies designed and conducted to determine the efficacy of Lexapro for MDD in either children under the age of 12 or adolescents are Lexapro Study 15 and Lexapro Study 32.

74. Lexapro Study 15 was negative, i.e., it did not show a benefit when compared to placebo for the treatment of MDD in either children or adolescents.

75. Lexapro Study 32 only involved study participates between 12 to 17 years old.

76. Celexa Study 18 which was used to obtain approval of Lexapro in adolescents (ages 12 to 17 years old), did not demonstrate efficacy over placebo for the treatment of MDD for children (ages 7 to 11 years old).

77. Forest, many of the senior executives, and co-conspirators, including, but not limited to, Karen Wagner, were aware of both Celexa and Lexapro's lack of efficacy in children under the age of 12, but through the publication of Celexa Study 18, manipulated and concealed the fact that Celexa Study 18 was negative for the treatment of MDD in children aged 7 to 11 years old.

78. For every clinical trial conducted where children younger than 12 were tested with Celexa and/or Lexapro for the treatment of MDD, there was no efficacy observed in that population.

79. Although the FDA approved Lexapro for use in adolescents between the ages of 12 and 17 in 2009, the drug was never approved for pediatric use in children under the age of 12. Consequently, Forest and the co-conspirator's promotion and marketing of Lexapro for children under the age of 12 was illegal and caused damage to Plaintiff Ramirez and the class members as

discussed herein.

V. The FDA Requires Forest to Add Black-Box Warning to Celexa and Lexapro

80. In 2004, the FDA required that the Celexa and Lexapro labels be revised to include the most severe label warning – a "black box" warning – which includes the explicit language that the drugs may increase the risk of suicidality in children and adolescents. In fact, internal documents indicate that Forest had sufficient knowledge of the risk of suicidality years before the FDA required the black box warning. Notably, this information was not provided to Plaintiffs or their children's prescribers. The determination by the FDA that this black-box warning be included with Celexa and Lexapro was born out of concern of the serious safety risks associated with the drugs. Indeed, the data from Celexa Study 94404, which Forest deliberately concealed, was an important source of the data the FDA used to add the black box warning.

81. In 2007, the Celexa and Lexapro labels were again modified to state that, after evaluating the pooled analyses of placebo-controlled antidepressant trials in children and adolescents and of trials in adults, "[t]here was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied."

82. This information about the risk of suicidality created in pediatric populations was known by Forest during and throughout the fraudulent conduct alleged herein, and reflects the malicious nature of Forest's conduct in actively promoting and selling these drugs for pediatric use, despite clear data that the drugs lacked clinical efficacy and were unsafe.

THE ENTERPRISES AND RACKETEERING ACTIVITIES

83. Forest and the co-conspirators conducted or actively participated in conduct of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c). Additionally, and in the alternative, Forest and the co-conspirators, through an agreement to commit two or more predicate acts, conspired to conduct or participate in the conduct of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). The

actions of Forest and the co-conspirators (otherwise known as "Enterprise participants") were in furtherance of the Enterprises and in violation of 18 U.S.C. § 1962(d) and caused damages to Plaintiffs and the members of the Classes.

84. [redacted] The Enterprises are distinct from, albeit conducted by, Forest, through the aforementioned co-conspirators/Enterprise participants, and has an ongoing existence. The Enterprise participants include Forest and all co-conspirators identified herein, among others

[redacted]

[redacted]

86. Using these marketing plans and tactics, Forest and the co-conspirators executed these strategies to increase sales of Celexa and Lexapro for use in pediatric patients throughout the United States. This Enterprise consisted of several important sub-enterprises who participated in fraudulent and illicit activities in order to conceal and omit material information. Although each sub-enterprise, activity, and omission was, itself, illegal and in violation of 18 U.S.C. § 1962(c), (d), and various state consumer protection laws, the Enterprise consists of all sub-enterprises, activities, and omissions which, in concert, played a substantial factor in defrauding consumers and prescribers.

I. The Direct-to-Prescriber Sub-Enterprise: Forest and the Co-conspirators Relayed Directly to Prescribers False and Misleading Information about Celexa and Lexapro's Pediatric Efficacy in Violation of Federal Law

87. One of Forest's and the co-conspirators' primary sub-enterprises, designed to further the overall Enterprise purpose -- to promote the sales and use of Celexa and Lexapro for pediatric depression -- centered on direct off-label promotion to prescribers by sales representatives. The purpose of this sub-enterprise was to introduce prescribers to false and deceptive representations about the efficacy of Celexa and Lexapro in treating pediatric depression so that they would issue more prescriptions and Forest could make more money.

[redacted]

[redacted]

[redacted]

93. These communications were transported electronically by wire and physically by mail, in violation of numerous federal laws.

[redacted]

[redacted]

[redacted]

98. In addition to making misrepresentations and false claims to prescribers, the Direct-to-Prescriber Sub-Enterprise also used lavish gifts and kickbacks to induce prescribers to write prescriptions for Celexa and Lexapro.

[redacted]

[redacted]

[redacted]

II. The Peer-Selling Sub-Enterprise: Forest and Co-conspirators Paid and Influenced Prescribers to Fraudulently Promote the Use of Celexa and Lexapro for Pediatric Depression

[redacted]

[redacted]

Forest and the other Enterprise participants/co-conspirators involved in this scheme targeted child psychologists, pediatricians, and other physicians throughout the United States who specialized in treating children. The purpose of the Peer-Selling Sub-Enterprise was to induce prescribers to issue more prescriptions for Celexa and Lexapro for children and adolescents. [redacted]

[redacted]

[redacted]

[redacted]

a. Fraudulent Continuing Medical Education ("CME") Programs

114. *Bona fide* CME programs, and similar educational events, are exempt from FDA rules prohibiting off-label promotion since the sponsoring organization is supposed to be independent and control the programs' content. There is nothing *per se* wrong with one independent prescriber giving their earnest opinion about the off-label use of a drug to another prescriber. When that prescriber is not independent, however, the integrity and "unbiased" nature of a CME is corrupted, and the activity becomes merely another opportunity for a drug company to engage in illegal promotion. [redacted]

[redacted]

[redacted]

[redacted]

124. Many of the invitations, payments, and logistics for organizing these fraudulent CMEs, were transported in interstate commerce via wire and mail.

[redacted]

[15] An opinion leader is someone who drives local trends in a given therapeutic area by influencing their peers on a specific medical/scientific subject. They are looked to as the local authority on a given area of medicine. A thought leader is a figure who is a national or international leader in medicine in a given area. These physicians are predominantly academic

[redacted]

based, conduct the research, write medical textbooks, speak on the subject at large meetings and are looked to as the authority on the topic.

[redacted]

[redacted]

[redacted]

[redacted]

d. Advisory boards

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

III. The Publication Sub-Enterprise: Forest and other Co-conspirators Wrote and Published Misleading and Biased Scientific Information for the Purposes of Giving Scientific Credibility to the Pediatric Use of Celexa and Lexapro

155. To justify the sale and marketing of Celexa and Lexapro for pediatric depression, Forest and the Publication Sub-Enterprise needed to cultivate "scientific evidence" that supported, medically, the use of Celexa and Lexapro in children and adolescents. Forest, however, had to make it appear that its control of this strategy was minimal. Scientific articles supporting pediatric efficacy had to appear as if they emanated from independent physicians who were investigating Celexa and Lexapro, not the marketing department at Forest. To perform this task and cultivate a body of supporting medical literature, Forest established the Publication Sub-Enterprise. The purpose of the Publication Sub-Enterprise was to create "independent" clinical trial manuscripts, articles and other publications, which provided a scientific framework from which Forest and the Enterprise participants could actively promote the off-label use of Celexa and Lexapro.

[redacted]

[redacted]

[redacted]

[redacted]

a. Step One: Cultivating Misrepresentations and Misleading Statements in Articles and Journals

[redacted]

[redacted]

[redacted]

[16] Notably, although Dr. Karen Wagner was the lead investigator in Celexa Study 18, Forest provided all of the statistical evaluations for the data from the study.

[redacted]

[redacted]

b. Step Two: Leveraging Misleading Publications to Promote Off-Label Pediatric Use of Celexa and Lexapro

[redacted]

[redacted]

IV. The Material Omissions Sub-Enterprise: Forest and the other Co-conspirators Crafted Misleading Drug Labels and Actively Suppressed the Dissemination of Negative Efficacy Data to Further the Enterprise

181. A central method by which Forest and the co-conspirators were able to advance the Enterprises' objectives was by deliberately concealing negative efficacy information about Celexa and Lexapro from consumers and prescribers. The Material Omissions Sub-Enterprise's objectives consisted of suppressing the release and disclosure of negative efficacy information to ensure that consumers and prescribers would be misled into purchasing and prescribing Celexa and Lexapro for children and adolescents.

[redacted]

a. Suppressing Disclosure of Celexa Study 94404 and the Truth about Celexa Study 18

183. The Material Omissions Sub-Enterprise participants knew that if they could ensure that there was no negative efficacy information or safety concerns disseminated about Celexa and Lexapro in pediatric populations, prescribers would be inclined to believe that the drugs were safe and effective in treating children and adolescents.

[redacted]

[redacted]

185. 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, the Material Omissions Sub-Enterprise 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 and the other Enterprise participants' false, misleading and deceptive marketing and the resulting indirect statements that spread within the medical community, that Celexa was effective in treating pediatric MDD and came without serious safety concerns.

[redacted]

b. Distribution of Misleading Drug Labels

187. The labels for Celexa and Lexapro are directed at every consumer and prescriber. They serve as the primary authority for understanding the potential risks and proposed benefit of

a drug. The label, in other words, is the single most important source of information about a drug. [redacted]

188. As alleged herein, the drug labels for Celexa and Lexapro were misleading and inadequate. Specifically, the drug labels for Celexa and Lexapro omitted material information about pediatric safety and efficacy that was required for a patient, parent or prescribing physician to make an informed decision about whether to purchase or prescribe Celexa and Lexapro for pediatric use.

189. 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 labeling requirements. 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."

[redacted]

[redacted]

1. Celexa's Misleading Label

191. In July-2001 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 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.

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

193. 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 added any 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 any way, in carefully chosen words, Celexa's inability to effectively treat pediatric depression.

194. But Forest was aware, prior to 2005, of Celexa's lack of efficacy in adolescents and its risk of suicidality, both of which had been demonstrated in its Study 94404. Yet it omitted this material information from its Celexa labels and other communications with

prescribers. Had Forest disclosed this information to the medical community, physicians could have made an informed decision whether to prescribe Celexa for their pediatric patients suffering from major depression.

195. Accordingly, 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 safe and 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.

196. Although, the Celexa label was amended to include a cursory description of Celexa Study 18 and 94404, these descriptions were wholly inadequate, particularly in light of the intense off-label promotion campaign (as described herein) that had already taken root between 1998 and 2005. The new labeling did not discuss the actual observed differences between Celexa and Lexapro, failed to make any mention of clinical efficacy or provide information for prescribers to make an adequate determination of clinical efficacy, and did not discuss negative Lexapro Study 15.[17] Also, the label did not discuss in any meaningful way how Celexa Study 18 was able to achieve statistically significant results, *i.e.*, using un-blinded data, and did not indicate how marginal the differences between placebo and Celexa really were, especially in light of the significant risks.

2. Lexapro's Misleading Label

197. 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.

198. In July-2001, 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 two clinical trials had been conducted to evaluate the safety and efficacy of Celexa in pediatric populations and that they were both negative. Forest has 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. This deprivation of information robbed consumers of being able to make an informed decision in purchasing Lexapro.

199. In 2005, the Lexapro label was amended to include a cursory discussion of Lexapro Study 15. But this label change, just like with Celexa, came too late and was not descriptive enough to fully inform prescribers and consumers of Lexapro lack of efficacy nor to overcome the widespread and deliberate off-label promotion campaign perpetrated by Forest and the other co-conspirators between 1998 and 2005. Specifically, the label change did not include any description of Celexa's negative clinical trial data and did not provide any specific descriptions of the negative data so that prescribers and consumers could understand how Lexapro would likely work in treating pediatric depression.

200. In 2009, however, when Forest was able to get an adolescent indication for Lexapro, Forest changed the Lexapro label. Specifically, under the Section "Pediatric Use" the label stated:

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

Under the Section Clinical Trials the label stated:

> Adolescents

> The efficacy of Lexapro as an acute treatment for major depressive disorder in adolescent patients was established in an 8-week, flexible-dose, placebo-controlled study that compared Lexapro 10-20 mg/day to placebo in outpatients 12 to 17 years of age inclusive who met DSM-IV criteria for major depressive disorder [*i.e.*, Lexapro Study 32]. The primary outcome was change from baseline to endpoint in the Children's Depression Rating Scale - Revised (CDRS-R). In this study, Lexapro showed statistically significant greater mean improvement compared to placebo on the CDRS-R.
>
> The efficacy of Lexapro in the acute treatment of major depressive disorder in adolescents was established, in part, on the basis of extrapolation from the 8-week, flexible-dose, placebo-controlled study with racemic citalopram 20-40 mg/day [*i.e.*, Celexa Study 18]. In this outpatient study in children and adolescents 7 to 17 years of age who met DSM-IV criteria for major depressive disorder, citalopram treatment showed statistically significant greater mean improvement from baseline, compared to placebo, on the CDRS-R; the positive results for this trial largely came from the adolescent subgroup.
>
> Two additional flexible-dose, placebo-controlled MDD studies (one Lexapro study in patients ages 7 to 17 and one citalopram study in adolescents) did not demonstrate efficacy.

201. This label is fundamentally misleading for a variety of reasons. First, the label states that Celexa Study 18 "showed statistically significant greater mean improvement from baseline, compared to placebo, on the CDRS-R[.]" This statement is materially false since, as described above, the statistical significance of Celexa Study 18 is predicated on a manipulation of data. Second, the label states that the data in Lexapro Study 32 demonstrated that "Lexapro showed statistically significant greater mean improvement compared to placebo on the CDRS-R." While this statement is not *per se* false, it is nonetheless inherently misleading because it does not provide any indication that the difference between Lexapro and placebo as seen in Lexapro Study 32 was marginal. Without some indication of how much Lexapro outperformed placebo, which in this case turns out to be clinically insignificant, consumers and prescribing healthcare professionals cannot properly weigh the risk and benefit of using Lexapro to treat adolescent MDD. Thus, the 2009 label change to Lexapro is fundamentally misleading because it suggests, despite the clinical data to the contrary, that Lexapro is more effective at treating adolescent MDD than it actually is. Consumers and prescribing healthcare professionals deserve to know what Lexapro's efficacy truly is in treating adolescent MDD and decide, in light of accurate clinical data, whether purchasing Lexapro is worth the risks. By omitting this material

information and misrepresenting Celexa Study 18, Forest robbed consumers and prescribing healthcare professionals of having sufficient information to properly decide whether to purchase or prescribe Lexapro.

[redacted]

INCORPORATION OF CRIMINAL PLEA AGREEMENT

203. As a result of Forest's marketing practices and off-label promotion of Celexa for use in children and adolescents suffering from depression, the United States Attorney for the District of Massachusetts conducted an investigation and ultimately filed a criminal information against Forest in *United States v. Forest Pharmaceuticals, Inc*. On September 15, 2010, Forest pleaded guilty to several violations of the Food, Drug and Cosmetic Act, including Distribution of a Misbranded Drug: Inadequate Directions for Use, 21 U.S.C. §§ 331(a)(1) & 352(f)(1)), agreed to pay $313 million and agreed to cease and desist its pattern of misconduct.

204. In the plea agreement, Forest admitted the following to this Court: "Forest expressly and unequivocally further admits that it committed the offenses charged in the Information and is in fact guilty of those offenses. Forest agrees that it will not make any statements inconsistent with its explicit admission of guilt to these offenses." These admissions

of facts lend further support to Plaintiffs' allegations that Forest engaged in fraudulent and deceptive promotion of Celexa and Lexapro throughout the United States.

205. Plaintiffs incorporate by reference all those admissions contained in the plea agreement.

PLAINTIFFS-SPECIFIC ALLEGATIONS

I. Plaintiff Delana Kiossovski

206. On or about July 17, 2001, Plaintiff Delana Kiossovski's daughter, aged twelve, was prescribed a ten (10) mg daily dose of Celexa for depression by her physician at the Overlake Hospital Medical Center. Through the remainder of 2001 and until March of 2002, Elizabeth was prescribed and ingested various doses of Celexa until her admission to Overlake Hospital Medical Center due to worsening depression and the emergence of suicidal ideation. Kiossovski paid for her daughter's prescriptions of Celexa, which also included the payment of co-payments, while her daughter was an adolescent. Kiossovski spent her own money, out-of-pocket, in conjunction with insurance, to purchase Celexa to treat her daughter's depression. In total, Kiossovski spent approximately $60 of her own money on purchasing Celexa for her daughter.

207. The Enterprise participants, including Forest, conspired to misrepresent to Kiossovski and each consumer and their prescribers Celexa's and Lexapro's ability to treat pediatric depression. Because of these misrepresentations, Kiossovski purchased Celexa for her daughter. The Enterprise participants' conduct caused Kiossovski and the members of the Classes to make payments for Celexa that, absent the fraud and deception, would never have occurred.

208. The Enterprise participants deprived Kiossovski and each member of the classes and their prescribers of material information they needed to make an informed decision about whether to purchase Celexa and Lexapro to treat pediatric depression. This deception directly caused an overvaluation of the drugs, which resulted in payments for Celexa and Lexapro that,

absent the fraud and deception, would never have occurred.

209. Plaintiff Kiossovski relied on her daughter's treating physicians to make informed decisions about which drugs to prescribe her daughter. Upon information and belief, the physicians who prescribed Celexa to Kiossovski's daughter was also misled into prescribing Celexa because the physician was led to believe, based on Forest's deceptive and unlawful marketing, that Celexa was more effective in treating adolescent MDD than it actually was. This deception occurred as a result of the same misleading conduct perpetrated by the Enterprise participants that was directed toward Kiossovski – a fraudulent scheme to off-label promote and sell Celexa and Lexapro for pediatric use.

210. During the period in which Kiossovski was purchasing Celexa for her minor child, she did not know that Celexa's drug label and advertising were deceptive or that they lacked material information about the drug's efficacy in treating adolescent depression.

211. During the period Kiossovski was purchasing Celexa for her minor child, Plaintiff was never informed, nor did she read or see, any information about Celexa's or Lexapro's negative efficacy trials or that, in a majority of Celexa's and Lexapro's placebo-controlled efficacy trials, the drugs failed to clinically outperform placebo. Likewise, neither Forest nor the co-conspirators conveyed any of the negative efficacy results in the clinical trials to Kiossovski, her daughter's physicians, or the public in general.

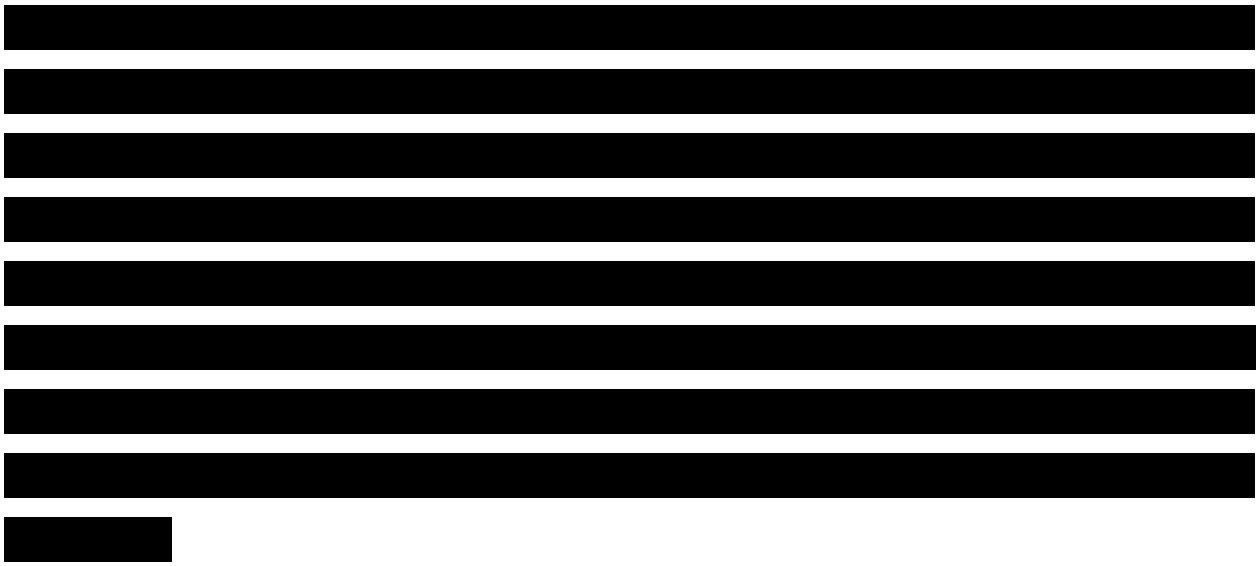
212. During the period Mrs. Kiossovski was purchasing Celexa for her minor child, Plaintiff did not see any media, journal articles, press releases, websites, letters, or statements concerning Celexa and its inability to display clinical significance in treating depression. Upon information and belief, no media or information criticizing Celexa's efficacy existed during this time period to which a reasonably diligent consumer would have been exposed.

213. During the period Kiossovski was purchasing Celexa for her minor child, Plaintiff had no reason to believe she was the victim of consumer protection violations or that her purchase of Celexa was made without material information about the drug.

214. During the period Kiossovski was purchasing Celexa for her minor child, Plaintiff did not know that she had been deprived of material information.

215. During the period Kiossovski was purchasing Celexa for her minor child, she was not provided information about Celexa's or Lexapro's negative clinical trials or Forest's off-label marketing scheme aimed at increased sales of Celexa to children and adolescents. In the absence of a full and fair disclosure by the manufacturer, a reasonably diligent consumer could not have been aware of the negative efficacy information about the drugs. Moreover, Kiossovski had no reason to suspect that she had been the victim of a consumer protection violation. Nothing in the course of her child's treatment provided her any impetus to suspect Forest's or the co-conspirators' foul play.

216. In an effort to avoid sanction and regulation by the FDA, Forest's illegal, off-label marketing scheme depended on the Enterprises' concealment of their involvement in the off-label promotion of Celexa and Lexapro for pediatric use. Indeed, the Celexa and Lexapro Deceptive Off-Label Promotion Enterprise and sub-enterprises were created precisely to make it appear to the public that Forest did not have a hand in any discussions of pediatric use.



217. From the original establishment of the Enterprises until the present, Kiossovski nor her daughter were aware of any of the specific fraudulent or predicate acts alleged as part of

the Enterprises in this Complaint. Kiossovski did not see any media or receive any communication describing any of the fraudulent conduct alleged as part of the Enterprises or Forest. Kiossovski did not know about Celexa's and Lexapro's negative efficacy data. Indeed, Kiossovski was unaware that it had been the victim of Forest's fraudulent scheme until January of 2014. Prior to learning about the fraud, Kiossovski did not have any reason to investigate Forest's or the Enterprises' conduct or reason to suspect she had been a victim.

218. Any applicable statutes of limitations have been tolled by Forest's knowing and active concealment and denial of the facts alleged herein. Kiossovski and members of the Classes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Kiossovski and members of the Classes could not reasonably have discovered the fraudulent nature of Forest's conduct any earlier. Accordingly, Forest is estopped from relying on any statute of limitations to defeat any of Kiossovski's or the Classes' claims.

219. Information about Celexa's true performance against placebo in treating depression is information that a reasonable consumer and prescriber would consider important in making a purchasing and prescribing decision.

II. Plaintiff Renee Ramirez

220. On or about May 20, 2004, Plaintiff Renee Ramirez's nine-year-old son, while living in Riverside, California, was prescribed a 10 mg daily dosage of Lexapro for depression and anxiety by his pediatric neurologist at Riverside Medical Clinic. From May 2004 through his 12th birthday on January 24, 2007, Ramirez's son was prescribed and ingested Lexapro at doses of 10 mg and 15 mg daily. Ramirez paid for her son's prescriptions of Lexapro, which also included payment of co-payments, while her son was a child under the age of 12. Ramirez spent money, out-of-pocket, in conjunction with insurance, to purchase Lexapro to treat her son's depression. In total, Ramirez spent approximately $741.06 out-of-pocket to purchase Lexapro for her son before he turned 12 years old, not including payments by insurance.

221. Ramirez's son quit taking Lexapro in 2011 due to the emergence of side effects, such as muscle spasms and a lack of concentration in school, which he suffered since he began taking Lexapro. In early to mid-2013, Renee Ramirez learned that Lexapro had not been proven effective for children. With that benefit of hindsight, this realization was consistent with her observations of her son's experience with Lexapro, including before he turned 12 years old, that the drug was ineffective.

222. Prior to ingesting Lexapro, Ramirez's son was prescribed and ingested a 20 mg daily dosage of Celexa for pediatric depression from February 2003 through April 2004, which resulted in out-of-pocket payments in the amount of $375.00. The Celexa was not effective in treating his condition.

223. The Enterprise participants, including Forest, conspired to misrepresent to Ramirez and each consumer and their prescribers, the efficacy of Lexapro for the treatment of depression in children under the age of 12. Because of these misrepresentations, Ramirez purchased Celexa and Lexapro for her son. The Enterprise participants' conduct caused Ramirez and the members of the Classes to make payments for Lexapro and Celexa that, absent the fraud and deception, would never have occurred.

224. The Enterprise participants deprived Ramirez and each member of the Classes and their prescribers of material information necessary to make an informed decision about whether to purchase Lexapro in order to treat MDD for children under the age of 12. This deception directly caused an overvaluation of the drugs, which resulted in payments for payments for Lexapro that, absent the fraud and deception, would never have occurred.

225. Plaintiff Ramirez relied on her son's treating physicians to make informed decisions about which drugs to prescribe her son. The physicians who prescribed Lexapro to Ramirez's son were misled into prescribing Lexapro because the physicians were led to believe, based on Forest's deceptive and unlawful marketing and promotion, that Lexapro was effective in treating MDD for children under the age of 12. This deception occurred as a result of the

same misleading conduct perpetrated by the Enterprise participants directed toward Ramirez—a fraudulent scheme to off-label promote and sell Lexapro for use in children under the age of 12.

226. During the period Plaintiff Ramirez's son took Lexapro (while he was under the age of 12), she did not know Lexapro's advertising and promotion were deceptive or that they lacked material information about the drug's efficacy in treating MDD for children under the age of 12.

227. During the period Ramirez was purchasing Lexapro for her son, (while he was under the age of 12), she was never informed, nor did she read or see, any information about Lexapro's negative efficacy trials or that, in all of the placebo controlled efficacy trials of Lexapro involving the treatment of MDD for children under the age of 12, the drugs failed to outperform placebo. Likewise, neither Forest nor the co-conspirators conveyed any of the negative efficacy results from the clinical trials to Ramirez, her son's physicians, or the public in general.

228. During the period Mrs. Ramirez was purchasing Lexapro for her son (while he was under the age of 12), she did not see any media, journal articles, press releases, websites, letters or other statements concerning Lexapro's failure to outperform placebo in treating depression in children under the age of 12. Upon information and belief, no media or information criticizing Lexapro's efficacy for children under the age of 12 existed during this time period to which a reasonably diligent consumer would have been exposed.

229. During the period Ramirez was purchasing Lexapro for her son (while he was under the age of 12), she had no reason to believe she was the victim of consumer protection or RICO violations or that her purchase of Lexapro was made without material information about the drug.

230. During the period Ramirez was purchasing Lexapro for her son (while he was under the age of 12), she was not provided information about the negative clinical trials of Lexapro for the treatment of MDD in children under the age of 12 or Forest's off-label marketing

scheme aimed at increasing sales of Lexapro for use in children under the age of 12. In the absence of a full and fair disclosure by the manufacturer, a reasonably diligent consumer could not have been aware of the negative efficacy information about the drugs. Moreover, Ramirez had no reason to suspect that she had been the victim of a consumer protection or RICO violation. Nothing in the course of her son's treatment provided her any impetus to suspect Forest's or the co-conspirators' foul play.

231. In an effort to avoid sanctions and regulation by the FDA, Forest's illegal, off-label marketing scheme depended on the Enterprises' concealment of their involvement in the off-label promotion of Lexapro for use in children under the age of 12. Indeed, the Celexa and Lexapro Deceptive Off-Label Promotion Enterprise and sub-enterprises were created precisely to make it appear that Forest did not have a hand in discussions of pediatric use. Additionally, as described above, through the Enterprises, Forest performed off-label promotional activities under the guise of legitimate speakers' bureaus, consultants' meetings, continuing education seminars, journal articles and medical education events. Also, as described above, Forest's involvement was hidden because Forest hid its financial connections with the Enterprise participants by making payments to intermediaries. Through these activities, and others described above, Forest concealed its off-label promotion of Lexapro for use in children under the age of 12 and, therefore, Ramirez could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme to this day remains concealed by Forest and the co-conspirators.

232. From the original establishment of the Enterprises until the present, neither Ramirez nor her son were aware of any specific fraudulent or predicate acts alleged as part of the Enterprises in this Complaint. Ramirez did not see any media or receive any communication describing any of the fraudulent conduct alleged as part of the Enterprises. Ramirez did not know about Lexapro's negative efficacy data as it relates to children under the age of 12 being treated for MDD. Indeed, Ramirez was unaware that she had been the victim of Forest's

fraudulent scheme until February of 2014. Prior to learning about the fraud, Ramirez did not have any reason to investigate Forest's or the Enterprises' conduct or reason to suspect she had been a victim.

MOTIVES AND CAUSATION OF DAMAGE

233. Forest's and the co-conspirators' motive in creating and operating the fraudulent scheme and Enterprise described herein was to obtain additional revenues from the marketing and sale of Celexa and Lexapro for pediatric and adolescent use.

234. The fraudulent scheme and Enterprises were designed to, and did, cause Plaintiffs and members of the Classes to pay for Celexa and Lexapro prescriptions in order to treat children and adolescents for whom the drugs had been shown to be ineffective and unsafe. Moreover, as alleged above, the Enterprises' deceptive conduct caused an overvaluation of the drugs, which resulted in monies being lost by Plaintiffs and members of the Classes through payments for Celexa and Lexapro. The fraudulent scheme also caused Plaintiffs and members of the Classes to pay for Celexa and Lexapro prescriptions to treat conditions and populations for which it was not effective. In the absence of Forest's improper conduct, Plaintiffs and members of the Classes would not have paid for such Celexa and Lexapro prescriptions.

USE OF THE MAILS AND WIRES

235. During the Class Period, Forest and the other Enterprise participants used thousands of mail and interstate wire communications in order to organize, schedule, create, develop, monitor and manage their fraudulent scheme as chronicled throughout this Complaint. The scheme involved national marketing and sales plans and programs, and encompassed physicians and victims across the country.

236. Forest's and the other Enterprise participants' use of the mails and wires to perpetrate their fraudulent Enterprises involved thousands of communications throughout the Class Period, which involved, among others, the following:

[redacted]

materials being sent to doctors across the country;

b [redacted]

[redacted]

237. In addition, Forest's corporate headquarters in New York and Missouri have and continue to communicate by United States mail, telephone, and facsimile with various local district managers, medical liaisons and pharmaceutical representatives and Enterprise participants in furtherance of Forest's schemes.

SCOPE OF ALLEGATIONS

238. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Celexa, occurred between 1998, the date that the FDA approved the marketing of Celexa, and the present day. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Lexapro occurred before the date that the FDA approved Lexapro for use in adults in 2002 and until the present day.

239. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Celexa and Lexapro for pediatric use, took place throughout the entire United

States and District of Columbia.

RICO CLASS ALLEGATIONS

240. This matter is brought as a class action pursuant to Federal Rule of Civil Procedure 23, by putative class representatives Delana Kiossovski and Renee Ramirez, on behalf of themselves and consumers who are purchasers of Celexa and Lexapro for use in children and adolescents throughout the United States. Delana Kiossovski and Renee Ramirez will serve as class representatives for the nationwide Celexa Class and Lexapro Classes.

241. As discussed at length in this Complaint, Forest and the other Enterprise participants have engaged in a comprehensive program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's efficacy and safety in treating pediatric depression. Forest's conduct and that of the co-conspirators 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 claimants such as Plaintiffs and the consumers Plaintiffs seeks to represent, class resolution can be an effective tool to redress the harm. This action is well suited for class-wide resolution.

242. Forest's deceptive and misleading marketing scheme increased the number of prescriptions of Celexa or Lexapro written and filled during the Class Period. Because Forest withheld material information about the true safety and efficacy of Celexa or Lexapro, prescribing physicians did not have the knowledge necessary to make informed decisions regarding Celexa or Lexapro prescriptions. Physicians thus wrote prescriptions they would not otherwise have, and Plaintiffs and the members of the Classes, unaware of Forest's scheme, paid and/or reimbursed for payments for these prescriptions. Although effective, safer, and less expensive alternatives are available, Forest's promotion and marketing of Celexa or Lexapro's safety and effectiveness has been highly successful, resulting in Forest receiving billions of dollars in profits, representing ill-gotten gains to which Forest is not entitled.

243. Plaintiffs and similarly-situated class members bear the ultimate responsibility of paying for Celexa or Lexapro prescriptions for pediatric use.

244. Patients relied on Forest's misrepresentations of Celexa or Lexapro's safety and efficacy when making purchases of the drugs. Physicians relied on Forest's misrepresentations of Celexa or Lexapro's safety and efficacy in prescribing the drugs for their patients. From both groups, Forest withheld material information about the drugs' safety and efficacy that was not otherwise available and undercut the entire rationale for their use. Had Forest or its co-conspirators disclosed the true safety and efficacy information about these drugs during its promotion, physicians would have been faced with the prospect of prescribing an ineffective medication that would increase their patients' risk of suicidality over 2.5 times compared to doing nothing at all.

245. The proposed classes sought here ("Class" or "Classes") are defined as follows:

Celexa Class

All persons, in the United States of America and its territories, who paid or incurred costs for the drug Celexa for use by a child or adolescent (a person under the age of 18 years), for purposes other than resale, since 1998. Excluded from the Class are employees of Forest, including its officers and directors, and the Court to which this case is assigned.

Lexapro Class

All persons, in the United States of America and its territories, who paid or incurred costs for the drug Lexapro for use by a child or adolescent (a person under the age of 18 years), for purposes other than resale, since 2002. Excluded from the Class are employees of Forest, including its officers and directors, and the Court to which this case is assigned.

Lexapro Under 12 Years Old Subclass

All persons, in the United States of America and its territories, who paid or incurred costs for the drug Lexapro for use by a child under the age of 12 years old, for purposes other than resale, since 2002. Excluded from the Class are employees of Forest, including its officers and directors, and the Court to which this case is assigned.

246. The Classes are properly brought and should be maintained as a class action 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 for use by children and adolescents.

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 the Classes, their members, and their respective prescribing healthcare professionals. Thus, all members of the Classes have common questions of fact and law, *i.e.*, whether Forest engaged in a comprehensive program and conspiracy 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 and a racketeering conspiracy. Plaintiffs and members of the Classes paid for Celexa and/or Lexapro for use by children and adolescents, expecting it to be effective and safe. 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 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.

247. 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 depression. 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.

WASHINGTON CLASS ALLEGATIONS

248. This matter is brought as a class action pursuant to Federal Rule of Civil Procedure 23, on behalf of all persons who purchased the drugs Celexa and Lexapro for use by a child or adolescent within the State of Washington. As discussed at length in this Complaint, Forest has engaged in a comprehensive program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's efficacy in treating pediatric MDD. Forest's conduct has been directed at consumers in the State of Washington 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 categorically directed at a class of claimants harmed by that conduct. Accordingly, Plaintiff Delana Kiossovski's Washington causes of action are uniquely suited for class-wide resolution.

249. The Washington Consumer Classes consist of:

Washington Celexa Class

All persons who paid or incurred costs for the drug Celexa for use by a child or adolescent (a person under the age of 18 years), within the State of Washington, for purposes other than resale, since 1998. Excluded from the Class are employees of Forest, including its officers and directors, and the Court to which this case is assigned.

Washington Lexapro Class

All persons who paid or incurred costs for the drug Lexapro for use by a child or adolescent (a person under the age of 18 years), within the State of Washington,

for purposes other than resale, since 2002. Excluded from the Class are employees of Forest, including its officers or directors, and the Court to which this case is assigned.

250. The Washington Consumer 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: Thousands of Celexa and Lexapro prescriptions for pediatric use were purchased in the State of Washington by members of the Classes.

b. Commonality: Questions of law and fact are common to all members of the Washington Classes. Specifically, Forest's misconduct was directed at all members of these Classes and the prescribing healthcare professionals and consumers in Washington. Thus, all members of the Washington 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: Kiossovski's claims are typical of the claims of the Washington members of the Classes because their claims arise from the same course of conduct by Forest, *i.e.*, false, misleading and deceptive marketing. Plaintiff Kiossovski and all members of the Classes were exposed to Forest's misleading and deceptive marketing program and Plaintiff Kiossovski and all members of the Classes purchased Celexa and/or Lexapro for use in a child or adolescent. Accordingly, their claims are typical of the Classes.

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

251. The Washington 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 Washington 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 depression. 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*:

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

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

g. 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;

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

i. Managing and administering Washington refund classes for those members of the Washington Classes would be relatively easy in light of the wealth of information available to Forest regarding its documented promotion of Celexa and/or Lexapro for pediatric use to specific physicians in Washington.

COUNT I: VIOLATIONS OF 18 U.S.C. § 1962(c)

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

253. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the Enterprises through the pattern of racketeering activity detailed throughout this Complaint in violation of 18 U.S.C. § 1962(c).

[redacted]

[redacted]

255. The Enterprises functioned as an ongoing organization and continuing unit. The Enterprises were created and/or used as tools to effectuate a pattern of racketeering activity. Each of the Enterprise participants, including Defendants, is a "person" distinct from the respective Enterprises.

256. Each of the Defendants, in concert with the other Enterprise participants, created and maintained systematic links for a common purpose, *i.e.*, to aid in marketing Celexa and Lexapro as effective and safe for use by children and adolescents, while suppressing evidence to the contrary. Each of the participants in the Enterprises received revenue, directly or indirectly and/or otherwise benefitted, from the scheme to promote Celexa and Lexapro as safe and effective for use by children and adolescents. Such revenue was exponentially greater than it would have been if Celexa and Lexapro were marketed appropriately and the true efficacy and safety risks of Celexa and Lexapro disclosed. All participants of the Enterprise were aware of Defendants' control over the activities of the Enterprises in promoting Celexa and Lexapro for pediatric use. Furthermore, each portion of the Enterprises benefited from the existence of the other parts.

257. Defendants established the Enterprises to accomplish goals that were instrumental to its scheme designed to market and sell Celexa and Lexapro for pediatric and adolescent uses.

First, it created parallel marketing structures that appeared independent from Forest's ordinary promotion forces in an attempt to avoid federal regulations concerning off-label promotion. Second, to execute the publication strategy, favorable articles had to be generated and published that appeared to emanate from independent physicians. Third, in order to widely disseminate the fraudulent pediatric message, Defendants' Enterprises developed misleading labeling which was widely disseminated by the Material Omissions Sub-Enterprise across the country to physicians and prescribers. These three goals were complementary and mutually reinforcing. The production of favorable publications created a "buzz" regarding Celexa and Lexapro, while the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with the appearance of legitimacy.

258. There was a common strategy employed by these Enterprise participants, whereby the Enterprise participants would recruit and use physicians, both for marketing and publication, to foster the pediatric use of Celexa and Lexapro by creating the perception that independent physicians were achieving favorable results with Celexa and Lexapro and achieving clinically successful results from Celexa and Lexapro in the pediatric population.

259. The various participants of the alleged Sub-Enterprises performed work that Forest could not appear to be doing, including funneling payments to physicians, misleading the public into believing the message was coming from a neutral source, covering up Forest's control over the Enterprises, and actively concealing any negative information.

260. These systematic linkages between physicians, marketing participants, physician participants, Forest and all the Enterprise participants were established for a common purpose: to aid in marketing and selling Celexa and Lexapro for pediatric uses. Many of the Enterprise participants received substantial revenue from the scheme to promote Celexa and Lexapro off-label for pediatric use. Such revenue was exponentially greater than it would have been if Celexa and Lexapro had been marketed appropriately.

261. All participants of the Enterprises were fully aware of Forest's control over the

Enterprises. Furthermore, each portion of the Enterprises benefited from the existence of other parts. For example, the Publication Sub-Enterprise provided literature which provided medical legitimacy to the Direct-to-Prescriber Sub-Enterprise.

262. The common fraudulent purpose of the Enterprise was effectuated through this broad network consisting of Forest and the other Enterprise participants. Alternatively, the Enterprises was and is comprised of the various large Sub-Enterprises and smaller sub-enterprises, each of which is in and of itself an association-in-fact within the meaning of 18 U.S.C. § 1961(4).

263. The sub-enterprises can be broken down into additional, smaller enterprises which were formed and controlled by the Defendants for the purpose of marketing, promoting and selling Celexa and Lexapro for pediatric and adolescent uses. Each of these smaller entities is a RICO enterprise and association-in-fact within the meaning of 18 U.S.C. § 1961(4). These smaller enterprises are comprised of one "marketing participant" and one "physician participant" in the Peer Selling Sub-Enterprise discussed above, or one participant in the Publication Sub-Enterprise listed above, along with Defendants, including their employees and agents, and the participating physicians [redacted] Alternatively, these smaller enterprises can also be comprised of only an individual marketing participant and Defendants, without the physician participants.

264. These Sub-Enterprises are each ongoing organizations that function as a continuing unit. Each Sub-Enterprise was created and/or used as a tool to effectuate Forest's pattern of racketeering activity and, by itself, could constitute a RICO enterprise. The Defendants are "persons" who are distinct from each of the Sub-Enterprises.

265. The Enterprises (and each of the sub-enterprises) engaged in and affected interstate commerce, because, *inter alia*, it marketed, promoted, sold, purchased, or provided

Celexa and Lexapro to thousands of individuals throughout the United States.

266. The named Defendants exerted control over the Enterprises (and each of the Sub-Enterprises), and Defendants have participated in the operation or management of the affairs of the Enterprises (and each of the Sub-Enterprises).

267. Defendants conducted and participated in the affairs of the Enterprises (and each of the Sub-Enterprises) through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

268. As detailed above, Defendants' pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under 18 U.S.C. § 1343. Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting the uses for which Celexa and Lexapro were safe and effective so that Plaintiffs and members of the Classes paid for these drugs for which it was not scientifically proven to be safe and efficacious; (b) providing or publishing or causing to have provided or published presentations and materials containing false and/or misleading information upon which physicians, Plaintiffs, and members of the Classes relied upon when choosing to prescribe or pay for Celexa and Lexapro for pediatric use; (c) actively concealing, and causing others to conceal, information about the true safety and efficacy of Celexa and Lexapro to treat conditions for which it had not been approved by the FDA; [redacted]

269. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiffs and members of the Classes depend on the honesty and integrity of Defendants in representing the efficacy of Celexa and Lexapro uses. It is impractical and unduly expensive for the Class Members to perform their own clinical trials or assemble all known medical evidence

relating to Celexa's and Lexapro's safety or efficacy. The Class members also rely on federal law obligating Defendants to provide fair and balance information about their drug products and reasonably presume that when such marketing of Celexa and Lexapro was conducted for pediatric use, it complied with Defendants' obligations under federal law.

[redacted]

271. As detailed above, Defendants pattern of racketeering activity also includes acts indictable under 18 U.S.C. § 1952 (use of interstate facilities to conduct unlawful activity). Defendants' acts consisted of, *inter alia*: (a) paying substantial fees and extensive travel benefits to physician participants for agreeing to engage in peer-to-peer marketing (illegal kickbacks); (b) paying physicians for studies that had minimal, if any scientific value or paying physicians to use their names on ghost-written articles; and (c) making outright payments, in the form of grants, to reward doctors who actively prescribed Celexa or Lexapro or promoted them for use in children in adolescents.

272. At all times during the fraudulent scheme, Defendants and the other Enterprise

participants had a legal and ethical obligation of candor to, and honest dealing with, public and private payors, physicians, and the medical community.

273. The conduct of the Enterprises (and each of the Sub-Enterprises) described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decision for the Enterprises (and each of the Sub-Enterprises) to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

274. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the members of the Classes. Indeed, Plaintiffs were one of the primary victims of Forest's fraudulent conduct. Forest knew that, if it misrepresented the ability of Celexa and Lexapro to treat pediatric depression, physicians and patients would prescribe and purchase the drugs and Plaintiffs would foot the bill. Forest knew that many, if not most, of all prescriptions for Celexa and Lexapro were paid by consumers such as Plaintiffs and members of the proposed Classes. Forest's racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiffs and members of the Classes. Forest's racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and the Classes.

275. Forest's motive in creating and operating the fraudulent scheme and the Enterprises was to obtain additional revenues from the marketing and sale of Celexa and Lexapro for pediatric use. The fraudulent scheme was designed to, and did, cause Plaintiffs and the Classes to pay for Celexa and Lexapro prescriptions to treat pediatric depression without being fully informed about the likelihood of the drugs' efficacy.

276. Plaintiffs and members of the Classes have been injured in their property by reason of these violations in that Plaintiffs and members of the Classes paid hundreds of millions of dollars for Celexa and Lexapro that they would not have paid had Defendants not engaged in

this pattern of racketeering activity.

277. The injuries to Plaintiffs and members of the Classes were directly and proximately caused by Defendants' racketeering activity. In the absence of Forest's improper conduct, Plaintiffs and the Classes would not have been deprived of material information about Celexa and Lexapro efficacy, thereby causing economic harm in the form payments for Celexa and Lexapro they would not have otherwise made.

278. Above all, the Enterprise participants, including Forest, have misled and deceived physicians and the consumers who rely on their professional judgment, including Plaintiffs and the members of the Classes proposed herein, about the safety and effectiveness of Celexa and Lexapro in treating children and adolescents. Forest has deprived and continues to deprive prescribing healthcare providers of the information needed to evaluate the true risks and benefits of prescribing Celexa and Lexapro for children and adolescents, and has deprived consumers of this same information which is utilized in determining whether the consumer will pay for such prescriptions.

279. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiffs and the Classes for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

280. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs and members of the proposed Classes have suffered damages. Plaintiffs and the Class members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

COUNT II: VIOLATION OF 18 U.S.C. § 1962(d)

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

282. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

283. Defendants and the other co-conspirators violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy was to conduct or participate in, directly or indirectly, the affairs of the Enterprises described previously through a pattern of racketeering activity. [redacted]

284. Defendants, as co-conspirators, engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the members of the Classes of money.

285. The nature of the co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

286. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs and the members of the Classes have been and are continuing to be injured in their business or property as set forth more fully above.

287. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts discussed extensively herein, including but not limited to:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and

d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

288. Defendants' violations of the above federal laws are continuing and will continue. Plaintiffs and members of the Classes have been injured in their property by reason of these violations in that Plaintiffs and members of the Classes have paid hundreds of millions of dollars for Celexa and Lexapro that they would not have made had Defendants not conspired to violate 18 U.S.C. § 1962(c).

289. Injuries suffered by Plaintiffs and members of the Classes were directly and proximately caused by Defendants' racketeering activity as described above. Had prescribers and patients known that Celexa and Lexapro were not clinically superior to placebo and increased the risk of suicide, no reasonable prescriber would have prescribed nor any patient/consumer, including Plaintiffs and the members of the Classes, would have purchased Celexa or Lexapro.

290. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiffs and the members of the Classes for three times the damages Plaintiffs and the Class members have sustained, plus the cost of this suit, including reasonable attorney's fees.

291. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs and members of the Classes have suffered damages. Plaintiffs and members of the Classes are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

COUNT III: WASHINGTON CONSUMER PROTECTION ACT

292. Plaintiff Delana Kiossovski incorporates by reference all proceeding paragraphs as if fully set forth herein.

293. Plaintiff Delana Kiossovski brings this Count pursuant to the Washington Consumer Protection Act ("CPA"), RCW § 19.86.010, *et seq.* Washington's CPA makes it unlawful to engage in any unfair methods of competition in commerce, and unfair or deceptive

acts or practices in commerce.

294. Plaintiff Kiossovski and the members of the Washington Classes are consumers who purchased Lexapro and Celexa for use by their children and adolescents. The State of Washington, where Plaintiff Kiossovski resides and is domiciled, has enacted laws to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. The Washington Consumer Protection Act broadly prohibits unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce.

295. Forest's comprehensive deceptive marketing program for Celexa and Lexapro, combined with its misleading drug labels and misrepresentations and non-disclosure of material information, misled consumers about Celexa's and Lexapro's safety and efficacy in treating pediatric depression and, as a result, Forest engaged in unfair and deceptive acts or practices in violation of the statute. By the misrepresentations and non-disclosures of material facts alleged above, Forest deceived and continues to deceive consumers, such as the Plaintiff Kiossovski and the members of the Washington Classes.

296. As alleged throughout this Complaint, Forest engaged in unfair, deceptive, and/or unlawful marketing in violation of the CPA by representing to the Washington members of the Classes that Celexa and Lexapro were safe and effective in treating pediatric depression when, in truth, Celexa and Lexapro have not been shown to be clinically effective and also present serious side effects. Forest sold and marketed Celexa and Lexapro while omitting and/or misrepresenting negative clinical trial results as they relate to efficacy of the drugs and which omissions and/or misrepresentations materially affect a consumers' decision to purchase Celexa and Lexapro. These unfair and/or deceptive acts or practices would cause a consumer to believe, incorrectly, that Celexa and Lexapro is effective and safe for treatment of children and adolescents.

297. Forest has misled consumers about the safety and efficacy, or lack thereof, of Lexapro and Celexa in treating children and adolescents with major depressive disorder. Forest has consistently maintained that Celexa and Lexapro are safe and efficacious for the pediatric

population by touting purported "positive" studies while failing to disclose and, instead, intentionally concealing negative studies concerning these drugs through a concerted effort to defraud consumers and treating physicians. In truth, Forest's own clinical studies have shown that the antidepressants Lexapro and Celexa are not efficacious for treating depression in children and adolescents [redacted]

298. Despite having clear knowledge about Celexa and Lexapro's impotent efficacy data, Forest perpetrated a carefully-orchestrated and illegal scheme to market and promote Celexa and Lexapro for "off-label" pediatric use for which the safety and efficacy of the drugs had not been established. Forest's scheme was designed to and in fact directly misled prescribing doctors about Celexa's and Lexapro's efficacy in treating pediatric depression. This program of deception included, but is not limited to, the following:

[redacted]

[redacted]

299. Forest, through deliberate actions and omissions, concealed material negative efficacy information about Celexa and Lexapro in treating children and adolescents, thereby depriving all consumers their prescribers of the ability to make an informed decision about purchasing or prescribing the drugs for pediatric depression.

300. Forest knew that disclosing Celexa's and Lexapro's true pediatric efficacy and safety risks, which includes the increased risk of suicidality and suicide, to consumers and prescribing healthcare professionals, such as Kiossovski and members of the putative Classes, 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 risks, Forest hid the efficacy and safety data, misled Kiossovski, the members of the Classes she seeks to represent and their prescribing healthcare professionals and positioned Celexa and Lexapro as effective and safe pediatric medications into the medical community and to the public.

301. Forest's conduct offends any notion of public policy and is unlawful, unfair and deceptive because it effectively promotes the use of a drug with known side effects and a lack of efficacy. The public has an interest in ensuring that drugs are sold safely, for indicated uses, that drug companies do not engage in unlawful promotion and sale of their drug products, and that physicians and other prescribers who prescribe drugs do so with full disclosure of their risks and benefits, 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.

302. Prosecution of this claim therefore will result in a substantial public benefit because this class action will prevent Forest from continuing to deceive and mislead Plaintiff and the Washington Classes and will provide an important public health benefit by apprising consumers and prescribing physicians of the substantial risk and lack of efficacy associated with Celexa and Lexapro used by children and adolescents.

303. These acts and/or omissions are unlawful, unfair and/or deceptive within the meaning of RCW 19.86.010 *et seq.* and constitute unfair competition or unfair, deceptive acts or fraudulent acts or practices.

304. Forest's misrepresentations, non-disclosure and concealment occurred with respect to the advertising, marketing, promoting and sales of Celexa and Lexapro, and therefore occurred in "trade" or "commerce" within the meaning of Wash. Rev. Code § 19.86.010.

305. Forest's practices have and continue to affect the public interest and cause disparate and unequal impacts on Washington consumers, including Plaintiff Kiossovski and the members of the Washington Classes. Forest's unfair and deceptive practices, as alleged herein, have caused injury and damages to Kiossovski and the members of the Washington Classes

within the meaning of the Washington consumer fraud laws, in the form of payments made for purchases of Celexa and/or Lexapro for their children and adolescents, which purchases Plaintiff Kiossovski and the members of the Classes would not have made had they been made aware of the deceptive and fraudulent scheme.

306. Because Forest was prosecuted criminally for its conduct in promoting Celexa, in violation of federal laws, it is alleged that Forest has engaged in conduct which is against public policy and *per se* unlawful within the meaning of the Washington CPA.

307. Under the CPA, Plaintiff Delana Kiossovski and the members of the Washington Classes are also entitled to actual damages, return of purchase price, restitution, an injunction against the use of unlawful trade practices, a trebling of the amount of any refunds they may obtain, and to an award of attorney fees.

COUNT IV: UNJUST ENRICHMENT

308. The allegations of each of the preceding and subsequent paragraphs are incorporated by reference as if fully set forth herein.

309. The misrepresentations and non-disclosures by Forest of the material facts detailed above have caused Forest to be unjustly enriched at the expense of Plaintiffs and the members of the Classes.

310. Forest's use of various forms of media to influence prescribing health care providers and advertise, promote and otherwise call attention to Celexa and Lexapro, deceptively misrepresented Celexa and Lexapro's attributes, performance/efficacy, characteristics and risks. Celexa and Lexapro could not and cannot perform as advertised and promoted, and Forest's promotion of Celexa and Lexapro constitutes unfair, deceptive, untrue or misleading advertising and promotion. Forest's advertisements and labeling provided to the medical community deceived and continue to deceive that community and the consuming public. These advertisements and promotional efforts were disseminated for the purposes of unfairly gaining consumer market share by unfair competition. Forest either knew, recklessly disregarded, or

reasonably should have known that such advertising was untrue and/or misleading.

311. As a result of the conduct described above, Forest has been and continues to be unjustly enriched at the expense of minor Celexa and Lexapro users, their parents and guardians, and the general public, including the Plaintiffs and the putative Classes. Specifically, Forest has been unjustly enriched by the receipt of millions of dollars in monies and profits from selling Celexa and Lexapro for and to minors under misleading pretenses.

312. Defendants have voluntarily accepted and retained these profits, with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and members of the putative Classes paid for Celexa and Lexapro when they otherwise would not have done so.

313. Forest has unjustly retained financial benefits at the expense of Plaintiffs, the members of the Classes, and the general public. Forest's unjust enrichment has caused damage to Plaintiffs and the Classes of persons and entities they intend to represent because Forest has retained the financial benefits from the sale of Celexa and Lexapro which Forest knew was no more effective than placebo and which Forest knew increased the risk of the serious adverse events described herein. It would be inequitable for Defendants to retain the profits, benefits, and other compensation they obtained through their wrongful acts.

314. Plaintiffs and the members of the Classes are therefore entitled to an award of compensatory and punitive damages in amount to be determined at trial for the payments made by Plaintiffs and members of the Classes.

EXEMPLARY DAMAGES ALLEGATIONS

[redacted]

[redacted]

DEMAND FOR JURY TRIAL

318. Plaintiffs respectfully request a trial by jury on all claims triable as a matter of right.

PRAYER FOR RELIEF

319. 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 Classes;

b. Designate Plaintiffs as representatives for the respective classes and Plaintiffs' undersigned counsel as Class Counsel for the respective classes;

c. Issue a judgment against Forest that:

   i. Grants Plaintiffs and the various Classes alleged herein a refund of all monies acquired by Forest by means of its deceptive and unlawful marketing of Celexa and Lexapro;

   ii. Grants Plaintiffs and the Classes alleged herein an award of restitution

and/or disgorgement of Forest's profits from its deceptive and unlawful marketing, promoting and selling of Celexa and Lexapro in violation of the consumer protection claims;

iii. Grants Plaintiffs and the various Classes alleged herein any actual or compensatory damages for the payments made by Plaintiffs and members of the Classes for Celexa and Lexapro used in children and adolescents in such amount to be determined at trial and as provided by applicable law;

iv. Grants Plaintiffs and the various Classes alleged herein exemplary, treble, and punitive damages sufficient to punish and deter Forest and others from future deceptive and unlawful marketing practices;

v. Grants Plaintiffs and the various Classes alleged herein pre-judgment and post-judgment interest

vi. Grants Plaintiffs and the various Classes alleged herein reasonable attorneys' fees and costs of suit; and

vii. Grants Plaintiffs and the various Classes alleged herein such other and further relief as the Court deems just and proper under the circumstances.

Dated: November ___, 2015

Respectfully submitted by,

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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).

Dated: January 15, 2016

Respectfully submitted,

/s/ R. Brent Wisner
R. Brent Wisner