UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON, SEATTLE DIVISION

MARLENE T. LOCONTE and [redacted], on behalf of themselves and all others similarly situated, Plaintiffs, v. FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC. Defendants.	CASE NO. COMPLAINT CONSUMER CLASS ACTION JURY TRIAL DEMANDED

COMPLAINT

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 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). In every clinical trial designed to test efficacy, the observed benefit received by those taking Celexa and Lexapro was not clinically different than the benefit children and adolescents received taking placebo. 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. In fact, for an overwhelming majority of the time that Forest has marketed Celexa and Lexapro, Forest's own clinical trial data has shown that the drugs do not provide a clinically significant benefit over placebo in treating pediatric MDD. 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:

- Crafting a marketing plan with the assistance of certain co-conspirators involved in the Celexa and Lexapro Off-label Deceptive Promotion Enterprise to specifically increase pediatric use of Celexa and Lexapro;
- Conspiring to train an aggressive sales force designed to persuade prescribing healthcare professionals that Celexa and Lexapro are effective treatments for children and adolescents using fraudulent clinical trial data and paid-for endorsements from leaders in the medical profession;
- Paying millions to medical professionals to "present" the use of Celexa and Lexapro in pediatric populations as an effective treatment for pediatric MDD, despite the scientific data suggesting that Celexa and Lexapro are not clinically effective at treating pediatric depression;
- Paying physicians to participate in "advisory boards" wherein Forest and the Enterprise was better able to convey marketing messages including the fraudulent promotion of Celexa and Lexapro for pediatric use;
- Paying physicians to participate in bogus "clinical trials" whereby physicians were given kickback payments under the guise of conducting useless clinical trials; and

- 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 Marlene T. LoConte (hereafter "LoConte" and "Plaintiff") is a citizen of the State of Massachusetts, domiciled in the city of Malden, Massachusetts. During the class period, LoConte paid, in whole or in part, for Lexapro prescribed to her minor child for the

treatment of pediatric MDD. LoConte was injured by the conduct alleged herein by paying for a drug while being misled about a material aspect of the product and, in addition, for purchasing a product that no reasonable consumer would have purchased knowing all the facts.

10. Plaintiff [redacted] (hereafter [redacted] and "Plaintiff") is a citizen of the [redacted]. During the class period, Mrs. [redacted] paid, in whole or in part, for Celexa prescribed to her minor daughter for the treatment of pediatric depression. [redacted] 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.

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:

a. H. Lundbeck A/S ("Lundbeck"), a Danish corporation and partner of Forest in the development of Celexa and Lexapro, conspired with Forest at least between 2001 and 2005 to conceal material information about the pediatric efficacy of Celexa and Lexapro. Lundbeck disclosed the results of a failed clinical trial to Forest, and then proceeded to aid Forest in concealing this material information. Lundbeck, as a prominent pharmaceutical company, owed a unique duty to consumers to disclose material information about its products to consumers and prescribing healthcare professionals, but deliberately chose to further the Enterprise by keeping silent.

b. Karen Wagner is a citizen of the State of Texas and a professor at the University of Texas Medical Branch in Galveston. Among other involvement in the Enterprises, Wagner was a lead investigator in the Celexa pediatric study (Study 18) and lead "author" of an article ghostwritten by a Forest-paid "medical communications company" and published in *The American Journal of Psychiatry* touting the efficacy and safety of Celexa in pediatric patients. In addition, Dr. Wagner presented the results of Study 18 at numerous medical conferences. Dr. Wagner was also a member of a Forest advisory board concerning Celexa and Lexapro and a consultant to Forest. Forest compensated Dr. Wagner considerably for her role and participation in the Enterprises.

c. Jeffery Bostic, the Medical Director of the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital, from 1996 through 2006, was a highly influential opinion leader in the field of child and adolescent psychiatry, a Forest Speaker Bureau member, and was a key cog in Forest's elaborate and fraudulent promotion of Celexa and Lexapro for pediatric use. As discussed more thoroughly below, Dr. Bostic

collaborated extensively with Forest and other co-conspirators in furtherance of the Celexa and Lexapro Enterprises.

d. Graham Emslie was a principal investigator in a Forest-funded clinical trial of Lexapro ("Lexapro Study 32" discussed below) which began in 2005, was completed in 2007, and was submitted to the FDA in 2008 along with Study 18 to obtain approval of Lexapro for use in adolescents. Dr. Emslie's study was published under his name (along with three other Forest "experts") in the *Journal of the American Academy of Child and Adolescent Psychiatry* in 2009. Dr. Emslie has served as a speaker for Forest, including presenting the data from Study 32 at medical conferences, and has received honoraria from the company to sit on advisory boards concerning Celexa and Lexapro, all designed to further Forest's unlawful and fraudulent promotion of Celexa and Lexapro through the Enterprise.

e. Andres Martin was the editor in chief of the *Journal of the American Academy of Child and Adolescent Psychiatry* in 2009 when Emslie's Lexapro Study 32 was published. Martin served as the conduit for the publication of the Emslie study and manuscript and, on information and belief, he knew the results of the study were flawed and did not support efficacy in pediatric patients. These acts were carried out in support of the Enterprise.

f. Parke-Davis, a division of Warner Lambert, headquartered in Morris Plains, New Jersey entered into a co-promotion agreement and arrangement with Forest in which Parke-Davis and Forest jointly introduced and launched Celexa to the public and received the initial FDA approval for Celexa. Parke-Davis promoted and marketed Celexa in furtherance of the Enterprises from 1998 until the arrangement was terminated on April 20, 2000 due to the merger of Warner Lambert and Pfizer Inc. During this period, Parke-Davis promoted and sold Celexa through its sales force, including promoting the drug for pediatric use in furtherance of the Enterprises.

g. inVentiv Health, Inc., headquartered in Burlington, Massachusetts, used its sales force to illegally promote Celexa in furtherance of the Enterprises, including promotion for pediatric use, once the agreement with Parke-Davis was terminated.

h. IntraMed Educational Group ("IntraMed"), headquartered in New York, New York, participated in the pediatric promotion of Celexa and Lexapro in furtherance of the Enterprises by creating online webcasts for Forest's online continuing medical education programs. IntraMed also had a lead role in organizing the Celexa and Lexapro Advisory Boards, which, as discussed below, played an important role in furthering the Enterprises.

i. GCI Healthcare ("GCI"), headquartered in New York, New York, is a public relations firm that assisted the Enterprises in presenting information, including flawed data and questionable study results, to the consuming public and treating physicians in order to promote and further advance the purposes of the Enterprises. GCI worked extensively with Karen Wagner and other co-conspirators in promoting Celexa Study 18 and getting it published in the *American Journal of Psychiatry*.

j. BSMG Worldwide ("BSMG"), which was acquired by Weber Shandwick Worldwide, and headquartered in New York, New York, was a third-party medical marketing firm, specializing in medical publications, that was engaged by Forest to develop manuscripts, presentations, and journal articles related to the Enterprises' support of Celexa and Lexapro use in the pediatric population. BSMG ghostwrote medical manuscripts and articles for the Enterprises to be submitted for publication in medical journals by other authors in furtherance of the purpose of the Enterprises. In 2001, BSMG, through its employee Natasha Mitchner, drafted a journal article published that year in the *Journal of Child and Adolescent Psychopharmacology* entitled, "A Retrospective Study of Citalopram in Adolescents with Depression" and "authored" by Jeffrey Bostic.

k. Natasha Mitchner was a Senior Account Executive of BSMG, employee of Weber Shandwick, and a physician who served in a publication planning role assisting the

Enterprises in tracking and ghostwriting medical articles promoting the use of Celexa and Lexapro in children and adolescents. Mitchner was the medical communications writer who took the lead in ghostwriting and completing the Celexa Study 18 manuscript and article during her employment at BSMG and Weber Shandwick. Her actions were taken in furtherance of the Enterprises.

l. Prescott Medical Communications Group ("the Prescott Group"), headquartered in Chicago, Illinois, is a marketing communications company that participated in the Enterprises by assisting in the ghostwriting and promoting of the Celexa Study 18 manuscript.

m. Mary Prescott was the President of BSMG and the Prescott Group. Prescott had an integral role in the ghostwriting and publication of the Celexa Study 18 article in the *American Journal of Psychiatry* and aided in the concealment of negative data in the study and its publication.

n. Jack Gorman, a professor of Psychiatry at Columbia College of Physicians and Surgeons in New York, New York, was a Forest and Parke-Davis consultant, speaker, and executive advisory board member. Dr. Gorman was a main organizer of Forest's EXCEED trial (discussed below) and also the editor of the *American Journal of Psychiatry*. Jack Gorman served as the conduit for the publication of the Celexa Study 18 manuscript in the *American Journal of Psychiatry*, although he knew the results of Forest's Celexa pediatric studies were flawed. Dr. Gorman's acts were in furtherance of the Enterprises.

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.

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 [redacted] 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 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.[1] Trial participants are divided (unbeknownst to them) into a treatment

[1] 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

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 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.*,

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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.

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.

37. Commercially, Celexa was an enormous success. In Forest's brochure to investors in 1999, it stated that, in "[j]ust eight months after launch, Celexa has captured more than a seven percent share of new prescriptions that are written for antidepressants." In fact, following Celexa's launch, sales of Celexa comprised 17% of all of Forest's revenue in 1999, 49% in 2000, 61% in 2001, 69% in 2002, and 77% in 2003. During that same period, Forest's annual revenue increased from $527 million in 1998 to $2.25 billion in 2003. This expansion of revenue was directly caused by Forest's success in marketing and selling Celexa which, according to Forest's annual report, "has come at the expense of the market leaders."

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.[2] 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 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

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

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.[3] Celexa Study 18 consisted of eight (8) weeks of treatment with either Celexa or placebo. At the end of the eight (8) weeks, the participant's CDRS-R score was taken again. Celexa Study 18 was completed in April 2001 and was subsequently distributed to Forest Executives 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,

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

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.[4] 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 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.*

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[4] 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.

49. As it turns out, Dr. Mathews' criticism of Celexa Study 18 was well founded. The unpublished version of Celexa Study 18 reveals that the first nine (9) participants in the study were given "1 week of medication with potentially unblinding information (tablets had an incorrect color coating)." Excluding these potentially unblinded patients from the analysis would have been appropriate. After all, this was supposed to be a "double-blind" clinical trial, and unblinding would compromise the integrity of the study. Without the potentially unblinded patients, the statistical analysis showed that Celexa was *not statistically superior to placebo*. However, for reasons not disclosed in the study report, a decision was made by Forest and other co-conspirators to include eight of the nine potentially unblinded patients. By adding the unblinded patients' data, Celexa Study 18 was able to find statistical significance between the treatment and placebo-control group—even if only marginal. Neither Forest nor the co-conspirators ever disclosed this lapse to the medical community or public. It was not disclosed in Wagner's publication of the study or in the labels for Celexa and Lexapro. Use of unblinded patients is inconsistent with the whole point of a double blinded placebo-controlled trial – using them meant it was not a double blinded placebo-controlled trial, and promoting Celexa Study 18's results as if they were a fully randomized, double blinded placebo-controlled trial was misleading.

50. Forest and the co-conspirators also misrepresented the authorship of Celexa Study 18 which was integral to the success of the Celexa and Lexapro Deceptive Off-Label Promotion Enterprise and sub-enterprises with the purpose of promoting pediatric use.

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.[5]

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

[5] 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 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.

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.

65. When Lexapro Study 32 was submitted for publication, much of these flaws were commented on by researchers. One reviewer made the following comments:

> [Comment 6.] The effect size (ES) reported as 0.27 may be comparable to prior reports, however, it should be noted that according to Chen this is a relatively small ES. Given this small ES, there were no data to see if this level of change had any quality of life meaning.
>
> [Comment 7.] It was not clear why the authors consider the baseline difference in

the CDRS-R (~2 points) between the two treatment groups as not clinically significant even though it was statistically significant. This is confusing as the authors' then note that a CDRS-R treatment difference between the groups of ~2pts, which is statistically significant, shows efficacy. It was clear the authors controlled for these baseline severity scores but then what does a 2-point difference really mean for the adolescent? Is this a quality of life difference?

*The primary outcome (CDRS-R) was significant but there was little discussion of why most of the secondary outcome measures were not significant.

[Comment 8.] Finally, one has to wonder whether the restrictive entry criteria in conjunction with the small effect size limit the utility of [Lexapro] in the real world of adolescent MDD. Are these results statistically significant but clinically not meaningful?[6]

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.[7] The following chart reflects the clinical trials submitted in support of Lexapro's efficacy:

Study	*Stat. Efficacy*	*Clin. Efficacy*	*Plac. Effect*	*Drug Effect*	*Delta*
Celexa Study 94404	Negative	Negative	12.7 pts[8]	12.4 pts	(-0.3 pts)
Celexa Study 18	Positive[9]	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

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

[7] 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.

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

[9] Based on fraudulent data.

adolescents for MDD. Nonetheless, the FDA decided that, for the 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[10] 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.[11] 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.[12] 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:

> 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*

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[10] 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.

[11] 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.

[12] There were, in fact, only two studies performed on Lexapro, and only one of them purported to be positive.

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].
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> . . .
>
> 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[.]"

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

72. 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.

73. 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."

74. 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

75. 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.

76. The Enterprises alleged herein are associations-in-fact of Forest, Forest

subsidiaries, Forest executives and employees, Forest's business partners, third-party medical communications companies, marketing firms, publishing companies, public relations firms, physicians, university professors, and consultants, among others and including the co-conspirators identified herein. 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

77. The purpose of the Enterprises was to mislead and deceive consumers and prescribers about the ability of Celexa and Lexapro to treat pediatric depression and the safety of the drugs. Simply stated, Forest and the co-conspirators deliberately concealed Celexa and Lexapro's negative efficacy and safety data while actively engaging in a calculated and coordinated effort to promote Celexa and Lexapro for pediatric use. Indeed, since 1998, Forest has specifically targeted consumers and prescribing healthcare professionals for promoting the use of Celexa and Lexapro in pediatric patients. Forest's 2001 Celexa marketing plan states that "[t]he elderly patients and pediatric/adolescents represent a growing market. Refining messages to these specific patient segments will increase market share for Celexa. Together these segments represent over $1.5 billion." In defining Forest's "market segment objectives" for 2001, Forest expressed a goal "[t]o achieve 11.6% [new prescription] share by end of Q4 in pediatrics (0-19)." This objective was also stated in a "2001 Marketing Plan and Tactical Presentation" dated February 10, 2000. The presentation shows that a communication objective was to disseminate "off-label data" for pediatric patients, and that one of the "tactics" was to promote the Celexa 10 mg tablet and oral liquid for the pediatric population and "[e]ncourage child and adolescent psychs to present/publish case reports on Celexa." In the same plan, one of Forest's announced "communication objectives" involved leveraging the Washington Legal Foundation in order to disseminate off-label data for the pediatric use of Celexa. Similarly, a 2004 Lexapro marketing plan stated as part of its "summary/conclusion" that "[a]ll tactics are designed to increase

promotional share of voice and help Lexapro outperform in all market segments of indications (anxiety), providers (psychiatrists), third-party payers (managed care) and age groups (pediatric and geriatric development programs)."

78. 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

79. 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.

80. This Direct-to-Prescriber Sub-Enterprise involved Forest, and various departments, executives, and employees within Forest; Lundbeck; Karen Wagner; Jeffery Bostic; Forest Therapeutics; Forest Healthcare; Forest Ethicare; Forest Specialty Sales; Forest Research Institute; Parke-Davis; inVentiv Health; IntraMed; CGI; BSMG; Natasha Mitchner; Mary Prescott; the Prescott Group; and Dr. Gorman. Forest, Parke-Davis, and inVentiv Health were responsible for training sales representatives on methods for detailing prescribers about the use of Celexa and Lexapro in children and adolescents with the use of false and misleading

information. The remaining co-conspirators played a role in cultivating "scientific evidence" to support the Direct-to-Prescriber Sub-Enterprise.

81. Beginning in 1998 and continuing thereafter, Forest and the Direct-to-Prescriber Sub-Enterprise participants promoted Celexa and Lexapro for use in treating children and adolescents suffering from depression. Forest's deceptive and off-label promotion scheme, which was devised and executed by the Enterprise participants, consisted of various sales, marketing and promotional techniques including, but not limited to: (1) directing Forest sales representatives who promoted Celexa and Lexapro to make sales calls to physicians who treated children and adolescents; (2) promoting Celexa and Lexapro through various Forest sales representatives and certain co-conspirators nationwide for use in children and adolescents; (3) hiring outside speakers to talk to pediatricians, child psychiatrists, and other medical practitioners who specialized in treating children and adolescents about the benefits of prescribing Celexa and Lexapro to that patient population; (4) publicizing and circulating the purported "positive" results of pediatric Celexa and Lexapro studies, while failing to discuss the negative results of other studies; and (5) devising and disseminating a label for both Celexa and Lexapro which failed to identify these negative studies. These fraudulent activities were executed by use of wire and mail.

82. As part of the marketing plan designed by the Direct-to-Prescriber Sub-Enterprise participants, Forest assigned its sales representatives to specific geographic regions across the United States. Within each region, sales representatives encouraged specific doctors to increase their prescriptions of Celexa and Lexapro by making false and misleading representations about Celexa's and Lexapro's pediatric efficacy. Indeed, on information and belief, Forest, Parke-Davis, and inVentiv Health, specifically trained sales representative on promotion methods of selling and detailing to prescribers and were encouraged to state that Celexa and Lexapro were effective for children and adolescents.

83. The Direct-to-Prescriber Sub-Enterprise expressly and frequently used wire and

mail to perpetrate the fraud. Beginning in 1998, Forest and certain co-conspirators obtained data identifying medical practitioners who prescribed SSRIs. Using this data, Forest created "call panels," which consisted of a list of medical practitioners who prescribed SSRIs. These Celexa and Lexapro "call panels" intentionally included thousands of child psychiatrists and pediatricians who specialized in treating children and adolescents. Indeed, Forest and the other co-conspirators from this sub-enterprise specifically generated pediatric prescriber call panels as part of this Direct-to-Prescriber Sub-Enterprise.

84. On information and belief, using these panels, Forest, Parke-Davis, and inVentiv Health, would call, email, and write to prescribers all over the United States. These communications would contain false and fraudulent representations about Celexa and Lexapro and their ability to treat pediatric depression. Indeed, these communications were knowingly false because Forest and the co-conspirators were well aware of the overwhelming negative efficacy data.

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

86. In certain regions of the country, various Forest Division Managers actively encouraged the promotion of Celexa and Lexapro as safe and effective for use in children and adolescents despite evidence to the contrary. In 2001, for example, a Forest Division Manager in Massachusetts distributed sample "opening statements" to various Celexa sales representatives, including one that recommended Celexa for the treatment of an adolescent patient. A Forest Regional Director subsequently forwarded these sample opening statements to other Forest Division Managers and field sales personnel in the Northeast, with a copy to Forest national Vice President of Sales. The Regional Director stated in a cover memo: "There are some good opening statements here." These communications were transferred by mail and/or wire in furtherance of the Enterprises.

87. Similarly, in February 2002, another Forest Division Manager in Massachusetts

required a Forest sales representative to prepare sample "closing statements" for various patient types, including children. One of the written closing statements stated "I have provided you with some information on treating children with mood and anxiety disorders. . . . Will you prescribe [Celexa] to your pts in this pt population to gain more comfort and experience with it?" The Division Manager commended the sales representative and forwarded the closing statements to a Forest Regional Director.

88. At various times, Forest Regional Directors and Division Managers provided their sales representatives with copies of posters and journal articles on studies of Celexa for use in children and adolescents and directed the sales representatives to read the studies, and use them as sales aids in their details to physicians. Various Forest Division Managers also directed sales representatives to show off-label studies to physicians, but not leave copies of those studies with the physicians so as to avoid detection that would get the sales representative and Forest into trouble.

89. On information and belief, Forest, Parke Davis, and inVentiv Health had more than 500,000 promotional sales calls or "details" with pediatric prescribers, many thousands of which took place by phone. The sales representatives would then document these communications in "call notes," which were then filed in an electronic database. A cursory review of these call notes evidences the false and misleading nature of the Direct-to-Prescriber Sub-Enterprise. Examples of such notes include the following:

- discussed cx [Celexa] use in children . . . and results of dr. karen wagner study [Celexa Study 18] regarding cx use for children and adolescents.
- went over peds use, 0 drug interactions, less ae [adverse events], less compliance issues for children, he is sold on that. closed on keeping cx first choice.
- went over Celexa children, the invitation to the winery.
- [doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!

- discuss lx [Lexapro] brief and what he [is] using dosing w children . . . reinforce safety for children.
- Let him know some child psychs are using LX for children.
- Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat the anxiety and depression and OCD.
- dinner program [with child psychiatrist as speaker] at amato's with yale child study center.
- focus on Lexapro efficacy at just 10mg. . .great choice for child/adolescents. mainly sees children but always felt comfortable with CX & children -got his commitment to give [Lexapro] a fair clinical trial. went over lxp use on children and efficacy.

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

90. 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.

91. From 1998 through at least 2005, each sales representative typically had a quarterly marketing budget of thousands of dollars to spend on gifts to physicians. As a Forest Regional Director put it in an April 2006 memo to his sales team, "we have a ton of promotional money." Sales managers put pressure on their sales representatives to spend their entire marketing budgets.

92. Prior to 2003, sales representatives commonly spent their marketing money on fishing, golf, spa outings, and tickets to sporting events and the theater. Many of these physicians were pediatric specialists who exclusively or primarily treated pediatric populations. Both prior to and after 2003, sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an

expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."
- In September 2002, a sales representative gave a high-prescribing child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.
- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.
- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.
- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.
- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."
- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.
- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would

"always rxlex [i. e. , prescribe Lexapro] 141 aslong [sic] as we have fun and take care of him."

93. These illegal kickbacks are examples of the lengths to which the Direct-to-Prescriber Sub-Enterprise participants were willing to go to entice doctors to prescribe Celexa and Lexapro for pediatric use. The purchases of gifts provided to physicians and the call activity information associated with calls to physicians was tracked by wire through Forest's sales force automated tracking system, called "Jornada."

94. As a result of this Direct-to-Prescriber Sub-Enterprise, prescribers were induced to prescribe Celexa and Lexapro for pediatric use, even though the clinical trial evidence indicated they are clinically ineffective.

95. In furtherance of the Enterprises, in September 2004, a Forest executive, Lawrence Olanoff, falsely testified before Congress: "I want to emphasize that, because the FDA has not approved pediatric labeling for our products, Forest has always been scrupulous about not promoting the pediatric use of our antidepressant drugs, Celexa and Lexapro. This is the law, and we follow it." As Mr. Olanoff was well aware at the time, this statement was blatantly false. In fact, Forest, with the assistance of the other co-conspirators, had been illegally promoting the pediatric use of Celexa and Lexapro throughout the preceding six years.

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

96. The co-conspirators, including, but not limited to Parke-Davis, IntraMed, GCI, inVentiv Health, BSMG, Weber Shandwick, the Prescott Group, Mary Prescott, Natasha Mitchner, Jack Gorman and Forest, including Forest Executives and employees, created and implemented a peer-to-peer marketing scheme centered on hosting numerous events where doctors trained and/or approved by Forest would provide favorable information, while not disclosing negative information of which Forest and the co-conspirators were aware, related to the use of Celexa and Lexapro for pediatric depression, often under conditions where physicians

would be compensated for attending the presentation. 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. The announcements about events hosted by the Peer-Selling Sub-Enterprise were provided to target physicians by way of mail, and e-mail, among other methods.

97. Forest, with assistance of the Peer Selling Sub-Enterprise, funded thousands of such events beginning in 1998. As noted in Forest's Fiscal Year 2002 Marketing Plan, dated April 2, 2001, Forest acknowledged that physician meetings and events were a "crucial element of the marketing mix for any S[S]RI." During 2000, Celexa dominated the SSRI market with over 5,000 events that reached over 45,000 physicians with the cost for these events estimated at $27 million. These meetings were an integral part of the Peer Selling Sub-Enterprise's off-label and deceptive promotion campaign, especially as quarterly evaluations of event attendance and prescribing behavior consistently showed that physicians who attended Celexa events wrote more prescriptions. Indeed, the Peer Selling Sub-Enterprise considered such events as "investments" and would track how many additional prescriptions were issued as a direct result of these fraudulent marketing events. This number was tracked as a "return on investment."

98. Forest was prohibited from directly producing such events, so it created and controlled the Peer Selling Sub-Enterprise, composed of medical consulting firms and other co-conspirators, including Parke-Davis, IntraMed, GCI, inVentiv Health, BSMG, Weber Shandwick, the Prescott Group, Mary Prescott, and Natasha Mitchner (the "marketing participants") and thousands of physicians, including, but not limited to, Dr. Karen Wagner, Dr. Jeffery Bostic, Dr. Jack Gorman, Dr. Graham Emslie, members of the Celexa and Lexapro speakers bureaus and other physicians (the "physician participants"), who routinely promoted Celexa and Lexapro to other physicians in venues all across the country. Forest maintained

control over the Peer Selling Sub-Enterprise by making sure it had to approve the content of the programs and the physician participants who would deliver the off-label and deceptive messages. The physician-attendees who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Forest.

99. In an effort to hide the lack of scientific support for the off-label uses promoted by the Peer Selling Sub-Enterprise, and Forest's direct involvement in Celexa and Lexapro's promotion for pediatric use, the Peer Selling Sub-Enterprise had no choice but to employ improper and unlawful sales and marketing practices. These practices included, *inter alia*: (a) deliberately misrepresenting the safety and medical efficacy of Celexa and Lexapro for pediatric and adolescent use; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Celexa and Lexapro for pediatric and adolescent uses; (c) deliberately concealing negative findings, while touting alleged positive findings, relating to Celexa's and Lexapro's off-label use in children and adolescents; (d) wrongfully and illegally compensating physicians for prescribing Celexa and Lexapro for various unsupported and off-label uses; (f) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Celexa and Lexapro for use in children and adolescents; (i) intentionally misrepresenting and concealing Forest's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Celexa and Lexapro for use in children and adolescents; and (j) intentionally misrepresenting and concealing financial ties between Forest and the other participants in the Peer Selling Sub-Enterprise.

100. All of the participants in the Peer Selling Sub-Enterprise, especially Forest, actively planned to market Celexa and Lexapro for use in pediatric patients in an effort to increase the market share for the drugs and to increase Forest's and the Enterprise participants' profits. For example, although Forest knew that such promotion was illegal, Forest's 2001 Celexa marketing plan states that "elderly patients and pediatric/adolescents represent a growing

market. Refining messages to these specific patient segments will increase market share for Celexa. Together these segments represent over $1.5 billion."

101. The participants in the Peer Selling Sub-Enterprise, including Forest, shared the common purpose of aiding in marketing and selling Celexa and Lexapro for off-label uses in children and adolescents being treated for depression and, ultimately, to expand the market in these populations. Each of the Peer Selling Sub-Enterprise participants received substantial revenue from the scheme to promote Celexa and Lexapro for pediatric use. For example, as discussed below, one co-conspirator, Dr. Jeffery Bostic, obtained over $750,000 in payments to unlawfully promote the pediatric use of Celexa and Lexapro. The Peer Selling Sub-Enterprise participants knowingly and willingly agreed to assist Forest in its off-label and deceptive promotion of Celexa and Lexapro, despite the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery of, through kickbacks, thousands of physicians throughout the United States, and the promotion of Celexa and Lexapro for off-label uses in children and adolescents which was illegal.

102. The "marketing participants" were co-conspirators that included, but were not limited to, third party medical marketing, publishing, communications, and public relations companies, firms and consultants who were critical to the Peer Selling Sub-Enterprise. Forest's marketing plans called for information concerning Celexa and Lexapro to be widely disseminated in continuing medical education programs ("CME"), consultants' meetings, speaker programs, advisory boards, preceptorships, teleconferences, peer selling programs and other programs where physicians could instruct other doctors how to use Celexa and Lexapro for unsupported and unapproved indications in children and adolescents. Each of the marketing participants was in regular communication with Forest and the other participants in the Peer Selling Sub-Enterprise. In connection with major medical conferences and conventions of those physicians treating children and adolescents, the marketing participants coordinated their events to ensure their off-label message reached the most physicians in the most effective manner.

103. In addition to a large well-trained sales force, Forest also employed numerous physicians -- "physician participants" -- who included, among others, Dr. Karen Wagner, Dr. Jeffrey Bostic, Dr. Jack Gorman, the physicians on the Celexa and Lexapro Speakers' Bureaus, and the Forest Medical Liaisons whose purpose was to help create and disseminate false and misleading marketing messages about Celexa's and Lexapro's efficacy data in order to get doctors to prescribe the drugs to their pediatric patients. One of Forest's and the Marketing participants' principal strategies for marketing Celexa and Lexapro was to target key physicians, *i.e.*, the "physician participants," preferably within the major teaching hospitals and clinics, to serve as key opinion leaders for Forest. To lure physicians to participate in the Peer Selling Sub-Enterprise, Forest and the marketing participants approached target doctors and informed them of Forest's interest in funding research opportunities and clinical trials at their institutions. These doctors were then paid to promote Celexa and Lexapro to their peers through peer selling programs by making false and fraudulent representation about Celexa's and Lexapro's efficacy in treating pediatric depression.

104. The planning and coordination of all of these events by the Peer Selling Sub-Enterprise required extensive use of the wires and mails, including the mailing of invitations to physicians, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, the development and modification of the marketing plans, and the coordination of the content of the presentations on Celexa and Lexapro to be presented at the events, among others mentioned in this Complaint.

105. The components of the Peer Selling Sub-Enterprise included disguised CMEs, Forest-sponsored luncheons and meetings with Medical Science Liaisons ("MSLs'), fake "studies" designed to introduce prescribers to Celexa and Lexapro, advisory boards, preceptorships, and honoraria, among others.

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

106. *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. Forest and the co-conspirators used CMEs as yet another vehicle to perpetrate fraud on consumers and prescribers.

107. In an effort to further the Peer Selling Sub-Enterprise, Forest organized and sponsored hundreds of CME programs centered on pediatric depression. However, instead of having an accredited institution plan these "independent" CME programs, Forest and the co-conspirators carefully crafted and trained speakers to conduct CMEs which, in truth, were just events designed to promote the pediatric use of Celexa and Lexapro. Indeed, Forest employees, such as Jeffrey Lawrence, recruited, assembled, and trained the speakers who participated in these CMEs, with the express purpose of ensuring a systematic and positive messaging about the pediatric efficacy of Celexa and Lexapro.

108. Forest and certain Enterprise participants maintained a list of "approved" CME speakers, many of which were pediatric specialists. The Enterprise participants would organize promotional lunches and dinners on Celexa and Lexapro with these paid speakers to deliver sales pitches billed as "educational talks" to fellow doctors. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on pediatric use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment Options in Depressive Disorders in Adolescents," "Use of Antidepressants in Adolescents," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children," "Adolescents, and Adults," "Celexa in CHP/Ped Practice," "Treating Difficult Younger Patients," "Assessment and

Treatment of Suicidal Adolescents," and "Treating Pediatric Depression."

109. Forest and the Peer Selling Sub-Enterprise solicited accredited institutions to present these medical education programs. The resulting event was not an independent medical education seminar designed by an accredited medical education provider, but a promotional program designed to promote Celexa and Lexapro to treat pediatric depression.

110. An example of the Peer Selling Sub-Enterprise's use of CMEs involved presentations made by co-conspirator Dr. Wagner. Over the course of 2002, Forest and the co-conspirators, including, but not limited to, Mr. Lawrence, and other marketing participants, arranged for Dr. Wagner to give promotional presentations on the pediatric use of Celexa and to serve as the chair of a seven-city CME program on treating pediatric depression. Forest also sponsored twenty (20) CME teleconferences touting Celexa Study 18's alleged results and providing false and misleading information to physicians about the efficacy of Celexa based on Celexa Study 18.

111. In presenting at these CMEs, Dr. Wagner knew that the program did not provide fair and balanced drug information to the attendee physicians. Dr. Wagner, however, never disclosed that she was a Forest consultant and was assisting Forest in developing the market for the pediatric use of Celexa and Lexapro. Dr. Wagner had in fact received tens of thousands of dollars for acting as a speaker at Forest sponsored CME programs. Among the information deliberately omitted from the events, were the following:

- the lack of clinical trial evidence to support Celexa and/or Lexapro's use for treatment of MDD in children and adolescents;
- negative clinical trial results that demonstrated that Celexa and Lexapro were no more effective than a placebo for use in children and adolescents;
- evidence from Celexa study 94404 associating Celexa use with an increased risk of suicide-related behavior;
- information that virtually all publications and studies that allegedly supported Celexa's

and Lexapro's use for pediatrics had been funded by Forest;

- information that virtually all publications and studies that allegedly supported Celexa's and Lexapro's off-label use for children and adolescents had been initiated by Forest pursuant to a corporate marketing plan designed to increase pediatric, off-label sales;
- information that Forest and other Enterprise participants deliberately decided not to publish or publicize any studies that found that Celexa and Lexapro were not effective in treating depression in children and adolescents;
- information that the participating doctors who were conducting the peer selling had been provided substantial benefits in order to use Celexa and Lexapro on their pediatric patients in an off-label manner; and
- that the events the physicians were attending where pediatric uses of Celexa and Lexapro were discussed were neither fair nor balanced and were created to ensure the physicians would not hear a fair and balanced examination of Celexa and Lexapro for use in children and adolescents.

112. Many of the events developed, planned and hosted by the Peer Selling Sub-Enterprise participants were made to appear to the attending physicians to be *bona fide* educational events where disinterested leading clinicians shared their knowledge and experience in an educational setting. In fact, these events were peer selling promotional events designed to convince the attending physicians to prescribe Celexa and Lexapro for pediatric use. Important facts that would have warned the attending physicians that they were attending a promotional event for a drug company were concealed

113. Hiding Forest's control of the content of the programs and misrepresenting its financial support as an "unrestricted" grant were material omissions that concealed the promotional nature of the programs. Had the attending physicians known the programs were outright promotions, they would likely have viewed the presentations with greater skepticism and questioned the claims of the participating physicians that Celexa and Lexapro were effective

for pediatric use.

114. In addition to relaying false and biased promotional material to attendees of these Forest-backed CMEs, Forest and the Peer Selling Sub-Enterprise also made payments in various forms (essentially kickbacks) to certain prescribers at the CMEs. Forest and the Peer Selling Sub-Enterprise would target high prescription-writing physicians and give them grants for attending. Other, less-high-volume prescribers would receive free tuition, free accommodations, and free meals while attending the CME program. This was in addition to receiving CME credit for licensing purposes.

115. Forest and members of the Peer Selling Sub-Enterprise, a videotaped satellite program to extend the reach of Forest's medical education activities into the larger psychiatric community. The content of these satellite CME broadcasts focused on discussing new treatments for depression, anxiety and related disorders, *i.e.,* the use of Celexa and Lexapro to treat pediatric depression. These Forest-backed online CME programs were created with the help of various co-conspirators, including IntraMed.

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

b. Forest-Sponsored Luncheons and Meetings with Medical Science Liaisons ("MSLs")

117. Starting in 1995, Forest used Medical Science Liaisons (MSLs) to influence the prescribing habits of prescribers, *i.e.*, to encourage prescribers to use Celexa and Lexapro in treating pediatric depression. The MSLs communicated with influential medical professionals, labeled "opinion leaders" and "thought leaders" by Forest,[13] to promote Celexa and Lexapro for

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

pediatric use. These MSLs liaisons were also supposed to coordinate funding of studies and clinical trials with interested physicians with the assistance of other Peer Selling Sub-Enterprise participants. In particular, Forest admitted in a criminal plea that it hired these MSLs to talk to pediatricians, child psychiatrists, and other medical practitioners who specialized in treating children and adolescents about the benefits of prescribing Celexa.

118. The Peer Selling Sub-Enterprise participants would train MSLs to solicit requests for off-label information from physicians, by discussing the possible use of Celexa and Lexapro in other non-indicated populations. If prescribers "took the bait," the MSLs would then engage in full-scale promotion of Celexa and Lexapro for pediatric use, including providing non-scientific, anecdotal information designed to convince physicians that off-label usage of Celexa and Lexapro was safe and effective, while omitting material information that indicated they were not. In effect, Forest used the MSLs as a surrogate sales force who marketed Celexa and Lexapro for pediatric use. Indeed, medical liaisons were selected and promoted based on their ability to sell, and sales training was specifically encouraged.

119. According to Forest's marketing plans, the MSLs also facilitated various company educational programs, most notably the speakers' bureau (used to make fraudulent CME presentations), regional advisory boards (discussed below), and regional scientific program symposia (also discussed below), many of which were aimed at physicians prescribing to children and adolescents.

120. In 2002 alone, the MSLs targeted a group of 375 previously identified key U.S. opinion leaders and thought leaders, who drove the prescribing behavior of the average physician. Forest targeted these opinion leaders and thought leaders, and worked with them, in order to increase the sales of Celexa and Lexapro, including sales for pediatric use, in furtherance of the Peer Selling Sub-Enterprise and the objectives of the Enterprises.

121. In its 2004 Lexapro marketing plan, Forest announced that it had scheduled a number of major meetings in order to promote the drug to certain target groups. Invitations to

these "major medical meetings" were issued to attendees via the MSLs, presumably through the mail and wirings constituting predicate acts in furtherance of the Enterprises. According to Forest's Celexa Fiscal Year 2002 Marketing Plan, Forest MSLs co-sponsored 36 regional CMEs in conjunction with these MSLs and countless other CMEs across the country.

122. As an example, from 1999 through 2006, a pediatric specialist and co-conspirator, Dr. Bostic, Medical Director of the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital, gave more than 350 Forest-sponsored talks and presentations, many of which addressed pediatric use of Celexa and Lexapro. Dr. Bostic's programs, which took place in at least 28 states, included topics such as "Uses of Celexa in Children" and "Celexa Use in Children And Adolescents." Forest also paid Dr. Bostic to meet other physicians in their offices in order to ease their concerns about prescribing Celexa or Lexapro off-label for pediatric use. He was both a member of the Forest Speakers' Bureau where be conducted and presented fraudulent CMEs, and a MSL, where he spoke informally with prescribers to promote the use of Celexa and Lexapro in children and adolescents.

123. Dr. Bostic became Forest's star spokesman in the promotion of Celexa and Lexapro for pediatric use. As one sales representative wrote, "DR. BOSTIC is the man when it comes to child Psych!" Between 2000 and 2006, Forest paid Bostic over $750,000 in honoraria and other payments for his presentations and work promoting Celexa and Lexapro for pediatric use.

124. Nearly all communication with MSLs, payments made to them, and logistics of coordinating their off-label promotion to prescribers transpired over wire and mail.

c. Grants and "Preceptorships"

125. Forest also made payments, in the form of grants, to reward demonstrated Celexa and Lexapro believers and advocates in furtherance of the Peer Selling Sub-Enterprise and the Enterprises overall. Forest's sales managers identified key doctors/physician participants who actively prescribed Celexa or Lexapro or programs that were willing to host Celexa or Lexapro

speakers and encouraged such persons or programs to obtain "educational grants" from Forest.

126. Between 1999 and 2003, Forest paid millions of dollars to physicians who participated in so-called "preceptorships." Each physician who participated in a preceptorship received a "grant" of as much as $1,000 per preceptorship. Ostensibly, preceptorships were a training opportunity where Forest sales representatives and physician participants would spend a half-day or full day with a physician and learn about how Celexa and Lexapro were used in practice. In reality, Forest sales representatives and participating physicians used the preceptorships to induce physicians to prescribe Celexa and Lexapro for pediatric use. These preceptorships were just another ploy in furtherance of the Celexa and Lexapro Peer-Selling Sub-Enterprise.

127. Forest was fully aware of how sales representatives and the Peer Selling Sub-Enterprise participants actually used preceptorships. Company policy mandated that sales representatives fill out a return on investment ("ROI") form to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify the cost to Forest. Senior Forest sales managers and staff reviewed and approved the completed preceptorship ROI forms. Many of these preceptorship payments were directed at pediatric specialists. The Peer Selling Sub-Enterprise also crafted specific preceptorship programs for third-party payors and managed care organizations.

128. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments. Several of the justifications for giving a prescriber a preceptorship include:

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

129. These payments to prescribers were kickbacks. The more a doctor prescribed Celexa and Lexapro, the more likely that doctor would get a free $1,000 payment couched as a preceptorship. That Forest specifically considered such payments "investments" that yielded a return, *i.e.*, increased prescriptions for Celexa and Lexapro, clearly indicates the kickback nature of this conduct.

130. The Peer Selling Sub-Enterprise's work in isolating and determining which

doctors to target with a preceptorship / kickback, and the actual payments made to prescribers as a result, transpired in interstate commerce via wire and mail.

d. Advisory boards

131. In yet another component of the Peer Selling Sub-Enterprise, between 2000 and 2005, Forest, with the assistance of the Peer Selling Sub-Enterprise participants, developed, planned and hosted over 900 local or regional "advisory boards" concerning the use of Celexa and Lexapro which involved over 19,000 advisory board attendees Forest called "consultants." As a "consultant," Forest paid each attendee an honorarium of $500. Ostensibly, Forest paid physicians to attend these advisory boards to get their feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal company documents, Forest and the other Peer Selling Sub-Enterprise participants intended that the advisory boards would induce the attendees to prescribe more Celexa and Lexapro. Many of these advisory boards involved the deceptive promotional messages aimed at the use of Celexa and Lexapro in children and adolescents.

132. In a May 2000 proposal for a series of 44 Celexa advisory boards, co-conspirator and Enterprise participant, IntraMed, wrote that the advisory boards, each with 20 physicians attendees, would "give Forest an opportunity to influence more physicians." Forest's marketing department approved this proposal. Later that year, Steve Closter, the Forest marketing executive who organized the advisory boards, wrote that the Celexa advisory boards begun in June 2000 had been successful and, as a result, "will become an even large part of the promotional mix in the future." For years thereafter, Forest's marketing department included the cost of advisory boards in its annual promotional budgets for Celexa and Lexapro.

133. With the early success of the advisory board programs, the Forest sales force and the Peer Selling Sub-Enterprise enthusiastically used them to drive up sales. As one Forest District Manager told his Regional Director in a November 2000 planning document, he intended to conduct a local advisory board to "target the highest prescribers" in several of his territories

because "there is no doubt that a program of this magnitude will increase Celexa market share." In approximately January 2002, a marketing strategy slide deck given to Forest's chief executive, Howard Solomon, quoted a Regional Director stating that, "[w]ell planned Advisory Board meetings will be key to our efforts of reaching hesitant physicians."

134. In June 2002, Forest's two Vice Presidents of Sales mailed a memorandum to all sales managers observing that, notwithstanding new promotional guidelines for the industry, advisory boards remained among "the wealth of activities and programs that we can conduct that will impact physicians." Similarly, in August 2002, a Forest Regional Director sent an e-mail to his District Manager stating that, "with the new guidelines in place, Ad Boards have become even a more valuable resource, thus each one needs to be a home run! With your attention and focus, we can make [sic] maximize this opportunity!"

135. In the fall of 2002, to coincide with the launch of Lexapro, Forest conducted a series of 200 advisory boards reaching over 4,000 potential new Lexapro prescribers, with the assistance of the Peer Selling Sub-Enterprise participants. These advisory boards were organized, scheduled and developed through the use of the wires and mail.

136. Forest monitored its ROI from the advisory boards. To conduct its ROI analyses, Forest measured the increase in prescriptions written by physicians that attended the local advisory boards, and then compared the value of those prescriptions to the cost—primarily the honoraria payments—of putting on the programs. A November 2000 ROI analysis of a single advisory board program reached the following conclusion:

> Post program the Ad Board group [24 attendees] wrote an average of 19.6% Celexa as measured by a 5-week 1st Rx average. This is an increase of 3.7% in share. At first glance, the share increase might not appear substantial. However, considering the volume of the SSRIs written by these prescriptions, 3.7% translates into almost 2000 new prescriptions on a yearly basis.

137. In May 2001, an internal ROI analysis of all of the Celexa advisory boards in 2000 found that "participants in the program prescribed nearly 14 additional prescriptions of Celexa vs. the control group over a seven-month period."

138. Three months later, in August 2001, the author of the ROI analysis reiterated to the Celexa marketing team that, "our goal is to increase the ROI on these advisory boards." That same month, a Forest Regional Director reported to the company's Vice President of Sales that three local advisory boards had "generated close to $30K" from just a subset of the attendees and that "the scripts will continue, and continue to generate additional $$$ and ROI."

139. After 2003, Forest stopped conducting ROI analysis of advisory boards because of concerns about memorializing illegal intent, but the company continued to use the same types of advisory board programs through the Peer Selling Sub-Enterprise participants as a means of inducing doctors to prescribe Celexa and Lexapro. As a Forest Area Business Director noted in a September 2003 memorandum to his Regional Directors, "[w]e are not able to do as many Ad Boards as we have in the past, so it [is] critical that we get the best targets to the programs." Similarly, in March 2004, a Texas-based Forest District Manager reported to her Regional Director and fellow District Managers that she had met with her sales team about "the types of doctors" they wanted to recruit for an upcoming advisory board and then they had to come "up with 40 doctors that are either high Celexa writers or can be converted/persuaded to write Lexapro." In August 2004, a Massachusetts District Manager wrote to his colleagues and sales team that, for an upcoming Lexapro advisory board, "we are looking for the best ROI."

140. The Peer Selling Sub-Enterprise's work in setting up advisory board events, isolating and determining which doctors to target with an advisory board appointment, and the actual payments made to prescribers as a result, transpired in interstate commerce via wire and mail.

e. Bogus Clinical Trials

141. In addition to the advisory boards, in furtherance of the Peer Selling Sub-Enterprise, Forest and other Sub-Enterprise participants used fake "clinical trials" as a ruse to pay prescribers to start prescribing Celexa and Lexapro – other predicate acts in furtherance of the Enterprises. In 1998, Forest successfully used a so-called "seeding study"—a clinical study

intended to induce participating physicians to prescribe the drug under study—as part of the promotional strategy for the launch of Celexa. With the launch of Lexapro in 2002, Forest sought to replicate the success of the Celexa seeding study. Forest called the Lexapro seeding study EXCEED (Examining Clinical Experience with Escitalopram in Depression).

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

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

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

143. Forest, with the assistance of the Peer Selling Sub-Enterprise participants, aimed the EXCEED study at 2,000 physicians, many of whom were specialists in pediatric care. Under the study protocol, each participating physician could enroll up to five (5) patients in the study, which would last eight (8) weeks and involve three (3) patient visits. After the first visit, the physician would fill out a one-page form with the patient's age, race, gender, and basic medical history, and Forest would pay the physician $50. After each of the next two (2) visits, the physician would fill out an additional page requiring the physician to write the date of the visit and to check one of seven (7) boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two (2) other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten (10) patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference. This teleconference occurred over the wire, and payments were made by mail.

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

145. Much like advisory boards, grants, and preceptorships, these payments were simply another form of kickback, designed to induce doctors to prescribe Celexa and Lexapro.

146. The organization of these bogus clinical trials, dissemination of information and communications and the payment to various participants of the Enterprises, occurred through mail and wire.

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

147. 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.

148. Like the Peer Selling Sub-Enterprise, the Publication Sub-Enterprise was an association in fact of medical marketing, communications, and public relations companies and consultants, participating physicians, and Forest, all conspiring for the purpose of promoting off-label uses of Celexa and Lexapro for children and adolescents.

149. A non-exhaustive list of the Publication Sub-Enterprise participants includes Dr.

Karen Wagner, Dr. Jeffery Bostic, Dr. Jack Gorman, GCI, IntraMed, the Prescott Group, BSMG, Mary Prescott, Natasha Mitchner, Weber Shandwick, Parke-Davis and executives and employees of Forest.

150. The centerpiece of the Publication Sub-Enterprise involved having technical writers such as Natasha Mitchner, Mary Prescott, and the executives and employees of BSMG, Weber Shandwick and the Prescott Group, among others, creating medical journal articles designed to tout a specific marketing message—regardless of the truth of the medical assertions— and then pay actual key opinion leader doctors to be the articles' "authors." This practice is referred to as "ghostwriting."

151. In order to further advance its off-label promotion of Celexa and Lexapro for pediatric uses, Forest retained and/or conspired with the publication enterprise participants to write, edit, and manage drafting manuscripts and to submit the articles for publication in well-known medical journals. The subject matter of these articles centered on the use of Celexa and Lexapro in children and adolescents. Forest would direct the subject-matter and pay for all expenses associated with the creation of these publications. BSMG, Weber Shandwick, the Prescott Group, GCI, Natasha Mitchner, Mary Prescott, and others assisted Forest in creating publications and ensuring their publication in specific medical journals.

152. The Publication Sub-Enterprise ensured that all manuscripts submitted for publication contained the correct key marketing message. Based on internal email communications among the co-conspirators, the Publication Sub-Enterprise was aware of the promotional nature of these publications and the misleading nature of the publication strategy. Indeed, upon information and belief, internal emails reveal that the Publication Sub-Enterprise members were was aware of the negative results of Celexa Study 18 but nevertheless agreed and conspired to use the study as an example of pediatric efficacy.

153. Although Forest knew the results of the negative Celexa Study 94404 and that the results of Celexa Study 18 were suspect, Forest, with the help of the Publication Sub-Enterprise

participants, issued a press release regarding Celexa Study 18 in December 2001 stating that "Celexa was shown to reduce symptoms of depression in adolescents and children with major depressive disorder to a significantly greater extent than placebo in a randomized, double-blind, placebo-controlled, flexible dose study of 174 pediatric patients (83 children and 91 adolescents)." This press release, which contains material omissions and misrepresentations about Celexa's ability to clinically outperform placebo, was transmitted by wire through the Internet.

154. In addition, Forest, with the assistance of the Publication Sub-Enterprise participants Dr. Wagner, Dr. Gorman, the Prescott Group, BSMG, Weber Shandwick, Mary Prescott, and Natasha Mitchner drafted, publicized, and circulated the "positive" results of Celexa Study 18 through the publication and circulation of an article titled "A Randomized, Placebo-Controlled Trial of Citalopram for the Treatment of Major Depression in Children and Adolescents" published in the June 2004 edition of the *American Journal of Psychiatry*.

155. This issue of the *American Journal of Psychiatry,* which was mailed to its 37,000 readers, reported test results of the antidepressant drug Celexa, indicating that Celexa was an effective treatment for pediatric depression. This representation, however, was false and misleading because it failed to disclose that statistical significance was only achieved by using skewed data from several un-blinded participants, that even with the skewed data, the statistical significance did not reach clinical significance, that all of the study's secondary outcome measures were negative, or that the article was ghostwritten by Forest and medical communications companies paid by Forest. Indeed, the publication did not make any mention of the underlying flawed data but, instead, purported to be a positive study demonstrating the efficacy of Celexa in treating pediatric depression. Moreover, the publication did not mention or discuss the results of the contemporaneous Celexa Study 94404, which were known to Forest, clearly negative for efficacy and indicated that Celexa was associated with an increased risk of suicidality.

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

156. Publications that Forest and the other Publication Sub-Enterprise participants distributed as part of their publication strategy intentionally misrepresented Forest's role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the independent, unbiased research of the authors of the articles. They were not made aware of the fact that Forest had in fact solicited these articles or that they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Celexa and Lexapro.

157. The Publication Sub-Enterprise participants, including, but not limited to, Mary Prescott, Natasha Mitchner, BSMG, Weber Shandwick, the Prescott Group, Bill Heydorn and other Forest employees from Forest's in-house medical communications group, ghostwrote Celexa Study 18, which was published in the *American Journal of Psychiatry* under the title of "Placebo-controlled Trial of Citalopram for the Treatment of Pediatric Major Depressive Disorder." In conspiring to draft and publish Celexa Study 18, the Publication Sub-Enterprise participants communicated by wire and mail in furtherance of the Enterprises.

158. In an email from Mary Prescott, an executive and employee of the Prescott Group, Weber Shandwick, and BSMG, to Jeff Lawrence, Mary Prescott admits the Wagner article was ghostwritten, stating:

> Also I don't know that any decision has been made about who is going to write the manuscript, not to be confused with who is going to be the authors of the manuscript which also isn't decided as far as I know. But for reasons I'll list below I think it would make sense to have a first draft prepared in house, meaning at Forest if there is someone with time to do it or here if Bill Heydorn's group is swamped.
>
> . . .
>
> As we all know, it is easier to react to or edit something than it is to write it from scratch. Additionally, I have heard from the grapevine that not all the data looks as great as the primary outcome data. For these reasons, speed and greater control I think it would be make sense to prepare a draft in house that can be provided to Karen Wagner or whomever for review and comments. Since a poster is being developed for ACNP it is really not that much extra effort to develop a manuscript in the same time.

159. In response, Bill Heydorn, in house writer for Forest's medical communications group, responded to Mary Prescott and other employees of BSMG, the Prescott Group and/or Weber Shandwick:

> Given what I have seen of the data, I believe that we should maintain control, which means either writing in house or having an outside group like Weber Shandwick, BSMG or a CRO draft the manuscript.
>
> Our capacity in house is limited so we would be looking for an outside source to pull together the first draft of the manuscript. The study report for the pediatric study is being written by a contract research organization, PharmaNet. We have had extensive conversations with them regarding the data.

160. Due to the skewed study data collected in Celexa Study 18, Forest insisted that the publication be ghostwritten by an independent source but that Dr. Wagner be used as the "author" because Dr. Wagner was widely regarded in the field of child psychiatry as a thought leader. In fact, Bill Heydorn, as the Forest in-house medical communications writer, contributed greatly to the writing and publication of the Wagner article, making sure that the article satisfied Forest's marketing message. Forest's involvement in writing the article, however, was never disclosed in any of the publications of Celexa Study 18.

161. Despite knowing that the results of Celexa Study 18 were not favorable, Forest, BSMG, Mary Prescott, Natasha Mitchner, Dr. Wagner, Weber Shandwick, and PharmaNet promoted the published article at numerous public relations and marketing events aimed at promoting the pediatric use of Celexa and, by proxy, Lexapro.

162. Forest and the Publication Sub-Enterprise submitted the Celexa Study 18 manuscript to co-conspirator Jack Gorman, the editor of the *American Journal of Psychiatry*, for publication. Jack Gorman was a paid key opinion leader and spokesman for Forest and was a member of Forest's executive advisory board and instrumental in creating and promoting the EXCEED trial (discussed previously).

163. Forest knew that publication of an article stating that Celexa was effective for pediatric depression would advance the Enterprises' objectives. In fact, Forest marketing plans stated that journal publication "creates and elevates the awareness of Celexa and its benefits

among all key targets. It also reminds target audiences of the benefits of Celexa and reinforces the brand message with Celexa users to validate their decision and increase their Celexa prescribing."

164. Long before Celexa Study 18 was published in the *American Journal of Psychiatry*, Forest employees and Jack Gorman discussed whether the following language should be included in the publication: Celexa "showed a positive drug effect in adolescents, but due to a greater level of placebo response, no drug effect in children." After considering whether this language should be included in the article, the co-conspirators decided to remove the language because it did not comport with the Publication Sub-Enterprise's marketing objectives and ultimate purpose. Nevertheless, Dr. Gorman accepted the manuscript for publication.

165. In addition, Forest's publication committee and senior executives decided to strike language from the original Celexa Study 18 draft that mentioned the lack of statistically significant positive effects for secondary endpoints. The Publication Sub-Enterprise deliberately chose to limit any disclosure of negative efficacy data.

166. Not only did Dr. Wagner lend her name as the "author" of the published version of Celexa Study 18, she used her notoriety from the publication to promote the pediatric use of Celexa through presentations and events to physicians. Even though she understood the data to be weak, Dr. Wagner discussed the marketing advantages of having the article published in a medical journal article which provided maximum exposure to pediatric prescribers, such as the *Journal of the American Medical Association*.[14] Indeed, Dr. Wagner was complimented as being "excited about our pediatric regional CME series and will be a fundamental part of a speaker selection. She is extremely savvy about PR and is working well with GCI for surrounding PR opportunities." Dr. Wagner, however, never disclosed that she was a consultant with Forest and was assisting Forest in developing the market for pediatric uses of Celexa and Lexapro.

[14] 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.

167. Forest and the other non-Forest Publication Sub-Enterprise participants relied heavily on Celexa Study 18 to promote Celexa for pediatric uses, presenting data from the study at numerous events, just to name a few, including but not limited to:

- The American College of Neuropsychopharmacology – December 2001;
- The American Psychiatric Association meeting in May of 2002; and
- The 23rd Congress of Collegium Internationale Neuro-Psychopharmacologicum – June 2002.

168. Following the publication of Celexa Study 18 in the *American Journal of Psychiatry*, several physicians wrote letters to the editor and editorials which were highly critical of the methodologies and evaluation of the data and results. Some of these physicians wrote letters directly to Dr. Wagner, and in response, Andrew Korotzer, a Forest employee, ghostwrote responses on her behalf.

169. As another example of the Publication Sub-Enterprise participants' involvement in the Enterprises, Dr. Bostic took the lead in a co-authored manuscript (the "Bostic article") with Dr. Jefferson Prince concerning a pediatric study of Celexa. As detailed in emails between the Publication Sub-Enterprise participants Natasha Mitchner and Forest employees, the Bostic article was ghostwritten by Forest with the assistance of Natasha Mitchner of BSMG, among others. The emails reveal that on February 14, 2001, Dr. Bostic and Prince received a draft manuscript from Natasha Mitchner of BSMG. The manuscript was reviewed by Dr. Bostic and Dr. Prince who submitted it to the *Journal of Clinical Psychopharmacology*. Notably, neither BSMG, Natasha Mitchner nor Forest was identified as contributing to the article however.

170. Forest, BSMG, and Mitchner and other Publication Sub-Enterprise participants used the publicity from the publication of the Bostic article and developed materials which were disseminated to physicians promoting the use of Celexa in the pediatric population. Mitchner assisted Forest employee Jeff Lawrence in reproducing copies of the Bostic manuscript which were disseminated and used as internal marketing to Forest employees.

171. Internal Forest emails chronicle that Dr. Bostic was a highly influential opinion leader in the field of child and adolescent psychiatry "and would be a valuable proponent for use in Celexa in this population." Forest felt that "his publications" would present a great opportunity "for the rapid reproduction of manuscripts to be published in well-known and highly respected journals offering great positive exposure of Celexa in this often overlooked population." Clearly, Forest and the Publication Sub-Enterprise knew that by publishing positive but fraudulent and misleading information in medical journals, it would further the Enterprise's purpose and objectives by causing physicians to prescribe additional Celexa and Lexapro for use in children and adults.

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

172. As set forth above, Forest's marketing strategy was concentrated largely on using the Enterprise participants to: (a) prepare journal articles, which used false or misleading statements to suggest that Celexa and Lexapro are effective for pediatric use, and (b) present the content of those journal articles to thousands of physicians at scientific conferences and through the process of detailing. In addition to Forest's control of content through the preparation, writing, editing, and publication of the journal articles with the assistance of the Publication Sub-Enterprise participants, Forest was able to further control the content of information presented to consumers, including Plaintiffs and the members of the classes and their prescribing physicians through the use of various medical marketing, communications and publications firms and consultants including, but not limited to, Mary Prescott, Jack Gorman, Dr. Wagner, Dr. Bostic, the Prescott Group, GCI, Weber Shandwick, and BSMG. Forest used these Enterprise participants to create the appearance that the information being presented was accurate, objective and scientific, and that the content was not controlled by Forest. This second prong—leveraging the misleading publications to promote off-label pediatric use of Celexa and Lexapro—is discussed in detail in the allegations related to the Peer Selling Sub-Enterprise.

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

173. 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.

174. This Material Omissions Sub-Enterprise involved Forest, Lundbeck, Dr. Wagner, Dr. Bostic, Forest Therapeutics, Forest Healthcare, Forest Ethicare, Forest Specialty Sales, Forest Research Institute, Parke-Davis, inVentiv Health, IntraMed, CGI, BSMG, Ms. Mitchner, Ms. Prescott, the Prescott Group, and Mr. Gorman. This Material Omissions Sub-Enterprise conspired to remain silent about (1) the negative efficacy results of Celexa Study 94404, (2) the increased risk of suicidality with Celexa seen in Celexa Study 94404, (3) the fraudulently manipulated data that allowed for the positive result of Celexa Study 18, and (4) the negative results of Lexapro Study 15. In addition, the Material Omissions Sub-Enterprise remained silent about the lack of material information on Celexa and Lexapro labels, and actively worked together to disseminate knowingly misleading and deceptive information about Celexa's and Lexapro's efficacy, with the purpose of furthering the Enterprises.

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

175. 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.

176. Forest wanted to create a vacuum of negative information so that consumers and prescribers would not have any reason to question the efficacy of Celexa in pediatric

populations. Instead, Forest and the Material Omissions Sub-Enterprise promoted, disseminated, and touted the fraudulent results of Celexa Study 18 in various CMEs, direct-to-prescriber detailing, etc. In the absence of any available information to contradict the "one positive" study, prescribers and consumers, including the Plaintiffs and members of the Classes, were led to believe that Celexa and Lexapro were likely effective for children and adolescents—after all, there was no publicly available reason to think they would be clinically ineffective.

177. 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.

178. After promoting the supposedly positive results of Celexa Study 18 and suppressing the results of Celexa Study 94404 the damage caused by Forest's and the Material Omissions Sub-Enterprise participants' pervasive and one-sided promotion of manipulated "science" designed to legitimize the use of Celexa in pediatric populations had taken a strong hold in the medical community. By July 2004, the proliferation of Celexa and Lexapro use in the pediatric population constituted a substantial percentage of Celexa and Lexapro sales.

b. Distribution of Misleading Drug Labels

179. 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. Indeed, Forest's 2002 Celexa marketing plan acknowledged that the label, as represented in the Prescriber's Desk Reference ("PDR") provided physicians with the latest, "most accurate data available" on prescription drugs. Forest knew that the study data and labeling concerning Celexa and Lexapro were among the most authoritative sources for information in the eyes of prescribers and that the labeling would be provided to hundreds of thousands of prescribers.

180. 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.

181. 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."

182. Forest, Parke Davis, and various other co-conspirators of the Material Omissions Sub-Enterprise were responsible for promoting Celexa and Lexapro to prescribers. They provided field samples of Celexa and Lexapro to physicians and prescribers of children and adolescents and left "package insert leave-behinds" with full, but misleading, prescribing information for Celexa and Lexapro for the treatment of children and adolescents. Each time any literature, promotional material, or samples which contained the misleading Celexa and/or Lexapro labeling were mailed, emailed, or faxed to physicians, by detailers and sales

representatives across the country by the Material Omissions Sub-Enterprise participants, mail and wire fraud were committed.

1. Celexa's Misleading Label

183. 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.

184. 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.

185. 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.

186. 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.

187. 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.

188. 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.[15] 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

189. 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

[15] Forest also did not send any "dear doctor" letters notifying prescriber or consumers that the label had been changed to reflect previously concealed negative information, thereby putting prescribers on notice of Forest's unlawful conduct. Rather, the label change was done as part of a separate label change involving the inclusion of a black box warning involving pediatric suicidality. Thus, the 2005 label change came far-too late and was buried in an avalanche of controversy involving the black box warning. The deception of promoting efficacy for over seven years had already taken root and this quiet and vague label change was not enough to undo the already-perpetrated fraud.

patients have not been established." This description, however, was fundamentally misleading and deceptive because it omitted material information.

190. 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.

191. 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.

192. 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.

193. 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.

V. The Material Omissions Sub-Enterprise Participants Knowingly Disseminated the Misleading Labels

194. Armed with drug labels that failed to properly disclose the ability of Celexa and Lexapro to treat pediatric and adolescent depression, the Material Omissions Sub-Enterprise actively distributed the misleading labels, via wire and mail, to prescribers and consumers, with the aim of furthering the overall Enterprise's objective of promoting the off-label use of Celexa and Lexapro in children and adolescents. The participants of the Material Omissions Sub-Enterprise knew that the labels were deficient, but nonetheless used mail and wire to send these misleading labels for the purpose of advancing the Enterprise. In fact, Forest specifically trained the Enterprise participants to use the label in all aspects of its fraudulent promotion of Celexa and Lexapro for pediatric use while deliberately withholding material negative information.

INCORPORATION OF CRIMINAL PLEA AGREEMENT

195. 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.

196. 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.

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

PLAINTIFFS-SPECIFIC ALLEGATIONS

Plaintiff Marlene T. LoConte

198. On or about November 7, 2004, Plaintiff Marlene T. LoConte's son, age fourteen (14), was prescribed a ten (10) mg daily dose of Lexapro by his physician at Boston Children's Hospital to treat his ongoing depression. LoConte spent her own money, out-of-pocket, in conjunction with insurance coverage, to purchase Lexapro to treat her son's depression, which was spent while her son was an adolescent, *i.e.*, under eighteen years of age. In total, with insurance payments, Forest received approximately $1,475.71 for pediatric prescriptions of Lexapro ingested by Plaintiff's son.

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

200. The Enterprise participants deprived Plaintiff LoConte 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.

201. LoConte relied on her son's treating physicians to make informed decisions about which drugs to prescribe her son. Upon information and belief, the physician who prescribed Lexapro to LoConte's son was also misled into prescribing Lexapro because the physician was

led to believe, based on Forest's deceptive and unlawful marketing, that Lexapro was more effective in treating adolescent MDD than it actually was. This deception occurred as a result of the same misleading conduct perpetrated by the Enterprise participants that was directed toward Plaintiff LoConte – a fraudulent scheme to off-label promote and sell Celexa and Lexapro for pediatric and adolescent use.

202. LoConte continued to purchase Lexapro for her son through the age of majority and at least until March of 2010.

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

204. During the period LoConte was purchasing Lexapro for her minor child, LoConte 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 Plaintiff LoConte, her son's physicians, or the public in general.

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

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

207. During the period LoConte was purchasing Lexapro for her minor child, she did not know that she had been deprived of material information.

208. During the period LoConte was purchasing Lexapro for her minor child, she was not provided information about Celexa or Lexapro's negative clinical trials. In the absence of 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, LoConte 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.

209. 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 the 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. Additionally, as described above, Forest through the Enterprises performed off-label promotional activities in the semblance of legitimate speakers' bureau, 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 between the Enterprise participants as payment intermediaries. These activities, and others described above, concealed Forest's off-label promotional activities of Celexa and Lexapro for pediatric use and, therefore, LoConte 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.

210. From the original establishment of the Enterprises until recently, LoConte nor her son were aware of any of the specific fraudulent or predicate acts alleged as part of the Enterprises in this Complaint. LoConte did not see any media or receive any communication describing any of Forest's fraudulent conduct alleged as part of the Enterprises. LoConte did not know about Celexa's and Lexapro's negative efficacy data. Indeed, LoConte was unaware that

she had been the victim of the Forest's fraudulent and deceptive conduct until sometime after late November 2013. Prior to learning about the fraud, LoConte did not have any reason to investigate Forest's or the Enterprises' conduct or reason to suspect she had been the victim of a RICO enterprise.

211. Any applicable statutes of limitations have been tolled by Forest's knowing and active concealment and denial of the facts alleged herein. LoConte 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. LoConte 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 LoConte's or the Classes' claims.

212. Information about Lexapro'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.

Plaintiff [redacted]

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

total, [redacted] spent approximately $60 of her own money on purchasing Celexa for her daughter.

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

215. The Enterprise participants deprived [redacted] 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.

216. Plaintiff [redacted] 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 [redacted] 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 [redacted] – a fraudulent scheme to off-label promote and sell Celexa and Lexapro for pediatric use.

217. During the period in which [redacted] 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.

218. During the period [redacted] 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 [redacted] her daughter's physicians, or the public in general.

219. During the period Mrs. [redacted] 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.

220. During the period [redacted] 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.

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

222. During the period [redacted] 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, [redacted] 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.

223. 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. Additionally, as described above, Forest through the Enterprises performed off-label promotional activities in the semblance of legitimate speakers' bureau, 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 between the Enterprise participants as payment intermediaries. These activities, and others described above, concealed Forest's off-label promotional activities of Celexa and Lexapro for pediatric use and, therefore, [redacted] 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.

224. From the original establishment of the Enterprises until the present, [redacted] nor her daughter were aware of any of the specific fraudulent or predicate acts alleged as part of the Enterprises in this Complaint. [redacted] did not see any media or receive any communication describing any of the fraudulent conduct alleged as part of the Enterprises or Forest. [redacted] did not know about Celexa's and Lexapro's negative efficacy data. Indeed, [redacted] was unaware that it had been the victim of Forest's fraudulent scheme until January of 2014. Prior to learning about the fraud, [redacted] did not have any reason to investigate

Forest's or the Enterprises' conduct or reason to suspect she had been a victim.

225. Any applicable statutes of limitations have been tolled by Forest's knowing and active concealment and denial of the facts alleged herein. [redacted] 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. [redacted] 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 [redacted] or the Classes' claims.

226. 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.

FOREST'S AND THE CO-CONSPIRATORS' MOTIVES AND CAUSATION OF DAMAGE

227. 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.

228. 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

229. 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.

230. 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:

- documents addressing the off-label, pediatric use of Celexa and Lexapro, with such materials being sent to doctors across the country;
- communications, including financial payments, between the participants of the Enterprises, including Forest, Forest executives and employees, Parke-Davis, marketing participants, physician participants, and publication enterprise participants discussing and relating to the publication of articles touting pediatric uses of Celexa and Lexapro for which the drug is not safe and medically efficacious;
- communications, including financial payments, between Forest, Forest executives and employees, Parke-Davis, marketing participants, physician participants, and publication enterprise participants relating to the production of each and every event developed and put on by the Enterprises, including communications concerning the content of the presentations to be made at such events;

- teleconferences arranged by Forest, Forest executives and employees, Parke-Davis and the marketing participants at which the marketing and physician participants made false and misleading statements about Celexa and Lexapro's unapproved uses for children and adolescents to physicians, including but not limited to statements that Celexa and Lexapro were effective for the treatment of pediatric depression;
- payments transported through the mail and the wires to physicians attending events held by the Enterprises in order to induce the physicians to prescribe Celexa and Lexapro;
- communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Forest and the co-conspirators' improper scheme;
- Forest's marketing plans identified that its "direct mail" and "clinical update mail" programs, which were implemented nationwide, were important in elevating awareness of Celexa to identified targets, such as the pediatric population. These programs resulted in the mailing of letters and promotional information to thousands of physicians across the country;
- Forest and the marketing participants sent "dimensional mailings" and "rep triggered mail" to the sales force which was designed to supplement the presentations of the sales force by dissemination new data in order to "capture the target's interest";
- The Forest sales force, and presumably the Parke-Davis sales force, was required to call "St. Louis" in order to request Celexa and Lexapro-related clinical studies and responses to questions from physicians concerning the pediatric use of Celexa and Lexapro. On these calls, Forest failed to encourage the disclosure of negative efficacy study results for Celexa and Lexapro for pediatric use;
- Lexapro and Celexa-related sales support, operations, warehousing, sales distribution, educational items, and other promotional items and field used by representatives to detail

physicians, including Celexa/Lexapro drug samples all originated and were distributed out of two locations in the St. Louis, Missouri area; and

- Celexa and Lexapro samples received by pediatric physicians were a means of off-label promotion and marketing by Forest which were distributed throughout the United States via mail from St. Louis, Missouri.

231. 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

232. 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.

233. 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

234. This matter is brought as a class action pursuant to Federal Rule of Civil Procedure 23, on behalf of consumers who are purchasers of Celexa and Lexapro for use in children and adolescents throughout the United States.

235. 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.

236. 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.

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

238. 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.

239. 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.

240. 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.

241. 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.

MASSACHUSETTS CLASS ALLEGATIONS

242. 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 Massachusetts. 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 depression. Forest's conduct has been directed at consumers in the State of Massachusetts 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 Marlene LoConte's Massachusetts causes of action are uniquely suited for class-wide resolution.

243. The Massachusetts Consumer Classes consist of:

Massachusetts 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 Massachusetts, 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.

Massachusetts 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 Massachusetts, 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.

244. The Massachusetts 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 Massachusetts by members of the Classes.

b. Commonality: Questions of law and fact are common to all members of the Massachusetts Classes. Specifically, Forest's misconduct was directed at all members of this Classes and the prescribing healthcare professionals and consumers in Massachusetts. Thus, all members of the Massachusetts 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: Plaintiff Marlene LoConte's claims are typical of the claims of the members of the Massachusetts Classes because their claims arise from the same course of conduct by Forest, *i.e.*, false, misleading and deceptive marketing. Plaintiff LoConte and all members of the Classes were exposed to Forest's misleading and deceptive marketing program and LoConte 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 LoConte will fairly and adequately represent and protect the interests of the Massachusetts Classes. Her interests in vindicating the class members' claims are shared with all members of the Classes. In addition, Plaintiff is represented by counsel who are competent and experienced in both consumer protection and class action litigation.

245. The Massachusetts 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 Massachusetts Classes. Forest deliberately engaged in a widespread program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's efficacy in treating pediatric MDD. Common questions of fact and law predominate over any questions that may affect individual members of the Classes. In addition, proceeding with these class actions is superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*:

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

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

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

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; and

e. Managing and administering Massachusetts refund classes for those members of the Massachusetts 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 Massachusetts.

WASHINGTON CLASS ALLEGATIONS

246. 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 [redacted] Washington causes of action are uniquely suited for class-wide resolution.

247. 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.

248. 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: [redacted] 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 [redacted] and all members of the Classes were exposed to Forest's misleading and deceptive marketing program and Plaintiff [redacted] 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 [redacted] 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 [redacted] is represented by counsel who are competent and experienced in both consumer protection and class action litigation.

249. 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*:

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

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

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

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

e. 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)

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

251. 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).

252. The Enterprises are associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including its executives employees, Parke-Davis, external consultants like Dr. Karen Wagner, Dr. Jeffery Bostic, Dr. Jack Gorman, physicians on the

speaker bureaus and other as yet unknown consultants, marketing firms and distribution agents employed by Defendants to promote Celexa and Lexapro, the Direct-to-Prescriber Sub-Enterprise participants, Peer-Selling Sub-Enterprise participants, Publication Sub-Enterprise participants, Material Omissions Sub-Enterprise participants, the marketing participants, physician participants, and all co-conspirators/Enterprise participants identified herein. All Enterprise participants are persons within the meaning of 18 U.S.C. § 1961(3) and engaged in acts that enabled Defendants to fraudulently market and sale Celexa and Lexapro as scientifically proven as safe and effective for use by children and adolescents.

253. 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.

254. 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.

255. 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.

256. 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.

257. 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.

258. 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.

259. 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.

260. 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).

261. 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. A smaller enterprise does include Defendants, Parke-Davis and any of the other Direct-to-Prescriber Sub-Enterprise participants. As an example, one such enterprise is comprised of Defendants, BSMG, Weber Shandwick, Mary Prescott, Natasha Mitchner, and the

physician participants. Alternatively, these smaller enterprises can also be comprised of only an individual marketing participant and Defendants, without the physician participants.

262. 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.

263. 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.

264. 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).

265. 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).

266. 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; (d) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles, and publications used to sell Celexa and Lexapro for pediatric use; and (e) intentionally misrepresenting and concealing the financial ties between the Defendants and other participants in the Enterprises.

267. 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.

268. Defendants' and the Enterprise participants' use of the mails and wires to perpetuate their fraud involved thousands of communications, including, but not limited to:

- communications with and among the enterprise participants that misrepresented the efficacy and safety of Celexa and Lexapro amongst themselves and others;
- communications with patients and members of the Classes, including Plaintiffs, inducing payments for Celexa and Lexapro by misrepresenting the efficacy and safety of Celexa and Lexapro;
- receiving the proceeds in the course of and resulting from Defendants' improper scheme;

- transmittal and receipt of monies from governmental health organizations and programs, including without limitation Medicare and Medicaid; and
- transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Celexa and Lexapro Deceptive Off-Label Promotion Enterprise and the sub-enterprises.

269. 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.

270. 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.

271. 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).

272. 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.

273. 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.

274. 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.

275. 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.

276. 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.

277. 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.

278. 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)

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

280. 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."

281. 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. The Defendants conspired with the Enterprise participants, *inter alia*, publicists, sales representatives, consultants, medical professionals, public relations professionals, communications professionals, academics, and other intermediaries to promote Celexa and Lexapro and suppress information about the drugs' efficacy and safety in children and adolescents.

282. 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.

283. 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.

284. 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.

285. 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:

- Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;

- Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and
- Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

286. 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).

287. 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.

288. 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.

289. 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: (MASSACHUSETTS SUBCLASS) VIOLATIONS OF MASSACHUSETTS'S CONSUMER PROTECTION ACT, MASS. GEN LAWS CH. 93A, §§ 1, *ET SEQ.*

290. Plaintiff Marlene LoConte incorporates by reference all preceding paragraphs as

if fully restated here.

291. Massachusetts's Consumer Protection Act, Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, makes it unlawful to engage in any unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. Unfair acts or practices include practices that are within at least the penumbra of some common-law, statutory, or other established concept of unfairness; immoral, unethical, oppressive, or unscrupulous acts; or acts that cause substantial injury. Deceptive acts or practices include those that would reasonably cause a person to act differently from the way he or she otherwise would have acted.

292. As alleged throughout this Complaint, Forest deliberately engaged in unfair, deceptive, and/or unlawful marketing in violation of Mass. Gen. Laws ch. 93A, § 2 by representing to the Massachusetts 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, including an increased risk of suicide. Forest sold and marketed Celexa and Lexapro while omitting and/or misrepresenting negative clinical trial results as it relates to efficacy of the drugs and which materially affects 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.

293. 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. In nearly every clinical trial designed to test for efficacy in the pediatric population, the observed benefit received by those taking Celexa and Lexapro was not clinically superior to the benefit patients received taking placebo.

294. 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:

- Concealing the results of Celexa and Lexapro's negative efficacy data on the drug labels, and providing little context about the demonstrated lack of efficacy indicated by the failed and negative clinical trials;
- Knowingly representing, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that it did not have, *i.e.*, that Celexa and Lexapro was clinically effective for the treatment of pediatric and adolescent MDD;
- Crafting a company-wide marketing plan in order to specifically increase pediatric use and sales of Celexa and Lexapro, despite knowing that there was no valid clinical benefit data suggesting that these drugs should be used in pediatric populations;
- Training an aggressive sales force to inform prescribing healthcare professionals that Celexa and Lexapro were effective treatments for children and adolescents, using fraudulent clinical data and paid-for endorsements from leaders in the medical

profession;

- Paying millions to medical professionals to "present" the use of Celexa and Lexapro in pediatric populations as an effective treatment for pediatric MDD, despite lacking proper scientific support;
- Paying physicians directly to participate in "advisory boards" wherein Forest was able to convey marketing messages, which included the off label promotion for pediatric use;
- Paying physicians to participate in Celexa and Lexapro speakers' bureaus designed to get physicians experienced prescribing Celexa and Lexapro;
- Paying third parties to ghostwrite articles with the sole purpose of promoting Celexa and Lexapro for pediatric use and having these articles widely published in medical journals and other publications;
- Paying physicians with money and lavish gifts to continue prescribing Celexa and Lexapro; and
- Advertising and selling Celexa and Lexapro indicating through deceptive promotion and misleading drug labels, that Celexa and Lexapro would effectively treat pediatric and adolescent MDD when Forest never intended to provide a product that would perform as advertised.

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

296. 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 Mrs. LoConte and the putative Classes she seeks to

represent, 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 Mrs. LoConte, the putative 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.

297. Forest violated M.G.L. c 93 A § 2 by engaging in unfair and deceptive practices with respect to the promotion, marketing and labeling of Celexa and Lexapro while misrepresenting information that treating physicians, Plaintiff LoConte and the Class members should have been provided in order to make an informed decision on whether or not to purchase the drugs. Mrs. LoConte and the Class members were denied the opportunity to make fully informed decisions about whether to purchase Celexa and Lexapro and were injured by paying for prescriptions for prescriptions of those drugs that no reasonable consumer would have purchased had they known the true facts, which Forest hid from the public.

298. Forest's misrepresentations and deceptive acts and omissions were likely to mislead reasonable consumers acting reasonably under the circumstances such as Plaintiff LoConte and the members of the Massachusetts Classes and their prescribing physicians.

299. Forest's conduct offends public policy and is immoral, unethical, oppressive, unscrupulous, or substantial injurious to consumers. Additionally, Forest's conduct was deceptive because it caused LoConte and members of the Massachusetts Classes to act differently from the way they would have otherwise acted.

300. Forest's unfair and/or deceptive acts or practices in violation of Mass. Gen. Laws Ch. 93A, § 2, proximately caused LoConte and the Massachusetts Classes adverse consequences

or losses, including the loss of money from purchasing Celexa and Lexapro. The losses and adverse consequences that LoConte and the Massachusetts Classes suffered by purchasing Celexa and Lexapro were foreseeable results of Forest's unfair, deceptive, and/or unlawful advertising and marketing.

301. Plaintiff and the Massachusetts Classes lost money as a result of Defendants' deceptive and unlawful marketing practices by purchasing Celexa and Lexapro that was illegally advertised, promoted, marketed and sold in violation of Mass. Gen. Laws ch. 93A, § 2.

302. As a result of Forest's violations of Massachusetts's Consumer Protection Act, the Massachusetts Classes seek an order of this Court awarding the Massachusetts Classes, *inter alia*, actual damages, and restitution against the use of unlawful trade practice, attorneys' fees and costs, and for such other relief as set forth below.

303. On January 30, 2014, LoConte made a demand for relief, in writing, to Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc., as required by G. L. c. 93A, § 9(3). See Exhibits 1 and 2, attached hereto. Plaintiff Marlene LoConte made this demand on her own behalf and on behalf of the proposed Class. The demand letter explained in detail the nature of the unfair and deceptive acts or practices, the injuries suffered by Plaintiff Marlene LoConte and the Classes and the consumer Classes she seeks to represent, as well as demanding compensation for those injuries and other relief. The letters were received by Defendants on February 6, 2014. Defendants have failed to tender a reasonable offer of relief in response to Plaintiff's written demand.

304. Based on the foregoing, Plaintiff and the other members of the Massachusetts Classes are entitled to all remedies available pursuant to ch. 93A, including, but not limited to actual damages, statutory damages (to the extent that they are greater than actual damages),

double or treble damages, disgorgement of Forest's profits derived from its unlawful activities, punitive damages, injunctive relief, attorneys' fees and other reasonable costs.

COUNT IV: (WASHINGTON SUBCLASS)
VIOLATIONS OF WASHINGTON CONSUMER
PROTECTION ACT, WASHINGTON REV. CODE § 19.86.010 *ET SEQ.*

305. Plaintiff [redacted] incorporates by reference all proceeding paragraphs as if fully set forth herein.

306. Plaintiff [redacted] 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.

307. Plaintiff [redacted] 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 [redacted] 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.

308. 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 [redacted] and the members of the Washington Classes.

309. 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.

310. 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. In nearly every clinical trial designed to test for efficacy in the pediatric population, the observed benefit received by those taking Celexa and Lexapro was not clinically superior to the benefit patients received taking placebo.

311. 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:

- Concealing the results of Celexa and Lexapro's negative efficacy data on the drug labels, and providing little context about the demonstrated lack of efficacy indicated by the failed and negative clinical trials;
- Knowingly representing, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that they did not have, *i.e.*, that Celexa and Lexapro were clinically effective for the treatment of pediatric and adolescent MDD;
- Crafting a company-wide marketing plan in order to increase pediatric use and sales of Celexa and Lexapro, despite knowing that there was no valid clinical benefit data suggesting that these drugs should be used in pediatric populations;
- Training an aggressive sales force to inform prescribing healthcare professionals that Celexa and Lexapro were effective treatments for children and adolescents, using fraudulent clinical data and paid-for endorsements from leaders in the medical profession;
- Paying millions to medical professionals to "present" the use of Celexa and Lexapro in pediatric populations as an effective treatment for pediatric MDD, despite lacking proper scientific support;
- Paying physicians directly to participate in "advisory boards" wherein Forest was able to convey marketing messages, which included the off label promotion for pediatric use;
- Paying physicians to participate in Celexa and Lexapro speakers' bureaus designed to get physicians experienced prescribing Celexa and Lexapro;
- Paying third parties to ghostwrite articles with the sole purpose of promoting Celexa and Lexapro for pediatric use and having these articles widely published in medical

journals and other publications;

- Paying physicians with money and lavish gifts to continue prescribing Celexa and Lexapro; and
- Advertising and selling Celexa and Lexapro indicating through deceptive promotion and misleading drug labels, that Celexa and Lexapro would effectively treat pediatric and adolescent MDD when Forest never intended to provide a product that would perform as advertised.

312. 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.

313. 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 [redacted] 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 [redacted] 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.

314. 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.

315. 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.

316. 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.

317. 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.

318. Forest's practices have and continue to affect the public interest and cause disparate and unequal impacts on Washington consumers, including Plaintiff [redacted] and the members of the Washington Classes. Forest's unfair and deceptive practices, as alleged herein, have caused injury and damages to [redacted] 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 [redacted] and the members of the Classes would not have made had they been made aware of the deceptive and fraudulent scheme.

319. 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.

320. Under the CPA, Plaintiff [redacted] 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.

UNJUST ENRICHMENT

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

322. 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.

323. 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.

324. 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.

325. 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.

326. 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.

327. 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

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

329. Forest's conduct as alleged herein was done with oppression, fraud, and malice. Forest was fully aware of Celexa's and Lexapro's true efficacy and safety risks as documented in

its own clinical trials and internal company documents. Nonetheless, Forest fraudulently misrepresented and omitted material information and deliberately crafted its drug label to mislead consumers and prescribing healthcare professionals into believing that these drugs are more effective at treating pediatric and adolescent depression than they actually are. Moreover, Forest's comprehensive program of deceptive marketing, promoting, and publishing was done in willful violation of federal and state law. Forest's conduct was not done by accident or through some justifiable negligence. Rather, Forest knew that it could turn a profit by convincing consumers and prescribing healthcare professionals that Celexa and Lexapro were safe and effective at treating pediatric and adolescent depression. Such conduct was done with a conscious disregard of Plaintiffs' and the members of the Classes' rights.

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

DEMAND FOR JURY TRIAL

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

PRAYER FOR RELIEF

332. 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: August 28, 2014

Respectfully submitted by,

/s/ Corrie Yackulic

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