UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, a third-party healthcare payor fund, on behalf of itself and all others similarly situated, Plaintiff, v. FOREST PHARMACEUTICALS, INC. and FOREST LABORATORIES, INC. Defendants.	MDL No. 2067 Master Docket No. 09-MD-2067-(NMG) Judge Nathaniel M. Gorton Magistrate Judge Marianne B. Bowler FIRST AMENDED COMPLAINT THIRD-PARTY PAYOR CLASS ACTION JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

This case is about Defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc. (collectively "Forest") leading an illegal and fraudulent Enterprise to sell the antidepressants Celexa and Lexapro for use in pediatric populations. Through the use of four 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 patients, despite knowing that their own clinical trial data establishes that Celexa and Lexapro do not provide clinical significance over placebo in treating pediatric depression. Through a calculated and orchestrated deceptive marketing scheme, Forest systematically robbed parents of being able to make an informed decision about treating their child with Celexa or Lexapro. This lawsuit seeks to hold Forest accountable for its leading role in this corrupt and fraudulent Enterprise, and obtain a refund for third-party payors that paid money for Celexa and Lexapro for pediatric use as a result of the Enterprise's fraudulent activity.

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NATURE OF ACTION

1. The clinical trials that examine 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 Celexa and Lexapro are not clinically superior to placebo (a sugar pill). In nearly every clinical trial designed to test for efficacy, the observed benefit received by those taking Celexa and Lexapro was not clinically different than the benefit children received taking placebo.

2. Since the inception of the drugs, Forest has known that adequate clinical trial data does not exist to support the assertion that Celexa and Lexapro have been proven to be clinically effective for treating pediatric MDD. In fact, for an overwhelming majority of the time that Forest has marketed Celexa and Lexapro, Forest has known that their own clinical trial data confirms 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 solely for the adult populations, Forest and the other Enterprise participants/co-conspirators concocted a comprehensive and aggressive program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's pediatric efficacy and safety.

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, consumers, and third-party payors 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 despite Forest and the Enterprise participants knowing that these drugs did not clinically outperform placebo in pediatric efficacy trials.

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 fraudulently "positive" study, Forest began a widespread campaign to promote the "positive" results to the medical community. At that time, there was a vacuum of information about Celexa's pediatric efficacy, 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 the same as Celexa. Due to years of off-label pediatric promotion of Celexa, by the time Lexapro was launched by Forest, the damage was done.

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 company-wide 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 the Celexa and Lexapro;
- Training an aggressive sales force in order 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, which was devised by Forest and third party medical marketing companies who are identified as co-conspirators herein;

- 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 pediatric use;
- Paying physicians to participate in a bogus "clinical trial" designed to get physicians experience prescribing Lexapro; and
- Paying physicians with money and lavish gifts to encourage them to begin or continue prescribing Celexa and Lexapro.

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 themselves, whether Celexa and Lexapro were worth the risk, Forest hid the efficacy and safety data, misled consumers and prescribing healthcare professionals and represented Celexa and Lexapro as effective and safe pediatric medications in the medical community.

7. Plaintiff seeks to serve as a representative of the putative class of third-party payors who paid for Celexa and Lexapro used by their member's children because Plaintiff and its members were misled to believe, because of Forest's comprehensive program of deceptive promotion through the Enterprise, that Celexa and Lexapro were effective treatments for pediatric depression.

8. Forest knew that Plaintiff and members of the putative class would be injured by its conduct because Plaintiff and its members were required to pay for Celexa and Lexapro used by Plaintiff's member's children. Plaintiff and it members 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, which Forest and its co-conspirators hid from the public.

THE PARTIES AND UNNAMED CO-CONSPIRATORS

I. Named Parties

9. Plaintiff Painters and Allied Trades District Council 82 Health Care Fund (hereafter "Plaintiff") is a health and welfare benefit fund with its domicile and principal place of business in the State of Minnesota. Plaintiff is involved in the business of providing health benefits for covered members and their families. Plaintiff is a multiemployer employee welfare benefit plan within the meaning of the Employment Retirement Income Security Act, 29 U.S.C. § 1002(1) and § 1002(37).

10. 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.

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

12. The parties 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").

II. Unnamed Co-conspirators

13. 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 role in participating in this scheme, which had the intended result of defrauding Plaintiff and the members of the putative Classes:

a. 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 Enterprise, 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 Enterprise.

b. 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 Enterprise.

c. 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.

d. 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, and Martin served as the conduit for the publication of the Emslie study and manuscript although 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.

e. Forest Therapeutics, Forest Healthcare, Forest Ethicare, and Forest Specialty Sales, all various organizations controlled by Forest Laboratories, Inc., were responsible for detailing products directly to physicians, pharmacies, hospitals, managed care, and other healthcare organizations. These organizations were responsible for disseminating and propagating information related to the Enterprise.

f. Forest Research Institute, Inc. ("FRI") is a wholly owned subsidiary of Forest Laboratories, Inc. FRI drives the research, development, and clinical evaluation of Forest pharmaceutical products and provides medical and scientific support for Forest drugs, including Lexapro and Celexa. Forest Research Institute operates research centers in Jersey City, New Jersey and Long Island, New York. Forest Research Institute staffs clinical trial personnel across the country in order to coordinate studies and is involved in other areas such as clinical development and medical affairs. Forest Research Institute was highly involved in advancing the fraudulent medical science used to further the Enterprise.

g. 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 with Forest 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 Enterprise.

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

i. IntraMed Educational Group ("IntraMed"), headquartered in New York, New York, participated in the pediatric promotion of Celexa and Lexapro in furtherance of the Enterprise 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 Enterprise.

j. GCI Healthcare ("GCI"), headquartered in New York, New York, is a public relations firm that assisted Forest and the co-conspirators 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 Enterprise. 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*.

k. 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 Forest's support of Celexa and Lexapro use in the pediatric population. BSMG ghostwrote medical manuscripts and articles for

Forest to be submitted for publication in medical journals by other authors in furtherance of the Enterprise. 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.

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

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

n. 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.

o. 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 and did not support efficacy in pediatric patients. Dr. Gorman's acts were in furtherance of the Enterprise.

JURISDICTION AND VENUE

14. This United States District Court for the District of Minnesota 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.

15. The United States District Court for the District of Minnesota also has federal question jurisdiction pursuant to 28 U.S.C. § 1331. The causes of action alleged in this First Amended Complaint arise under the laws of the United States.

16. Venue is proper before the United States District Court for the District of Minnesota to 28 U.S.C. § 1391(b). A substantial portion of the events giving rise to the claims alleged in this First Amended Complaint took place within the District of Minnesota.

17. The Judicial Panel on Multidistrict Litigation transferred this action from the United States District Court for the District of Minnesota to the *In re Celexa and Lexapro Marketing and Sales Practices Litigation* in the United States District Court for the District of Massachusetts. Thus, at this time, venue is proper within this Court.

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.

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.

I. FDA Approval Process

21. The process of gaining FDA approval for a new drug involves several steps. First, the company must conduct laboratory testing in animals to determine whether the drug will be safe and, to some extent, effective. If animal testing indicates that the drug or compound is relatively safe, the company then submits an investigational new drug ("IND") application to the FDA to gain approval to test the product with human subjects. These tests are called clinical trials and are carried out sequentially in three phases—Phase I, II, and III studies. Each phase increases the number of subjects and is designed to test for safety and efficacy of the drug for specific indications and patient populations. After the clinical trials are completed, the company then compiles the data and analysis in a new drug application ("NDA"). 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.[1] 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

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

> 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.[2] Trial participants are divided (unbeknownst to them) into a treatment group, where the participants receive the drug, or a control group, where they receive a placebo. Researchers then observe the results of the drug on the participants to see if the participants in the treatment group responded better than those taking a placebo.

29. Because Celexa and Lexapro are antidepressants, the issue of efficacy is particularly susceptible to the placebo effect. Unlike other ailments, where objective measurements are obtainable through blood and tissue samples, a physiological, objective test does not exist for determining the extent of a person's depression. Rather, researchers must rely exclusively on the subjective articulations of the patient concerning their depression. This is done using questionnaires completed by patients or their doctors designed to measure the severity of a patient's depression. However, this subjective measurement increases the potential for the placebo effect to drive the perceived efficacy of an antidepressant in a clinical trial. Specifically, if a patient believes she is feeling better because she is taking a drug that "cures" depression, unrelated to whether she is taking a particular antidepressant or not, she will be more inclined to respond positively to questions about her symptoms and appear better to the doctor

[2] The history of placebo control groups in drug trials can be traced to a lie told by an Army nurse during World War II. The nurse was assisting an anesthetist named Henry Beecher, who was tending to U.S. troops under heavy German bombardment. When the morphine supply ran low, the nurse assured a wounded soldier that he was getting a shot of potent painkiller, though her syringe contained only a saline solution. Amazingly, the injection relieved the soldier's agony and prevented the onset of shock. Returning to his post at Harvard after the war, Dr. Beecher became one of the nation's leading medical reformers. He launched a crusade to promote a method of testing new medicines to find out whether they were truly effective. Dr. Beecher proposed that if test subjects could be compared to a group that received a placebo, health officials would finally have an impartial way to determine whether a medicine was actually responsible for making a patient better. He published his findings in a 1955 paper titled, "The Powerful Placebo," in *The Journal of the American Medical Association*, and described how the placebo effect had undermined the results of more than a dozen trials by 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.

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*., *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.[3] Then, after the twelve (12) week trial, the participants were tested again using the Kiddie-SADS-P scale. The overall reduction of the Kiddie-SADS-P score was the measure of efficacy.

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.

b. Celexa Study 18

43. 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,

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

the participant's CDRS-R remained above forty (40) would they be allowed to participate in the trial.[4] Celexa Study 18 consisted of eight (8) weeks of treatment with either Celexa or placebo. At the end of the eight (8) weeks, the participant's CDRS-R score was taken again. Celexa Study 18 was completed in April 2001 and was subsequently distributed to Forest Executives and other co-conspirators in mid-2001.

44. Celexa Study 18 purported to be a positive study. According to the report, participants taking Celexa had an average 21.7 point improvement of their CDRS-R score, whereas participants taking placebo had an average 16.5 point improvement of their CDRS-R score. This difference in point averages, according to statistical modeling, resulted in a 4.6 point difference between Celexa and placebo in treating pediatric MDD. This 4.6 point difference was, according to the study, statistically significant.[5] When Celexa Study 18 was publicly published, the "authors" chose to represent the difference in effect between Celexa and placebo as a response rate. The response rate was calculated by determining whether the participant's CDRS-R score was lower than or equal to twenty-eight (28). In the published Celexa Study 18, the response rate for Celexa was 36% whereas the response rate for placebo was 24%.

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

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

45. 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.

46. 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.*

47. 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. Forest never 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.

48. Forest also misrepresented the authorship of Celexa Study 18 which was integral to the success of the Celexa and Lexapro Enterprise of promoting pediatric use.

49. The published version of Celexa Study 18 had numerous other flaws, including but not limited to the fact that Forest presented the effect size in an incorrect and misleading manner and intentionally decided not to report predetermined secondary outcomes, all of which proved unfavorable to Celexa.

c. The FDA Denies Celexa Pediatric Indication

50. 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.

51. 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.

52. 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 studies 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

53. 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.

54. 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.

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

56. 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

57. The first study, Lexapro Study 15, which was conducted by Dr. Wagner, was started in December 2002 and was completed in December 2004. The trial evaluated 264 children and adolescents (only 217 completed the trial), between the ages of 6-17 to determine whether the use of Celexa to treat depression was safe and effective. Lexapro Study 15 mirrored Celexa Study 18. For instance, to qualify for the study, the participant had to have been suffering from MDD for at least four (4) weeks and all participants had to have a CDRS-R score greater than or equal to forty (40). In addition, all participants were screened during a one-week placebo trial and only those participants whose CDRS-R remained above forty (40) after taking placebo for a week would be allowed to participate. Lexapro Study 15 consisted of eight (8) weeks of treatment with either Lexapro or placebo. At the end of the eight (8) weeks, the

participant's CDRS-R score was taken again. The difference of the patient's CDRS-R score from the beginning to the end served as the metric for efficacy.

58. 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

59. 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."

60. Lexapro Study 32 was started in February 2005 and was completed in May 2007. The trial evaluated 316 adolescents (only 260 completed the trial), between the ages of 12-17 to determine whether the use of Lexapro to treat depression was safe and effective. The study consisted of a two-week screening period, including single-blind placebo lead-in during the second week, followed by eight (8) weeks of double-blind treatment. Much like Celexa Study 18 and Lexapro Study 15, the study tracked changes in the participants CDRS-R score at week one and their CDRS-R score at week eight (8). The average baseline CDRS-R score of participants in the Lexapro control group was 57.6 and the average CDRS-R score of the placebo

group was 56.[6]

61. Lexapro Study 32 purports to be positive for efficacy. Participants taking Lexapro experienced an average 22.4 point improvement of their CDRS-R score, whereas participants taking placebo received an average 18.4 point improvement of their CDRS-R score. Even though eighty-two percent (82%) of Lexapro's observed efficacy was duplicated in the placebo group, this difference in point averages, according to statistical modeling, resulted in a statistically significant 3.4 point difference between Lexapro and placebo in treating *adolescent* MDD.

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

[6] 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.

involve the serious potential side-effects of using Lexapro.

63. 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?[7]

c. FDA Approves Lexapro Adolescent Indication

64. In May 2008, Forest submitted a supplemental NDA to the FDA requesting an indication for Lexapro in the treatment of adolescent MDD. As part of the application, Forest submitted Celexa Study 94404, the results of Celexa Study 18, Lexapro Study 15, and Lexapro Study 32.[8] The following chart reflects the clinical trials submitted in support of Lexapro's

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

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

efficacy:

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

65. Forest's supplemental NDA, therefore, did not provide two well-controlled studies demonstrating that Lexapro was statistically more effective than placebo in treating adolescents for MDD. Nonetheless, the FDA decided that, for 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[11] 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.[12] On March 20, 2009, Lexapro was approved by the FDA for use in adolescent MDD.

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

> We have long believed that Lexapro would be of benefit for the treatment of depression in adolescents and that is why we undertook the several studies

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

[10] Based on fraudulent data.

[11] 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.

[12] To be clear, Plaintiff's claims herein do not seek, in any way, to enforce FDA regulation or hold Forest accountable for committing fraud on the FDA.

described in the package insert.[13] 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.

67. 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.

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

> While only one RCT for escitalopram was statistically superior to placebo on the primary outcome measure, according to Forest Laboratories, Inc. … the FDA decision to approve escitalopram was based on two RCTs [randomly controlled trials] – the escitalopram RCT with positive results [Lexapro Study 32] and an earlier trial with citalopram [Celexa Study 18].
>
> . . .
>
> The citalopram trial [Celexa Study 18] that formed part of the basis for escitalopram FDA approval was alleged to have been written and submitted by a medical "ghost-writer" on behalf of Forest Laboratories, Inc. [citation omitted] In April 2009, one month after the FDA approval for escitalopram in adolescents was granted, Forest Laboratories admitted that a medical communication company, Prescott Medical Communications Group was not acknowledged as a contributor to the article at the time of publication.
>
> . . .
>
> The research groups that have studied citalopram and escitalopram for pediatric depression in RCTs are not independent groups, with the exception of the von Knorring group from Sweden [citation omitted]. However, the RCT by this group was a negative trial. [Celexa Study 94404].
>
> . . .

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

> 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.

69. 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

70. 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, at least as early as mid-2001. 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.

71. 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."

72. This information about the risk of suicidality created in pediatric populations was known by Forest during and throughout the fraudulent conduct alleged in this First Amended Complaint, 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.

THE ENTERPRISE AND RACKETEERING ACTIVITIES

73. 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 Enterprise and in violation of 18 U.S.C. § 1962(d).

74. The Enterprise alleged herein is an association-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. The Enterprise is distinct from, albeit conducted by, Forest, through the aforementioned co-conspirators/Enterprise participants, and has an ongoing existence. The participants in the Enterprise include Forest and all co-conspirators identified herein, among others

75. The purpose of the Enterprise was to mislead and deceive consumers, prescribers, and third-party payors about the ability of Celexa and Lexapro to treat pediatric depression. Simply stated, Forest and the co-conspirators deliberately concealed Celexa and Lexapro's negative efficacy 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, in a 2004 Lexapro marketing plan, it 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)."

76. 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 and illegal activities, as well as a concerted effort 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, prescribers, and third-party payors.

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

77. One of Forest's and the Co-conspirators' primary sub-enterprises, designed to further the overall Enterprise 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.

78. This Direct-to-Prescriber Sub-Enterprise involved Forest, and various departments, executives, and employees within Forest, Lundbeck, including but not limited to Jeffrey Lawrence, Andrew Korotzer, Karen Wagner, Jeffery Bostic, Forest Therapeutics, Forest Healthcare, Forest Ethicare, Forest Specialty Sales, Forest Research Institute, Parke-Davis, inVentive Health, IntraMed, CGI, BSMG, Natasha Mitchner, Mary Prescott, and the Prescott Group, and Dr. Gorman. Forest, Parke-Davis, and inVentive Health were responsible for training sales representatives on the methods for fraudulently detailing prescribers about the use of Celexa and Lexapro in children and adolescents. The remaining co-conspirators played a role in cultivating "scientific evidence" to support the Direct-to-Prescriber Sub-Enterprise.

79. 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 by the Enterprise participants, consisted of various sales, marketing and promotional techniques including: (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 by various Forest sales representatives and certain co-conspirators 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 the 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.

80. As part of the marketing plan designed by the co-conspirators and Forest, 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, Forest, Parke-Davis, and inVentive Health, among others, specifically trained sales representative on various illegal methods of selling and detailing to prescribers that Celexa and Lexapro were effective for children and adolescents.

81. 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 co-conspirators specifically generated pediatric prescriber call panels as part of this Direct-to-Prescriber Sub-Enterprise.

82. Using these panels, Forest, Parke-Davis, and inVentive Health, among others, 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 knew about the overwhelming negative efficacy data. Forest specifically directed its Celexa and Lexapro sales representatives to call on prescribers who worked in the pediatric wards of hospitals so that Forest could expand its market share for Celexa and Lexapro in pediatric markets.

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

84. 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 Enterprise.

85. 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.

86. 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.

87. Forest, Parke Davis, and inVentive 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.

88. 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 make prescriptions for Celexa and Lexapro.

89. 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." Forest sales managers put pressure on their sales representatives to spend their entire marketing budgets.

90. 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."

91. These illegal kickbacks are examples of the lengths to which the Direct-to-Prescriber Sub-Enterprise was 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 Jornada system.

92. 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.

93. In a continuation of the Enterprise, 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

94. 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 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 on 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 through their off-label and deceptive promotional campaign. 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.

95. Forest, with the 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."

96. 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, Ventiv 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 and the Peer Selling Sub-Enterprise participants.

97. 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 to children and adolescents; and (j)

intentionally misrepresenting and concealing financial ties between Forest and the other participants in the Peer Selling Sub-Enterprise.

98. All of the participants in the Peer Selling Sub-Enterprise, including 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."

99. All of the participants in the Peer Selling Sub-Enterprise, including Forest, shared the common purpose of aiding in marketing Celexa and Lexapro for off-label uses in children and adolescents being treated for depression and, ultimately, to expand the market. Each of the Peer Selling Sub-Enterprise participants received substantial revenue from the scheme to promote Celexa and Lexapro for pediatric use. 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.

100. The "marketing participants," 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. 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 that were the target of the off-label promotion campaign, the marketing participants coordinated their events to ensure their off-label message reached the most physicians in the most effective manner. All of the marketing participants were also in regular communication with the physician participants who would give the same presentation at different events hosted by the marketing participants.

101. In addition to a large well-trained sales force, Forest also employed numerous physicians, the "physician participants," who included 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 puppet marketing messages designed by Forest to disseminate false and misleading Celexa and Lexapro efficacy data in order to get doctors to prescribe the drugs to their pediatric patients. One of Forest's 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.

102. 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.

103. The components of the Peer Selling Sub-Enterprise included fraudulent CMEs, Forest-sponsored luncheon's and meetings with Medical Science Liasons ("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

104. *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, prescribers, and third-party payors.

105. 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.

106. Forest maintained a list of "approved" CME speakers, many of which were pediatric specialists. Forest sales representatives and managers would organize promotional lunches and dinners on Celexa and Lexapro with these paid speakers to deliver 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."

107. Forest and the Peer Selling Sub-Enterprise solicited accrediting 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.

108. An example of the Peer Selling Sub-Enterprise's use of CMEs involved presentations made by coconspirator 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.

109. In presenting her 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 consultant with Forest 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 speakers 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 off-label 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;
- information that virtually all publications and studies that allegedly supported Celexa's and Lexapro's off label 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 paid substantial subsidies 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.

110. All 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. These included:

- That virtually all of the publications and/or studies that purported to support Celexa and Lexapro's use for pediatric use were funded by Forest;
- That virtually all of the studies that purported to support Celexa and Lexapro's use for pediatric use had not been initiated by the physicians who were credited as authors, but by Forest and other members of the Enterprise pursuant to a corporate marketing plan designed to increase off-label sales;
- That data from the clinical trials found that Celexa and Lexapro were not statistically and/or clinically effective at treating pediatric patients; but Forest deliberately refused to publish or publicize such data; and
- That the participating doctors who were conducting the peer selling had been paid substantial subsidies to use Celexa and Lexapro on their pediatric patients or in reward for their recommending Celexa and Lexapro's use in children and adolescents

111. Hiding Forest's control of the content of the programs and misrepresenting its financial support as an "unrestricted" grant were materially false statements that concealed the promotional nature of the programs. Had the attending physicians known the programs were outright promotions they would have viewed the presentations with greater skepticism and doubted the claims of the participating physicians that Celexa and Lexapro were effective for pediatric use.

112. In addition to relaying false and biased promotional material to attendees of these fraudulent CMEs, Forest and the Peer Selling Sub-Enterprise also paid 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, free meals, and spending cash while attending the CME program. This was in addition to receiving CME credit for licensing purposes.

113. Forest also planned, with the assistance of the Peer Selling Sub-Enterprise, a

videotaped satellite program to extend the reach of Forest' 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 fraudulent online CME programs were created with the help of co-conspirators Avenue-E and IntraMed.

114. 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")

115. 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,[14] to promote Celexa and Lexapro for pediatric. 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.

116. The Peer Selling Sub-Enterprise participants would expressly 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

[14] 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.

providing non-scientific, anecdotal information designed to convince physicians that off-label usage of Celexa and Lexapro was safe and effective. 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.

117. 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.

118. 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 in order to increase the sales of Celexa and Lexapro, including sales for pediatric use in furtherance of the Peer Selling Sub-Enterprise and overall Enterprise.

119. 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 Enterprise. 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.

120. As an example, from 1999 through 2006, a pediatric specialist and coconspirator, 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 an excellent member of the Speakers' Bureau where be conducted and presented fraudulent CMEs, but he was also a MSL, where he spoke informally with prescribers to promote the use of Celexa and Lexapro in children and adolescents.

121. 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.

122. 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"

123. 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 overall Enterprise. 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.

124. 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 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 Off-Label and Deceptive Promotion campaign

125. 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 headquarters staff reviewed and approved the completed preceptorship ROI forms. Many of these preceptorship payments were directed at pediatric specialists.

126. The Peer Selling Sub-Enterprise also crafted specific preceptorship programs for third-party payors and managed care organizations. Indeed, Forest and the Peer Selling Sub-Enterprise specifically crafted marketing plans for third-party payor promotion in furtherance of the Enterprise.

127. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments. Several of these justification 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.

128. 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.

129. 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

130. 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 children and adolescents.

131. In a May 2000 proposal for a series of 44 Celexa advisory boards, coconspirator and Enterprise participant, Intramed, wrote that the advisory boards, each with 20 physicians attendees, would "give Forest and 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.

132. 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."

133. 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!"

134. 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.

135. 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.

136. 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."

137. 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."

138. 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 but 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."

139. The Peer Selling Sub-Enterprise's work in 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

140. 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 Enterprise. 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).

141. 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.

142. 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.

143. 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.

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

145. The organization of these bogus clinical trials, and the payment to various participants of the Enterprise, occurred through mail and wire.

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

146. 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 could actively promote the off-label use of Celexa and Lexapro.

147. 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.

148. A non-exhaustive list of the Publication Sub-Enterprise participants includes Dr. Karen Wagner, Dr. Jeffery Bostic, Jack Gorman, GCI, IntraMed, Jeffrey Lawrence, the Prescott Group, BSMG, Mary Prescott, Natasha Mitchner, Weber Shandwick, Parke-Davis and executives and employees of Forest.

149. 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, to create 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."

150. 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.

151. 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, internal emails reveal that the Publication Sub-Enterprise was aware of the negative results of Celexa Study 18 but nevertheless conspired to use the study as an example of pediatric efficacy.

152. Although Forest knew that 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.

153. In addition, Forest, with the assistance of the Publication Sub-Enterprise participants Dr. Wagner, Gorman, Lawrence, the Prescott Group, BSMG, Weber Shandwick, Mary Prescott, and Natasha Mitchner drafted, publicized, and circulated the "positive" results of Celexa Study 18 was 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*.

154. 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 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 corrupted and un-blinded data from several participants, that even with the corrupted 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 a contemporaneous study, Celexa Study 94404, which was clearly negative for efficacy.

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

155. 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.

156. The Publication Sub-Enterprise participants, including, but not limited to, Mary Prescott, Natasha Mitchner, BSMG, Weber Shandwick, the Prescott Group, Jeffrey Lawrence, Bill Heydorn and other Forest employees from Forest's in-house medical communications group, ghostwrote the 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 email or telephone in furtherance of the Enterprise.

157. In an email from Mary Prescott, an executive and employee of the Prescott Group, Weber Shandwick, and BSMG at all relevant times, 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.

158. 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.

159. Due to the skewed study data collected in Celexa Study 18, Forest insisted that the publication be ghostwritten by an independent source but use Dr. Wagner as the "author" because Dr. Wagner was widely regarded in the field of child psychiatry, i.e,. she was 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.

160. 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 in numerous public relations and marketing events aimed at promoting the pediatric use of Celexa and, by proxy, Lexapro.

161. Forest and the Publication Sub-Enterprise submitted the Celexa Study 18 manuscript to coconspirator 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).

162. Forest knew that publication of an article stating that Celexa was effective for pediatric depression would advance the Enterprise's objectives. In fact, Forest marketing plans stated that journal the 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."

163. 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 would be appropriate for 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.

164. 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.

165. 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*.[15] 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.

166. 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.

167. 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.

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[15] 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.

168. As another example of the Publication Sub-Enterprise participants' involvement in the Enterprise, 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. 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.

169. 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.

170. 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 getting fraudulent and misleading publications in medical journals, it would further the Enterprise's purpose and objectives by causing physicias 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

171. 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 enterprise participants, Forest was able to further control the content of information presented to consumers, including Plaintiff and its members, and 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 of course was not the case, as Forest used the medical marketing firms and consultants to ensure that the false and misleading results of the studies were faithfully communicated at the hundreds of scientific conferences, symposia, seminars, CMEs, and other events. 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 Co-conspirators Crafted Misleading Drug Labels and Actively Suppressed the Dissemination of Negative Efficacy Data to Further the Enterprise

172. A central method by which Forest and the co-conspirators were able to advance the Enterprise's objectives by deliberately concealing negative efficacy information about Celexa and Lexapro from consumers, prescribers, and third-party payors. The Material Omissions Sub-Enterprise consisted of suppressing the release and disclosure of negative efficacy information to ensure that consumers, prescribers, and third-party payor would not be able to make informed purchasing, prescribing, and reimbursing decisions.

173. This Material Omissions Sub-Enterprise involved Forest, and various departments and employees within Forest, Lundbeck, Dr. Wagner, Dr. Bostic, Forest Therapeutics, Forest Healthcare, Forest Ethicare, Forest Specialty Sales, Forest Research Institute, Parke-Davis,

inventive 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 results of Celexa Study 94404, (2) the fraudulently manipulated data that allowed for the positive result of Celexa Study 18, and (3) 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 a knowingly misleading and deceptive label, with the purpose of furthering the Enterprise.

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

174. The Material Omissions Sub-Enterprise knew that if it could ensure that there was no negative efficacy information about Celexa and Lexapro in pediatric populations, prescribers would be inclined to believe that the drug were effective in treating children and adolescents.

175. Thus, in 2002, although Forest submitted Celexa Study 94404 to the FDA to obtain a six-month extension of patent exclusivity for Celexa, Forest failed to otherwise disclose the negative study beyond a small group of its senior executives. This was deliberate. 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 proceed to promote, disseminate, and tout the fraudulent results of Celexa Study 18 in various CMEs, direct-to-prescribier detailing, etc. (various methods are described in detail throughout the First Amended Complaint). In the absence of any information to contradict the "one positive" study, prescribers, consumers, and third-party payors were led to believe that Celexa and Lexapro were likely effective for children and adolescents—after all, there was publically available reason to think they would be clinically ineffective.

176. 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 and the 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.

177. After promoting the supposedly positive results of Celexa Study 18 and suppressing the results of Celexa Study 94404 the damage caused by Forest's pervasive and one-sided promotion of manipulated "science" designed to legitimize the use of Celexa in pediatric populations had 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

178. The labels for Celexa and Lexapro are directed at every consumers, prescriber, and third-party payor. They serve as the primary authority for understanding the risks and likely 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 was one of the most authoritative sources for information in the eyes of prescribers and that the labeling would be given to hundreds of thousands of prescribers

179. 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 efficacy that would be required before a patient or prescribing physician could make an informed decision about whether to purchase or prescribe Celexa and Lexapro for pediatric use.

180. 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."

181. 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.

A. Celexa's Misleading Label

182. In July-2001when 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.

183. Then, in September 2002, when the FDA rejected Forest's supplemental NDA to get a pediatric indication for Celexa, Forest again did not update its label to reflect that the FDA

had expressly rejected a pediatric indication for Celexa.

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

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

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

185. Accordingly, between mid-2001 and February 2005, the Celexa drug label was fundamentally misleading and materially deficient because it failed to provide material information that was available to Forest regarding whether Celexa was 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.

186. In 2005, the Celexa label was amended to include a cursory description of Celexa Study 18 and 94404. However, these descriptions were wholly inadequate, particularly in light of the intense off-label promotion campaign (as described below) that had already taken root between 1998 and 2005. The new labeling did not discuss the actual observed differences observed 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.[16]

B. Lexapro's Misleading Label

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

188. In July-2001, when Celexa Study 94404 and Celexa Study 18 were unblinded and made available to Forest executives. Forest had an obligation to ensure that the Lexapro label, which was first issued in 2002, reflected that that two clinical trials had been conducted to evaluate the safety and efficacy of Celexa in pediatric populations and that they were both negative. Forest had consistently represented Lexapro as being nearly identical to Celexa and, thus, clinical trials relating to Celexa's efficacy in treating pediatric depression were essential in understanding Lexapro's pediatric efficacy. Forest's failure to include Celexa's negative data in the Lexapro label was misleading and deceptive. This deprivation of information robbed consumers of being able to make an informed decision in purchasing Lexapro.

189. 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 disabuse prescribers and consumers of the widespread and deliberate off-label promotion campaign perpetrated by Forest and the co-conspirators between 1998 and 2005. Specifically, the label change did not include any description of Celexa's negative clinical trial

[16] 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.

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.

190. 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.

191. 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.

C. The Enterprise Knowingly Disseminated the Misleading Labels

192. 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, consumers, and third-party payors, with the aim of further the large Enterprise objective of promoting the off-label use of Celexa and Lexapro in children and adolescents. The participants of the Material Omissions Sub-Enterprised 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

193. 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.

194. 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 Plaintiff's allegations that Forest engaged in fraudulent and deceptive promotion of Celexa and Lexapro throughout the United States.

195. Plaintiff incorporates by reference all those allegations contained in the plea agreement.

PLAINTIFF-SPECIFIC ALLEGATIONS

196. Plaintiff is a health and welfare benefit fund involved in the business of providing health benefits for covered members and their families. The Plaintiff is governed by approximately eight (8) board members, who oversee the fund on behalf of the members.

197. As a third-party payor, Plaintiff reimburses claims submitted by members.

198. Plaintiff relies on each member to submit claims for prescription medications that are medically reasonable and necessary for treatment. Since that decision is made by the prescribing physician and the patient, Plaintiff relies on those members and their prescribers to make informed decisions about which drugs will be prescribed and, in turn, submitted to Plaintiff for reimbursement.

199. The Enterprise participants, including Forest, as described throughout this First Amended Complaint, misrepresented to each consumer and prescriber Celexa and Lexapro's

ability to treat pediatric depression. This deception caused members of the Plaintiff's insurance plan to submit claims for reimbursement that were neither medically necessary nor reasonable, and which would never have been prescribed absent the fraud. The Enterprise's conduct, caused the Plaintiff to make payments for Celexa and Lexapro that, absent the fraud, would never have occurred.

200. The Enterprise participants, as described throughout this First Amended Complaint, deprived each member and their prescriber 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 monies being lost by the member (though co-pays) and by the third-party payor (through reimbursement).

201. Plaintiff has the authority to determine which drugs are covered under its plan, although, Plaintiff entrusts the administration of claims and formulary determinations to Prime Therapeutics, LLC, based in Eagan, Minnesota.

202. Between February 2001 and September 2013, forty-six (46) members of Plaintiff's plan submitted 313 claims for reimbursement for a Celexa and/or Lexparo pediatric patient. In total, Plaintiff paid $24,739.03 in claims for pediatric use of Celexa and/or Lexapro.

203. In an effort to avoid sanction and regulation by the FDA, Forest's illegal, off-label marketing scheme depended on their concealment of their involvement in the off-label promotion of Celexa and Lexapro for pediatric use. Indeed, the Promotion Enterprise was 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 had the Enterprise perform off-label promotional 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, Plaintiff 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.

204. From the original establishment of the Enterprise until the present, Plaintiff was not aware of any of the specific fraudulent or predicate acts alleged as part of the Enterprise in this First Amended Complaint. No members of the Plaintiff's management saw any media or received any communication describing any of the fraudulent conduct alleged as part of the Enterprise. No members of the management knew about Celexa's and Lexapro's negative efficacy data. Indeed, the Plaintiff was unaware that it had been the victim of the Enterprise until late October 2013. Prior to learning about the fraud, Plaintiff did not have any reason to investigate Forest's conduct or reason to suspect it had been the victim of a RICO Enterprise.

205. Any applicable statutes of limitations have been tolled by Forest's knowing and active concealment and denial of the facts alleged herein. Plaintiff and members of the Class 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. Plaintiff and members of the Class 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 Plaintiff's or the Class' claims.

FOREST'S MOTIVES AND CAUSATION OF DAMAGE

206. Forest's 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 use.

207. The fraudulent scheme and Enterprise was designed to, and did, cause Plaintiff and members of the Classes to pay for Celexa and Lexapro prescriptions in order to treat children and adolescents for which the drug is not effective. Moreover, as alleged above, the Enterprise's deceptive conduct caused an overvaluation of the drugs, which resulted in monies

being lost by the member (though co-pays) and by the third-party payor (through reimbursement). The fraudulent scheme also caused Plaintiff and members of the Classes to pay for Celexa and Lexapro prescriptions to treat non-FDA approved conditions and populations for which it was not effective. In the absence of Forest's improper conduct, Plaintiff and members of the Classes would not have paid for such Celexa and Lexapro prescriptions.

USE OF THE MAILS AND WIRES

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

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

- marketing materials about the off-label, pediatric use of Celexa and Lexapro, such materials being sent to doctors across the country;
- communications, including financial payments, between 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 Enterprise, 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 Enterprise 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 disclose the 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. The distribution of Celexa and

Lexapro samples under The Prescription Drug Marketing Act was tracked from, and sales reps were required to send all sample related forms to one of FPI's St. Louis facilities; and

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

210. In addition, Forest's corporate headquarters in New York, Missouri and New Jersey 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

211. 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 of marketing of Lexapro occurred before the date that the FDA approved Lexapro for use in adults on 2002 and until the present day.

212. 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, as well as various other territories and foreign countries.

RICO CLASS ALLEGATIONS

213. This matter is brought as a class action pursuant to Federal Rule of Civil Procedure 23, on behalf of third-party payors throughout the United States.

214. As discussed at length in this First Amended Complaint, Forest and the Enterprise participants have engaged in a comprehensive program to mislead consumers, prescribing healthcare professionals, and third-party payors about Celexa's and Lexapro's efficacy in treating pediatric MDD. Forest's conduct has been directed at consumers in all states in a uniform manner—using the same misleading and deceptive drug labels and same misleading and

deceptive promotional practices. Class action law has long recognized that, when a company engages in misconduct that has uniformly harmed a large number of claimants such as Plaintiff and the third party payors Plaintiff seeks to represent, class resolution can be an effective tool to redress the harm. This First Amended Complaint is well suited for class-wide resolution.

215. Defendants' deceptive and misleading marketing scheme increased the number of prescriptions of Celexa or Lexapro written and filled during the Class Period. Because Defendants withheld material information about the true safety and efficacy of Celexa or Lexapro, the prescribing physicians did not have the knowledge necessary to make informed decisions regarding Celexa or Lexapro prescriptions. Plaintiff and the Class, unaware of Forest's scheme, paid and/or reimbursed for payments for these prescriptions. Although more 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.

216. Plaintiff and similarly-situated Class members bear the ultimate responsibility of paying and/or reimbursing for their members' payments for Celexa or Lexapro prescriptions for pediatric use.

217. Patients, physicians, PBMs, pharmacy and therapeutic committee members, and third-party payors relied on Forest's misrepresentations of Celexa or Lexapro's safety. Physicians relied on Forest's misrepresentations of Celexa or Lexapro's safety in prescribing the drug for their patients. Patients relied on Forest's misrepresentations of Celexa or Lexapro's safety in purchasing the drug. PBMs and pharmacy and therapeutic committees relied on Forest's misrepresentations of Celexa or Lexapro's safety when approving and/or placing Celexa or Lexapro on formularies. Third-party payors relied on the Forest's misrepresentations of Celexa or Lexapro's safety in reimbursing and/or paying for prescriptions of Celexa or Lexapro for their members.

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

Celexa Class

All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for the drug Celexa for use by a minor, for purposes other than resale, since 1998. Excluded from the Class are employees of Forest, including its officers or directors, and the Court to which this case is assigned.

Lexapro Class

All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for the drug Lexapro for use by a minor, 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.

219. 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 a minor.

b. Commonality: Questions of law and fact are common to all members of the Classes. Specifically, Forest's misconduct was directed at all members of this Class, 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: Plaintiff's 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. All Plaintiff paid for Celexa and/or Lexapro for use by a minor, expecting it to be effective. Their claims are typical of the Classes.

d. Adequacy: Plaintiff 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, Plaintiff are represented by counsel who are competent and experienced in both consumer protection and class action litigation.

220. The Classes are properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Classes. Forest deliberately engaged in a widespread program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's efficacy in treating pediatric MDD. 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 de y 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.

MINNESOTA CLASS ALLEGATIONS

221. This matter is brought as a class action pursuant to Federal Rule of Civil Procedure 23, on behalf of third-party payors and consumers within the State of Minnesota. As discussed at length in this First Amended Complaint, Forest has engaged in a comprehensive program to mislead consumers, prescribing healthcare professionals, and third-party payors about Celexa's and Lexapro's efficacy in treating pediatric MDD. Forest's conduct has been directed at consumers in all states in a uniform manner—using the same misleading and deceptive drug labels and same misleading and deceptive promotional practices. Class action law has long recognized that, when a company engages in misconduct that has uniformly harmed a large number of people, class resolution can be an effective tool to redress the harm. This is

particularly true when the alleged misconduct was categorically directed at a class of claimants harmed by that conduct. Accordingly, Plaintiff's Minnesota causes of action are uniquely suited for class-wide resolution.

222. The Minnesota Consumer Class consists of:

Minnesota Celexa Class

All consumers and health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, in the State of Minnesota (other than governmental entities) which paid or incurred costs for the drug Celexa for use by a minor, for purposes other than resale, since 1998. Excluded from the Class are employees of Forest, including its officers or directors, and the Court to which this case is assigned.

Minnesota Lexapro Class

All consumers and health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, in the State of Minnesota (other than governmental entities) which paid or incurred costs for the drug Lexapro for use by a minor, for purposes other than resale, since 2001. Excluded from the Class are employees of Forest, including its officers or directors, and the Court to which this case is assigned.

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

a. Numerosity: Hundreds of thousands of Celexa and Lexapro prescriptions were filled in the State of Minnesota in which payments were covered or reimbursed by class members.

b. Commonality: Questions of law and fact are common to all members of the Minnesota class members. Specifically, Forest's misconduct was directed at all members of this Class and the prescribing healthcare professionals and consumers in Minnesota. Thus, all members of the Minnesota Class 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's claims are typical of the claims of the Minnesota Class members

because their claims arise from the same course of conduct by Forest, *i.e.*, false, misleading and deceptive marketing. Plaintiff and all class members were exposed to Forest's misleading and deceptive marketing program and Plaintiff and all class members either purchased and/or reimbursed its members for purchases of Celexa and/or Lexapro for use in a children or adolescents. Accordingly, their claims are typical of the Classes.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the Minnesota Class. Its 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.

224. The Minnesota Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Minnesota Class. Forest deliberately engaged in a widespread program to mislead consumers, prescribing healthcare professionals, and third-party payors about Celexa's and Lexapro's efficacy in treating pediatric MDD. Since each class member was exposed to the promotion at issue in this First Amended Complaint and, under the consumer protection laws of Minnesota, reliance is not an element of a consumer protection claim, 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 a Minnesota refund class for those members of the Minnesota Class 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 Minnesota

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

225. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

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

227. The Enterprise is an association-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. 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 marketing participants, physician participants, publication enterprise participants and all co-conspirators/Enterprise participants identified herein. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market and sale Celexa and Lexapro as scientifically proven as safe and effective for use by children and adolescents.

228. The Enterprise functioned as an ongoing organization and continuing unit. The Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of these Enterprise participants, including Defendants, is a "person" distinct from the Enterprise.

229. 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 Enterprise received substantial revenue 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 was 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 Enterprise in promoting Celexa and Lexapro. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

230. Defendants established the Enterprise to accomplish goals that were instrumental to its scheme to market Celexa and Lexapro for pediatric uses. First, it created parallel marketing structures that appeared independent from Forest's ordinary promotion forces 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, the Enterprise developed misleading labeling which was widely disseminated 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 a veneer of legitimacy. In addition, the labeling was relied on by the sales force while detailing Celexa and Lexapro to physicians and prescribers.

231. There was a common strategy employed by these Sub-Enterprises, whereby the Enterprise would recruit and use of 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.

232. 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 Enterprise, and actively concealing any negative information.

233. These systematic linkages between physicians, marketing participants, physician participants, Forest and all the participants of the Enterprise were established for a common purpose: to aid in marketing Celexa and Lexapro for pediatric uses. Each 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.

234. All participants of the Enterprise were fully aware of Forest's control over the Enterprise. Furthermore, each portion of the Enterprise 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.

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

236. 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.

237. The Enterprise (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.

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

239. Defendants conducted and participated in the affairs of the Enterprise (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), § 1512 (tampering with witnesses), and § 1952 (use of interstate facilities to conduct unlawful activity).

240. 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 Plaintiff and members of the Class paid for this drug for which it was not scientifically proven to be safe and effective; (b) providing or publishing or causing to have provided or published presentations and materials containing false and/or misleading information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe, pay, or reimburse 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 Enterprise.

241. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty and integrity of Defendants in representing the efficacy of Celexa's and Lexapro's 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 uses. 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.

242. 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 Class Members, including Plaintiff, 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 Promotion Enterprise.

243. 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.

244. At all times during the fraudulent scheme, Defendants and the Enterprise participants had a legal and ethical obligation of candor to, and honest dealing with, public and private payors, physicians, and the medical community.

245. The conduct of the Enterprise (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 Enterprise (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).

246. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiff and the members of the Classes. Indeed, Plaintiff was 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 Plaintiff would foot the bill. Forest knew that many if not most of all prescriptions for Celexa and Lexapro were paid by third-party payors such as Plaintiff 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 Plaintiff and members of the Classes. Forest's racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Classes.

247. Forest's motive in creating and operating the fraudulent scheme and the Enterprise 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 Plaintiff and the Classes to pay for Celexa and Lexapro prescriptions to treat conditions for which the drug without being fully informed about the likelihood of the drugs' efficacy.

248. Plaintiff and members of the Classes have been injured in their property by reason of these violations in that Plaintiff 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.

249. The injuries to Plaintiff and members of the Classes were directly and proximately caused by Defendants' racketeering activity. In the absence of Forest's improper conduct, Plaintiff and the Class would not have been deprived of material information about Celexa and Lexapro efficacy, thereby causing economic harm in the form of reimbursed

payments.

250. Above all, the Enterprise participants, including Forest, have misled and deceived physicians, the consumers who rely on their professional judgment, and third-party payors including Plaintiff 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 risks and benefits of prescribing Celexa and Lexapro for children and adolescents and third-party payors of this same information which is utilized in determining whether the third-party payor will pay for such prescriptions. Consequently, Forest with the help of the Enterprise have led to Plaintiff and the class members to pay for overvalued drugs.

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

252. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff and members of the proposed Classes have suffered damages. Plaintiff 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)

253. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

254. 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."

255. 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 conduct of the affairs of the Enterprise described previously through a pattern of racketeering activity. The corporate defendants conspired with the Enterprise

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

256. 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 Plaintiff and the Classes of money.

257. 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.

258. 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), Plaintiff 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.

259. 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.

260. Defendants' violations of the above federal laws are continuing and will continue. Plaintiff and members of the Classes have been injured in their property by reason of these violations in that Plaintiff and members of the Class 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).

261. Injuries suffered by Plaintiff and members of the Classes were directly and proximately caused by Defendants' racketeering activity as described above. Had prescribers, patients, and third-party payors known that Celexa and Lexapro were not clinically superior to placebo, no reasonable prescriber or patient would have submitted claims for reimbursement and Plaintiff would not have allowed the claims to be reimbursed.

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

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

COUNT III: VIOLATIONS OF MINN. STAT. § 325F.69

264. Plaintiff incorporates by reference all preceding paragraphs as if fully restated here.

265. Minnesota Statutes § 325F.69, subd. 1 makes it unlawful for any person by use of "any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby…."

266. Forest is considered a person pursuant to Minn. Stat. § 325F.68.

267. By engaging in the conduct described in this First Amended Complaint, Forest violated Minn. Stat. § 325F.69.

268. By making the misrepresentations set out in this First Amended Complaint, which are hereby incorporated, Forest used false pretenses, false promises, misrepresentations, and

misleading statements, all with the intent that others, including Plaintiff and members of the proposed Classes rely on those statements, in the course of the sale and promotion of Celexa and Lexapro for the treatment of pediatric depression.

269. The facts Forest misrepresented as alleged in this First Amended Complaint were material to Plaintiff, its members, physicians, prescribers and their representatives' decisions about whether to purchase Celexa or Lexapro for pediatric use, in that they concerned facts that would have been important to a reasonable consumer in making a decision whether to purchase Celexa or Lexapro for pediatric use.

270. Forest's misrepresentations and deceptive acts and omissions were likely to mislead reasonable consumers acting reasonably under the circumstances such as Plaintiff and physicians under Plaintiff's plan.

271. Forest's wrongful conduct and use of false pretenses, false promises, misrepresentations, and misleading statements, all with the intent that others relied on those statements, included, by way of example and not by limitation:

- Forest knowingly represented, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that it did not have, *i.e.*, that Celexa and Lexapro was clinically effective for the treatment of pediatric and adolescent MDD.
- Forest knowingly represented, through deceptive promotion and misleading drug labels, that Celexa and Lexapro were of a particular quality or standard, *i.e.*, capable of clinically treating pediatric and adolescent MDD, when, in truth, Forest knew or should have known that neither Celexa or Lexapro were clinically effective at treating pediatric or adolescent MDD.
- Forest advertised and sold 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.

- Forest, through deceptive promotion and misleading drug labels, engaged in a practice that was misleading, false, or deceptive when it represented to Plaintiff and consumers and prescribing healthcare professionals that Celexa and Lexapro were clinically effective for pediatric and adolescent depression. These deceptive acts had a likelihood of confusing or misleading consumers and prescribing healthcare professionals.
- Forest, through deliberate omission, concealed material negative efficacy information about Celexa and Lexapro in treating children and adolescents, thereby depriving all consumer their prescribers of being able to make an informed decision about purchasing or prescribing the drugs for pediatric depression.

272. Plaintiff and members of the proposed classes and their representatives, received the misrepresentations and omissions described herein when deciding to purchase Celexa and Lexapro for pediatric use.

273. As a result of Forest's fraud, false pretense, false promises, misrepresentations, misleading statements and deceptive practice practices relating to the sale of Celexa and Lexapro, Plaintiff and putative class members have suffered actual damages in that they purchased and paid for Celexa and Lexapro for pediatric use while being deprived of material information.

274. As a direct, proximate, and foreseeable result of Forest's violation of Minn. Stat. § 325F.69, subd. 1, Plaintiff and the putative class members sustained damages in an amount to be determined at trial.

COUNT IV: VIOLATIONS OF MINN. STAT. § 325D.13

275. Plaintiff incorporates by reference all preceding paragraphs as if fully restated here.

276. Minnesota Statutes § 325D.13 provides that, "[n]o person shall, in connection

with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."

277. By engaging in the conduct described herein, Forest violated Minn. Stat. § 325D.13.

278. By making the misrepresentations set out in this First Amended Complaint, which are hereby incorporated, Forest misrepresented the true quality of Celexa and Lexapro.

279. The facts Forest misrepresented as alleged in this First Amended Complaint were material to Plaintiff, its members, and their representatives' decisions about whether to purchase Celexa or Lexapro for use in children and adolescents, in that they concerned facts that would have been important to a reasonable consumer in making a decision whether to purchase Celexa or Lexapro for pediatric use.

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

281. Forest's misrepresentation about the true quality of Celexa and Lexapro included, by way of example and not by limitation:

- Forest knowingly represented, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that it did not have, *i.e.*, that Celexa and Lexapro was clinically effective for the treatment of pediatric and adolescent MDD.
- Forest knowingly represented, through deceptive promotion and misleading drug labels, that Celexa and Lexapro were of a particular quality or standard, *i.e.*, capable of clinically treating pediatric and adolescent MDD, when, in truth, Forest knew or should have known that neither Celexa or Lexapro were clinically effective at treating pediatric or adolescent MDD.
- Forest advertised and sold 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.

- Forest, through deceptive promotion and misleading drug labels, engaged in a practice that was misleading, false, or deceptive when it represented to Plaintiff and consumers and prescribing healthcare professionals that Celexa and Lexapro were clinically effective for pediatric and adolescent depression. These deceptive acts had a likelihood of confusing or misleading consumers and prescribing healthcare professionals.
- Forest, through deliberate omission, concealed material negative efficacy information about Celexa and Lexapro in treating children and adolescents, thereby depriving all consumer their prescribers of being able to make an informed decision about purchasing or prescribing the drugs for pediatric depression.

282. Plaintiff and the class members and their representatives, received the misrepresentations and omissions described herein when deciding to purchase Celexa and Lexapro for pediatric uses.

283. As a result of Forest's fraud, false pretense, false promises, misrepresentations, misleading statements and deceptive practice practices relating to the sale of Celexa and Lexapro, Plaintiff and putative class have suffered actual damages in that they purchased and paid for Celexa and Lexapro that were not clinically effective for pediatric and adolescent depression and there is a causal nexus between Forest's actions and the damages suffered by Plaintiff and the Classes.

284. As a result of Forest's practices relating to misrepresentation of the true quality of Celexa and Lexapro, Plaintiff and putative class are entitled to declaratory and injunctive relief informing them of the problems associated with the drugs, instructing them about the dangers posed by drugs, and the lack of clinical efficacy.

285. There is a causal nexus between Forest's actions and the injunctive and declaratory relief sought in this action under Minn. Stat. § 325D.13, because absent Forest's

illegal and deceptive conduct, consumers and prescribers would not have been deprived of material information and Plaintiff would not have had to reimburse certain claims.

COUNT V: VIOLATIONS OF MINN. STAT. § 325D.44

286. Plaintiff incorporates by reference all preceding paragraphs as if fully restated here.

287. Minnesota Statutes § 325D.44, subd. 1 provides in part:

> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:
>
> (5) Represents that goods or services have…characteristics, ingredients, uses, benefits…that they do not have…
>
> (7) Represents that goods or services are of a particular standard, quality, or grade,…if they are of another.
>
> (13) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

288. By engaging in the conduct described herein, Forest violated Minn. Stat. § 325D.44.

289. By making the misrepresentations set out in this First Amended Complaint, which are hereby incorporated, Forest knowingly misrepresented the true characteristics, standards, quality, and grade of Celexa and Lexapro with the intent that others would rely on those statements in the course of the sale and promotion of Celexa and Lexapro for use in children and adolescents.

290. The facts Forest misrepresented as alleged in this First Amended Complaint were material to Plaintiff, its members, and their representatives' decisions about whether to purchase Celexa or Lexapro for pediatric use, in that they concerned facts that would have been important to a reasonable consumer in making a decision whether to purchase Celexa or Lexapro for pediatric use.

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

292. Forest's wrongful conduct and use of deceptive trade practices, false pretenses, false promises, misrepresentations, and misleading statements to knowingly misrepresent the true characteristics, standards, quality, and grade of Celexa and Lexapro, includes, by way of example and not by limitation:

- Forest knowingly represented, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that it did not have, *i.e.*, that Celexa and Lexapro was clinically effective for the treatment of pediatric and adolescent MDD.
- Forest knowingly represented, through deceptive promotion and misleading drug labels, that Celexa and Lexapro were of a particular quality or standard, *i.e.*, capable of clinically treating pediatric and adolescent MDD, when, in truth, Forest knew or should have known that neither Celexa or Lexapro were clinically effective at treating pediatric or adolescent MDD.
- Forest advertised and sold 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.
- Forest, through deceptive promotion and misleading drug labels, engaged in a practice that was misleading, false, or deceptive when it represented to Plaintiff and consumers and prescribing healthcare professionals that Celexa and Lexapro were clinically effective for pediatric and adolescent depression. These deceptive acts had a likelihood of confusing or misleading consumers and prescribing healthcare professionals.
- Forest, through deliberate omission, concealed material negative efficacy information about Celexa and Lexapro in treating children and adolescents, thereby depriving all consumer their prescribers of being able to make an informed decision about purchasing or prescribing the drugs for pediatric depression.

293. Plaintiff and the class members and their representatives, received the misrepresentations and omissions described herein when deciding to purchase Celexa and Lexapro for pediatric use.

294. As a result of Forest's fraud, false pretense, false promises, misrepresentations, misleading statements and deceptive practice practices relating to the sale of Celexa and Lexapro, Plaintiff and putative class have suffered for pediatric and adolescent depression and there is a causal nexus between Forest's actual damages in that they purchased and paid for Celexa and Lexapro without knowing material information about the likelihood of the drugs' benefit.

295. As a direct, proximate, and foreseeable result of Forest's violation of Minn. Stat. § 325D.44, Plaintiff and putative class members sustained damages in an amount to be determined at trial.

EXEMPLARY DAMAGES ALLEGATIONS

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

297. Forest's conduct as alleged herein was done with oppression, fraud, and malice. Forest was fully aware of Celexa's and Lexapro's true efficacy as documented in its own clinical trials and internal company documents. Nonetheless, Forest deliberately crafted its drug label to mislead consumers and prescribing healthcare professionals into believing that these drugs are more effective at treating pediatric and adolescent depression than they actually are. Moreover, Forest's comprehensive program of deceptive marketing, 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, prescribing healthcare professionals, and third-party payors that Celexa and Lexapro were safe and effective at treating pediatric and adolescent depression. Such conduct was done with a conscious disregard of Plaintiff and the class members' rights.

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

DEMAND FOR JURY TRIAL

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

PRAYER FOR RELIEF

300. WHEREFORE, Plaintiff, 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 Plaintiff as representatives for the respective classes and Plaintiff's undersigned counsel as Class Counsel for the respective classes;

c. Issue a judgment against Forest that:

   i. Grant Plaintiff and the various classes alleged herein a refund of all moneys acquired by Forest by means of its deceptive and unlawful marketing of Celexa and Lexapro;

   ii. Grant Plaintiff and the classes alleged herein an award of restitution and/or disgorgement of Forest's profits from its deceptive and unlawful marketing of Celexa and Lexapro in violation of the consumer protection claims;

   iii. Grants Plaintiff and the various classes alleged herein any actual or compensatory damages for the payments or reimbursements made by plan members 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 Plaintiff 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 Plaintiff and the various classes alleged herein pre-judgment and post-judgment interest

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

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

Dated: February 5, 2014

Respectfully submitted by,

/s/ Christopher L. Coffin

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Counsel for Plaintiff and Putative Classes

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic filing (NEF) and paper copies will be sent to those indicated as non-registered participants on February 5, 2014.

Dated: February 5, 2014

Respectfully submitted,

/s/ Christopher L. Coffin
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