UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ALLIED SERVICES DIVISION WELFARE FUND, and NEW MEXICO UFCW UNION'S AND EMPLOYERS' HEALTH AND WELFARE TRUST FUND, on behalf of themselves and all others similarly situated, Plaintiffs, vs. FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC. Defendants.	CIVIL ACTION NO. JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Allied Services Division Welfare Fund and New Mexico UFCW Union's and Employers' Health and Welfare Trust Fund (collectively, "Plaintiffs"), on behalf of themselves and all others similarly situated, files this class action Complaint ("Complaint") against Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc. (collectively, "Forest" or "Defendants"), based upon personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, and alleges as follows:

I. NATURE OF THE ACTION

1. This matter arises out of Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc.'s deceptive and unlawful marketing of the "blockbuster" antidepressants Celexa and Lexapro for adolescent depression.[1] By using fundamentally misleading drug labels, the "endorsements"

[1] While Plaintiffs maintain that Forest's off-label promotion activity is illegal and relevant to the unethical pattern of conduct giving rise to this class action, it is not the sole focus of Plaintiffs' claims.

of paid opinion leaders, gerrymandered clinical trials, and a legion of specially trained sales personnel, Forest misled consumers and the medical community about Celexa's and Lexapro's efficacy in treating pediatric depression.

2. The clinical trials that examined whether the antidepressants Celexa and Lexapro are effective at treating adolescent major depressive disorder ("MDD") indicate that Celexa and Lexapro are no more effective clinically than a sugar pill. The clinical trials demonstrate that any perceived benefit adolescents receive from taking Celexa or Lexapro in treating their depression is primarily explained by the placebo effect - the perceived efficacy of a drug based upon one's belief that the drug works.

3. Starting in 2001, when the first two clinical trials of Celexa in pediatric patients indicated it was not superior to placebo in treating MDD, Forest definitively learned that Celexa lacked efficacy in pediatric patients. However, instead of limiting marketing efforts to promote Celexa and Lexapro to adult populations, Forest concocted a comprehensive and aggressive program to mislead consumers and prescribing healthcare professionals about Celexa's and Lexapro's pediatric efficacy.

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

[2]Throughout this Complaint, the term "drug label" refers to the product insert and various labels that are required by federal law to accompany a prescription medication.

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

5. In addition to a misleading and deceptive label, Forest also directly misled prescribing doctors, third-party payors and the medical community about Celexa and Lexapro's efficacy in treating pediatric MDD. This program of deception included:

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

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

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

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

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

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

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

6. Forest knew that disclosing Celexa and Lexapro's true pediatric efficacy to consumers, third-party payors and prescribing healthcare professionals would have drastically reduced the drugs' revenue potential. Rather than issue proper warnings and provide accurate information about Celexa and Lexapro's risks and benefits, Forest chose instead to keep their deceptive propaganda and marketing machine running full steam ahead and never took any affirmative steps to correct the misinformation and deceptive advertising scheme that it had and continued to perpetrate, ensuring that it would continue to maximize the prescription and sale of Celexa and Lexapro so long as consumers, third-party payors, prescribing healthcare professionals, and the medical community remained unaware of Celexa and Lexapro's true risks. Forest intentionally hid the efficacy data, misled consumers, third-party payors, and prescribing healthcare professionals, and positioned Celexa and Lexapro as effective pediatric medications in the medical community.

7. By knowingly and actively promoting Celexa and Lexapro for pediatric use without disclosing the negative evidence, Forest caused physicians to write prescriptions for Celexa and Lexapro for pediatric patients for non-proven uses, and caused Plaintiffs and members of the Classes to pay for more Celexa and Lexapro prescriptions than it would have absent Forest's unlawful conduct. Plaintiffs and the Classes were denied the opportunity to make fully informed decisions about whether and how to include Celexa and Lexapro on their formularies and paid for more prescriptions than it would have absent Forest's unlawful conduct.

8. Forest's omissions of, and deliberate misrepresentations related to, critical information regarding the pediatric use of Celexa and Lexapro have caused financial harm to Plaintiffs and the Classes, who hereby seek compensatory, punitive and statutory damages, injunctive relief to prevent Forest from continuing their unlawful activities, reasonable attorneys' fees and such other just relief as the Court may award.

II. PARTIES

9. Plaintiff Allied Services Division Welfare Fund ("ASD") is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. Plaintiff ASD has paid and/or provided reimbursement for some or the entire purchase price for Celexa and/or Lexapro during the Class Period. Plaintiff ASD has sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein.

10. Plaintiff New Mexico UFCW Union's and Employers' Health and Welfare Trust Fund ("NMUFCW") is a Taft-Hartley fund with its principle place of business in Albuquerque, New Mexico and is involved in the business of providing health and pension benefits, among others, to covered lives. Plaintiff NMUFCW has paid and/or provided reimbursement for some or the entire purchase price for Celexa and/or Lexapro during the Class Period. Plaintiff NMUFCW has sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein.

11. Defendant Forest Laboratories, Inc. is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York. Forest Laboratories, Inc. regularly conducts business, including the sale and marketing of Lexapro, within all states in the United States, and derives substantial revenues from goods consumed in

the United States. Forest Laboratories has a license from H. Lundbeck A/S ("Lundbeck"), a Danish pharmaceutical company, to promote and sell Celexa and Lexapro in the United States.

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

13. Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives, while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

14. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants. Jurisdiction also rests under 28 U.S.C. § 1331 because Counts I and II arise under the laws of the United States.

15. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

16. Venue is appropriate within this district under 28 U.S.C. §1391(b) and (c), because during the Class Period Defendants transacted business, were found, or had agents in

this District, and because a substantial portion of the affected interstate trade and commerce described herein is and has been carried out in this District.

17. Venue is also proper under the special provisions of the federal racketeering laws, 18 U.S.C. § 1965 because Defendants transact business within this District.

IV. BACKGROUND

A. Characteristics of the Antidepressant Marketplace

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, third-party payors 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 revenue exceeding $4 billion. Forest is also a leader in the antidepressant industry and has enjoyed considerable financial success from the manufacture and sale of Celexa and Lexapro, as well as other more recent psychotropic drugs.

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). It has been theorized that reduced levels of serotonin in the brain are the primary physiological cause of depression and, through use of a 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.

B. The Placebo Effect and Efficacy

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

22. The placebo effect is the effect that a drug has on a patient that has nothing to do with the drug, but is simply caused by the patient's *belief* that it works. During clinical trials, researchers must "control" for this effect by dividing a clinical trial population into a treatment group that receives the drug, and a control group that receives a sugar pill (placebo)[4]. Neither group knows whether the "drug" they receive is placebo or real. Thus, researchers can see if the effect created in the treatment group is significantly different than in the control group. If both

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

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

23. Because Celexa and Lexapro are antidepressants, the issue of efficacy is particularly susceptible to the placebo effect. Unlike other ailments, where objective measurements are obtainable through blood and tissue samples, there is no physiological test for determining whether a given antidepressant is working on a patient. Rather, researchers must rely exclusively on the subjective articulations of the patient concerning his or her depression. This is generally done using questionnaires designed to measure the severity of a person's depression. If a person believes he or she is feeling better because he or she believes he or she is taking a drug that cures his or her depression, then he or she will answer the subjective questions in a way that shows an improvement of depression. Thus, the potential for the placebo effect to drive the actual effectiveness of an antidepressant is very high.

24. The vulnerability of antidepressants being susceptible to the placebo effect is well documented. For instance, in an analysis of efficacy data submitted to the FDA between 1987 and 1999 for six of the most popular SSRI antidepressants, 75 to 80% of the response to medication was duplicated in placebo groups. *Irving Kirsch et al., The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration,* 5 Prevention & Treatment 23, 1-11 (2002). In another study evaluating the "relative benefit of medication vs. placebo across a wide range of initial symptom severity in patients diagnosed with depression[,]" the authors concluded that the "magnitude of benefit of antidepressant medication compared with placebo ... may be minimal or non-existent, on average in patients with mild or moderate symptoms." *Jay C. Fournier, et al., Antidepressant Drug Effect and Depression Severity: A Patient-Level Meta-analysis,* 303 J. Am. Med. Assoc. 47-53, 47

(2010); *see also Irving Kirsch, et al., Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, 5 PLoS Medicine 2 (Feb. 2008) (same findings). In fact, an analysis conducted by the FDA in 2006 of adult antidepressant clinical trial data showed that, while five out of every ten patients appear to respond to the drugs, in the same trials, four out of every ten patients respond to placebo. *See* Thomas P. Laughren, Dept. of Health and Human Services, *Memorandum: Overview for December* 13 *Meeting of Psychopharmacologic Drugs Advisory Committee* (Nov. 16, 2006), *available at* http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4272b1-01-FDA.pdf.

25. The vulnerability of antidepressant's benefits to be driven by the placebo effect is also applicable in treating pediatric populations. In an analysis of four SSRIs, which consisted of 477 patients on antidepressants and 464 on placebo, and a review of a report by the U.S. Food and Drug Administration (FDA) of a number of antidepressants, including Celexa, the authors concluded that the drugs could not confidently be recommended as a treatment option for childhood depression. The authors found that clinical investigators' conclusions on efficacy of antidepressants in childhood depression exaggerated their benefits and adverse effects were downplayed. *Jureidini et al., Efficacy and Safety of Antidepressants for Children and Adolescents,* 328 BRITISH MED. J.879 (2004). In a separate editorial, published in the *British Journal of Psychiatry* in 2005, titled "Wishful thinking: antidepressant drugs in childhood depression," the authors point out that: a) the use of SSRIs in children under 18 years old increased ten-fold in the UK from 1992 to 2001 and usage rates in the United States are even higher; b) reasons for the increasing rates of use are likely due to heavy promotion of both medication and illness, distortions of the published data related to safety and efficacy, and underestimation by clinicians of the importance of the placebo response; and c) continued

endorsements of the use of antidepressants in children and adolescents despite lack of efficacy is probably the result of how guidelines are developed and by whom, and potential conflicts of interest due to pharmaceutical industry influence. In conclusion, the authors argue that the "perceived need to 'do something' and the wishful thinking that the drugs may actually be better than the trial evidence indicates, the injunction to 'first do no harm' has been forgotten." *See also*, Whittington and Kendall, *"Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data,"* The Lancet, April 24, 2004.

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

27. In addition, federal law requires that the two positive studies show a statistically significant superiority over placebo. This, however, is different than clinical significance (or clinical importance). Statistical significance is a statistical term of art that means that the difference between the benefits observed in the treatment group and the control group was not the result of chance. Clinical significance, however, examines whether the observed benefit of a drug is enough to outweigh the risks associated with the drug, particularly when compared to alternative, less risky treatments. If, for example, a drug is proven to be statistically superior to placebo, it may still not be clinically significant because the additional benefit is so marginal that alternative treatments would be preferable. The question of clinical significance is not part of the

regulatory framework of the FDCA and drug manufacturers are not required to demonstrate the clinical significance of a drug before gaining premarket approval.

C. Approval, Labeling, and Promotion of Pharmaceuticals Marketed in the United States

28. Pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), a pharmaceutical must be approved by the FDA before it is transported or distributed across state lines. *See* 21 C.F.R. § 301; *see also* 21 U.S.C. § 331. The Center for Drug Evaluation and Research is a division of the FDA and conducts limited research in the areas of drug quality, safety and effectiveness.

29. In order for the FDA to approve a drug, the manufacturer must show that a drug is "safe for use" and effective for all "conditions prescribed, recommended, or suggested" on a drug's label. *See* 21 C.F.R. § 99.103; *see also* 21 C.F.R. § 201.5.

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

drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's strength, quality, and identity.

31. 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.[5] FDA approval of a medication for a specific indication does not mean that the drug is necessarily safe and effective, or in compliance with potentially more demanding state law requirements. FDA approval merely means the drug satisfied the baseline regulatory threshold. The FDA sets the floor, not the ceiling of drug regulation.

32. Once a drug is approved by the FDA, a pharmaceutical company is allowed to market and sell the drug *only* for the approved indication. Indications and dosages approved by the FDA are set forth in a drug's label, the content of which is reviewed and approved by FDA. 21 U.S.C. § 355(d)(1) & (2). An example of a drug's label is the printed insert contained in the drug's packaging. By federal regulation, the label must conform to the indications and dosages that the FDA has approved. 21 U.S.C. § 355(d).

33. Under the FDCA, if a manufacturer wishes to market or promote an approved drug for additional uses – *i.e.*, uses not listed on the approved label – the manufacturer must conduct another series of clinical trials similar to those which supported the initial FDA approval. Until the FDA has granted approval of the new use, the manufacturer cannot market the drug for that use. Off-label marketing restrictions are an important safety-related aspect of the FDCA because they require manufacturers to provide the efficacy of their drugs for additional uses, rather than avoid FDA review.

5*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).

34. "Off-label" or "unapproved" use refers to the use of a drug for any purpose or in any manner, other than the indications approved by the FDA and described in the drug's labeling or indications. Off-label use includes treatment beyond the indications and use, treatment of the indicated condition at a difference dose or frequency than specified in the label, or treatment of an unapproved patient population.

35. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352. Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. *Id.*

36. Although physicians may prescribe drugs for off-label use, the law prohibits drug manufacturers from marketing or promoting a drug for use that the FDA has not approved, or for a patient group that is unapproved. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include information (other than labeling) that originates from the same source as the product and is intended to supplement or explain the product.

37. The FDA regulations ban advertisements that are false, lacking in fair balance, or otherwise misleading. Specifically, the regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with

the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. § 202.1(e)(6)(iv).

38. The pharmaceutical company can market the drug to doctors, pharmacy benefit managers, health insurance companies and plans, and state and federal agencies, but the information cannot be false or misleading. If the drug manufacturer would like to add an additional indication for the drug, it must submit a separate supplemental NDA to the FDA for approval.

39. Historically, pharmaceutical companies have also 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 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.

40. 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.

D. The Celexa and Lexapro Story

41. Celexa (citalopram) and Lexapro (escitalopram) are SSRI drugs.

42. 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 Untied States.

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

E. Forest Knew Celexa was not Effective at Treating Pediatric Depression

44. 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 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."

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

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

47. The first study, Celexa Study 94404, evaluated 233 adolescents, between the ages of thirteen (13) and eighteen (18) who had been diagnosed with MDD lasting longer than four (4) weeks. The trial lasted twelve (12) weeks for each participant and the study was completed in March 2001. Half of the participants were given Celexa and half were given placebo. At the beginning of the twelve-week trial, participants were tested with the Schedule for Affective Disorders and Schizophrenia for School Aged Children ("Kiddie-SADS-P") which yielded a numeric baseline score.[6] Then, after the twelve (12) week trial, the participants were tested again

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

using the Kiddie-SADS-P scale. The overall reduction of the Kiddie-SADS-P score was the measure of efficacy.

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

49. The second study, Celexa Study 18, evaluated 178 children and adolescents, between the ages of 7-11 and 12-17 respectively, to determine whether the use of Celexa to treat depression was safe and effective. To qualify for the study, the participant had to have been suffering from MDD for at least four (4) weeks and all participants had to have a Children's Depression Rating Scale-Revised ("CDRS-R") score greater than or equal to forty (40). However, after initially qualifying, participants were put on a placebo for one week. Only if, after the week on placebo, the participant's CDRS-R remained above forty (40) would they be allowed to participate in the trial.[7] Celexa Study 18 consisted of eight (8) weeks of treatment with either Celexa or placebo. At the end of the eight (8) weeks, the participant's CDRS-R score

[7] Using a one week placebo lead-in period in all 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)

was taken again. Celexa Study 18 was completed in April 2001 and was subsequently distributed to Forest Executives in mid-2001.

50. Celexa Study 18 purported to be a positive study. According to the report, participants taking Celexa had an average 21.7 point improvement of their CDRS-R score, whereas participants taking placebo had an average 16.5 point improvement of their CDRS-R score. This difference in point averages, according to statistical modeling, resulted in a 4.6 point difference between Celexa and placebo in treating pediatric MDD. This 4.6 point difference was, according to the study, statistically significant.[8] When Celexa Study 18 was publicly published, the "authors" chose to represent the difference in effect between Celexa and placebo as a response rate. The response rate was calculated by determining whether the participant's CDRS-R score was lower than or equal to twenty-eight (28). In the published Celexa Study 18, the response rate for Celexa was 36% whereas the response rate for placebo was 24%.

51. 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 Dr. 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."

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

[8] To gain some perspective on whether a 4.6 point difference is clinically significant, studies show that requiring children and adolescents to exercise twice a week results, on average, in a *2004* 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.

the data presented in the published Celexa Study Dr. Mathews noted "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.*

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

53. Forest also misrepresented the authorship of Celexa Study 18. In fact, the manuscript was written by a "medical communications" (ghostwriting) company in coordination

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

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

F. The FDA Denies Celexa Pediatric Indication

55. 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.

56. 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.

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

G. Lexapro's Pediatric Efficacy Problem Emerges

58. 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.

59. 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 Danish pharmaceutical manufacturer H. Lundbeck *A/S* ("Lundbeck") began development of a "new" antidepressant - one that could replace the anticipated revenue lost from Celexa going generic. This was how Lexapro was conceived and Forest hoped that the revenues generated by new Lexapro sales could replace the anticipated lost revenue from Celexa going generic.

60. Forest and Lundbeck began development of Lexapro in the summer of 1997 and submitted an NDA to the FDA in March of 2001.

61. On August 14, 2002, the FDA approved Lexapro for the treatment of adult MDD. On December 18, 2003, the FDA approved Lexapro for the treatment of adult generalized anxiety disorder. 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.

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

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

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

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

66. Lexapro Study 32 was started in February 2005 and was completed in May 2007. The trial evaluated 316 adolescents (only 260 completed the trial), between the ages of 12-17 to determine whether the use of Lexapro to treat depression was safe and effective. The study consisted of a two-week screening period, including single-blind placebo lead-in during the second week, followed by eight (8) weeks of double-blind treatment. Much like Celexa Study 18 and Lexapro Study 15, the study tracked changes in the participants CDRS-R score at week one and their CDRS-R score at week eight (8). The average baseline CDRS-R score of participants in the Lexapro control group was 57.6 and the average CDRS-R score of the placebo group was 56.[9]

67. 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.

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

This difference in point averages, according to statistical modeling, resulted in a 3.4 point difference between Lexapro and placebo in treating adolescent MDD.

68. On its face, Lexapro Study 32 has several problems. First, the fact that the Lexapro group started with a baseline CDRS-R score that was significantly higher than the placebo group, indicates that there was selection bias (not true randomization into the Lexapro and placebo groups). When the difference in baseline CDRS-R score is 1.7 points, there is a substantial likelihood that it will affect the final results, particularly when the difference between Lexapro and placebo is only 3.4 points. Second, Lexapro Study 32 had a two-week screening period which creates, from the beginning, selection bias against people who are susceptible to the placebo effect, effectively making Lexapro seem more effective than it is. Third, and most importantly, the 3.4 point difference of CDRS-R scores between Lexapro and placebo participants is not clinically significant. Other, less risky treatments have been shown to be more effective, and they do not involve the serious potential side effects of using Lexapro.

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

> [Comment 6.] The effect size (ES) reported as 0.27 may be comparable to prior reports, however, it should be noted that according to Chen this is a relatively small ES. Given this small ES, there were no data to see if this level of change had any quality of life meaningful.
>
> [Comment 7.] It was not clear why the authors consider the baseline difference in the CDRS-R (~2 points) between the two treatment groups as not clinically significant even though it was statistically significant. This is confusing as the authors' then note that a CDRS-R treatment difference between the groups of ~2pts, which is statistically significant, shows efficacy. It was clear the authors controlled for these baseline severity scores but then what does a 2-point difference really mean for the

> adolescent? Is this a quality of life difference? The primary outcome (CDRS-R) was significant but there was little discussion of why most of the secondary outcome measures were not significant.
>
> [Comment 8.] Finally, one has to wonder whether the restrictive entry criteria in conjunction with the small effect size limit the utility of [Lexapro] in the real world of adolescent MDD. Are these results statistically significant but clinically not meaningful?[10]

H. FDA Approves Lexapro Pediatric Indication

70. Even though Forest had only one clinical trial that was allegedly positive for efficacy in adolescents, it still decided to "roll the dice" and apply to get Lexapro approved for adolescent populations. In May 2008, Forest submitted a supplemental NDA to the FDA requesting an indication for Lexapro in the treatment of adolescent MDD. As part of the application, Forest submitted Celexa Study 94404, the results of Celexa Study 18, Lexapro Study 15, and Lexapro Study 32.[11] The following chart reflects the clinical trials submitted in support of Lexapro's efficacy:

Study	*Stat Efficacy*	*Clinical Efficacy*	*Placebo Effect*	*Drug Effect*	*Difference*
Celexa Study 94404	Negative	Negative	12.7 pts[12]	12.4 pts	(-0.3 pts)
Celexa Study 18	Positive[13]	Negative	16.5 pts	21.7 pts	4.6 pts
Lexapro Study 15	Negative	Negative	20.9 pts	20.3 pts	(-0.6 pts)
Lexapro Study 32	Positive	Negative	18.4 pts	22.4 pts	3.4 pts

71. Forest's supplemental NDA, therefore, did not provide two well-controlled studies demonstrating that Lexapro was statistically more effective than placebo in treating adolescents

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

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

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

[13] Based on corrupted unblinded data.

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

72. Thus, the FDA accepted the questionable data from Lexapro Study 32 and the flawed data from Celexa Study 18 to conclude that Forest met its regulatory requirement of providing two well-controlled studies showing that Lexapro was effective for the treatment of adolescent MDD.[14] On March 20, 2009, Lexapro was approved by the FDA for use in adolescent MDD.

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

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

74. The FDA's approval of Lexapro for adolescents has received considerable criticism. For instance, the website Psychcentral run by Dr. John M. Grohol points 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."

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

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

76. The FDA's approval of Lexapro for adolescent MDD is not the first time the FDA has approved a drug of questionable efficacy. FDA officials and advisors have commented since the beginning of the modern antidepressant era that the agency's standards for approving antidepressants are minimal according to the law. For instance, during an FDA advisory

committee meeting related to one of the SSRI antidepressants, Dr. Paul Leber, the Division Director of the FDA at the time explained that "the law, as far as I know, never discussed multiplicity," *i.e.*, the law does not address drugs where multiple clinical trials failed to show efficacy. Dr. Leber pointed out that the FDA does "not have a systematic program" to analyze multiple studies not submitted for an efficacy determination, but admitted "[m]aybe there ought to be." He explained that: "I think you have to understand that when we face an application from a regulatory perspective, we are asked to face what the law requires us to do ... [W]e have to look at the application submitted to us and recognize, in a way, that we can exhort people to do more. But the law did not set out a very Draconian or Procrustean set of standards that have to be met." Dr. Leber admitted "I have no idea what constitutes proof of efficacy, except on the basis of what we, as a Committee, agree on and as *ad hoc* case as there needs to be. You can be guided by the past but the inference is an abstraction - what is an antidepressant?" He explained that "over the past 27 years or so since people have been looking at that question, we have taken changes on the HAM-D, the Clinical Global Impression of severity, POMS [Profile of Mood States] factors and a variety of other things and taken those as testimony or indicators of efficacy. But that is tradition. That is not truth." Dr. Leber told the advisory committee members that they could tell the FDA "look, we think the standards in this field are terrible. People have been getting away with non-substantive efficacy for years. We'd like you to change your standards." Unfortunately, those minimal standards did not subsequently change.

I. Forest Published Misleading and Inadequate Drug Labeling

77. 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.

78. 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 way, or if any required information appears on the label in such terms as to render it unlikely to be read and understood by the ordinary individual under customary conditions of purchase and use. The FDA has passed many regulations effectuating the FDCA and specifying, in detail, the labeling requirements of prescription drugs. Specifically, 21 C.F.R. § 201.56(a)(1) provides that "[t]he labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug." In addition, 21 C.F.R. § 201.56(a)(2) provides that "[the] labeling must be informative and accurate and neither promotional in tone or false or misleading in any particular."

1. Celexa's Misleading Label from July 2001 – February 2005

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

80. In July 2001, however, when Celexa Study 94404 and Celexa Study 18 were unblinded and made available to Forest executives, Forest had an obligation to update the Celexa label to reflect that the 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.

81. 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.

82. On March 22, 2004, the FDA issued a public health advisory requesting that certain SSRI manufacturers, including Forest, change the labels on their SSRI drugs to include "a [w]arning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality."

83. Later that year, the FDA directed SSRI manufacturers, including Forest, to include on their labels a black box warning and expanded statements to alert physicians about the potential for increased risk of suicidality in adolescents taking SSRIs. The black box warning specifically stated that "[a]ntidepressants *increased the risk* of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." (Emphasis added).

84. 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.

85. Prior to 2005, Forest was well aware of the increased risk of pediatric suicidality from the use of Celexa in adolescents and deliberately 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 for pediatric use. For instance, in a 2006 publication of results from Celexa Study 94404 — which were known to Forest in 2001 —the authors noted "suicide attempts, including suicidal thoughts and tendencies, were reported by 5 patients in the placebo group and by 14 patients in the citalopram group (not significant) with no pattern with respect to duration of treatment, time of onset, or dosage." The article presented results from study 94404, which had involved 244 adolescents, 13 to 18 years old, with major depression who were randomized to treatment with citalopram or placebo. Anne-Liis von Knorring *et al., A Randomized, Double-blind, Placebo-controlled Study of Citalopram in Adolescents with Major Depressive Disorder*, Journal of Clinical Psychopharmacology, 26:311-315 (2006).

86. The underlying data from Celexa Study 94404 indicated that: a) Celexa was no better than placebo as a treatment for major depression in adolescents, and b) Celexa was associated with a borderline statistically significant relative risk of 2.6 for suicide-related adverse events ("SREs") including suicide attempts, thoughts and tendencies compared to placebo. The fact that the incidence of SREs reached borderline significance in a study involving only 244 patients is not only alarming but also material and the type of information that physicians,

patients, parents and purchasers require to make informed decisions whether or not to prescribe or purchase Celexa for pediatric or adolescent use.

87. Had Forest accurately disclosed the results of Celexa Study 94404 prior to the FDA mandated warning — that Celexa was no more effective than placebo as a treatment for major depression in the pediatric population yet increased patients' risk of suicidality approximately 2.5 times as compared to placebo — physicians would have been able to make an informed decision whether or not to prescribe Celexa for their pediatric and adolescent patients suffering from depression and at increased risk of suicidality.

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

2. Lexapro's Misleading Label from 2002 – 2005

89. 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.

90. 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 the 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.

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

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

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

> *"Adolescents*
>
> The efficacy of Lexapro as an acute treatment for major depressive disorder in adolescent patients was established in an 8-week, flexible-dose, placebo-controlled study that compared Lexapro 10-20 mg/day to placebo in outpatients 12 to 17 years of age inclusive who met DSM-IV criteria for major depressive disorder [*i.e.*, Lexapro Study 32]. The primary outcome was change from baseline to endpoint in the Children's Depression Rating Scale - Revised (CDRS-R). In this study, Lexapro showed statistically significant greater mean improvement compared to placebo on the CDRS-R.
>
> The efficacy of Lexapro in the acute treatment of major depressive disorder in adolescents was established, in part, on the basis of extrapolation from the 8-week, flexible-dose, placebo-controlled study with racemic citalopram 20-40 mg/day [*i.e.*, Celexa Study 18]. In this outpatient study in children and adolescents 7 to 17 years of age who met DSM-IV criteria for major depressive disorder, citalopmm treatment showed statistically significant greater mean improvement from baseline,

> compared to placebo, on the CDRSR; 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."

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

93. Second, the label states that the data in Lexapro Study 32 demonstrated that "Lexapro showed statistically significant greater mean improvement compared to placebo on the CDRS-R." This statement is misleading because it does not provide any indication that the difference between Lexapro and placebo as seen in Lexapro Study 32 was statistically marginal, and not clinically meaningful. Without some indication of how much Lexapro outperformed placebo, consumers and prescribing healthcare professionals cannot properly weigh the risks versus benefits of using Lexapro to treat adolescent MDD.

94. Moreover, while Forest mentions that "[t]wo additional flexible-dose, placebo-controlled MDD studies (one Lexapro study in patients ages 7 to 17 and one citalopram study in adolescents) did not demonstrate efficacy" (Lexapro Study 15 and Celexa Study 94404), the

totality of the data, examined from every perspective, illustrates that Forest's representation that Lexapro is an effective treatment for adolescent depression is unsupported.[15]

95. Forest had a duty to fairly and honestly deal with consumers, third-party payors and prescribing healthcare professionals and by artfully omitting this material information, Forest misled consumers, prescribing healthcare professionals, third-party payors and the medical community.

J. Forest Crafted and Executed a Company-Wide Marketing Plan to Promote the Use of Celexa and Lexapro to Treat Pediatric MDD that was Deceptive and Misleading

96. In today's healthcare market, physicians face extreme time constraints in determining which drugs and treatments are best. Physicians, along with formulary committees, third-party payors ("TPPs"), Pharmacy Benefit Managers ("PBMs") and policy makers rely upon a variety of trusted sources including independent studies for such information. However, often unbeknownst to the public, many of these sources are directly controlled or heavily influenced by pharmaceutical manufacturers such as Forest. All of these sources contain susceptibilities that have been exploited by pharmaceutical manufacturers such as Forest.

97. From 1998 through at least 2005, Forest engaged in a widespread campaign to promote Celexa and Lexapro for pediatric use, even though neither drug was proven safe and effective for these uses. Forest used its sales representatives to detail or target pediatric specialists; paid pediatric specialists to give promotional speeches to other physicians on

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

pediatric use; selectively distributed publications on pediatric uses; misrepresented the safety and efficacy of the drugs; and made extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses.

98. Forest's deceptive and misleading marketing scheme increased the number of prescriptions of Celexa and Lexapro written and filled during the Class Period. Because Forest withheld material information about the true safety and efficacy of Celexa and Lexapro in the pediatric population, the prescribing physicians did not have knowledge necessary to make informed decisions regarding Celexa and Lexapro prescriptions. Plaintiffs and the Classes, unaware of Forest's scheme, paid for these prescriptions although more effective, safer, and less expensive alternatives were available.

1. One-Sided Publications – Cultivating Misleading "Science" to Encourage Pediatric Use

99. Although Forest submitted Celexa Study 94404 to the FDA in 2002 in order to seek a six-month extension of patent exclusivity for Celexa (which Forest later valued at $485 million), Forest failed otherwise to disclose the negative study beyond a small group of its senior executives. At the same time, Forest aggressively promoted Celexa Study 18 as a "positive" study even though it was based on a fraudulent manipulation of data. This one-sided publication strategy relayed the false impression that pediatric use of Celexa was safe and effective, even though the clinical data indicated otherwise.

100. Forest took aggressive steps to publicize the deceptively presented results of Celexa Study 18. On August 27, 2001, Forest presented Celexa Study 18 results to its Executive Advisory Board without making any mention of the contemporaneous negative results in Celexa Study 94404 or the negative data and flaws in Celexa Study 18, including how statistical significance was achieved by including unblinded patients. Forest thereafter arranged for Dr.

Wagner, the study's ostensible leader, to present a poster summary of the results of Celexa Study 18 to various professional groups, including the American Psychiatric Association, the American College of Neuropsychopharmacology, and the Collegium Internationale Neuro-Psychopharmalogicum. In these presentations, Dr. Wagner presented false, misleading and deceptive information concerning the efficacy of Celexa from Study 18 to those in attendance at the conferences. In conjunction with these presentations, Forest coordinated the "placement" of news stories about Celexa 18's "positive" results in numerous national and local media outlets.

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

102. Forest's failure to disclose the negative results of Celexa Study 94404 to the members of Forest's Executive Advisory Board caused those members to make false or misleading statements in promotional teleconferences on Celexa and Lexapro. During the teleconferences, which were targeted to large numbers of physicians across the country, the Forest Executive Advisory Board Members represented, based on the Celexa Study 18 data, that Celexa was safe and effective for pediatric use even though, unbeknownst to them, the FDA had specifically rejected Forest's attempt to gain approval for such a claim because of the negative Celexa Study 94404 data.

103. During details to physicians, Forest sales representatives made false or misleading representations by distributing off-label publications on the pediatric use of Celexa and Lexapro

that did not include the negative results of Celexa Study 94404. Forest sales managers, also unaware of the negative results, directed the dissemination of these publications.

104. Forest had a Professional Affairs Department that responded to health care provider inquires. Under the company's own written policy, the Professional Affairs Department was:

> *"Required to provide balanced information* to help the health care practitioner (HCP) make the best decision on behalf of the patient. For this reason, *there is an ethical prohibition in "cherry picking" studies that are favorable to Forest products*. The Food and Drug Administration Division of Drug Marketing, Advertising, and Communications (DDMAC) monitors drug information departments to insure information provided to HCPs is balanced, and that it is not selective. (Emphasis added). "

Forest's failure to disclose the negative results of Celexa Study 94404 to its Professional Affairs Department caused it to disseminate misleading information to physicians on the pediatric use of Celexa and Lexapro. When physicians sought information from Forest's Professional Affairs Department in the years following the un-blinding of the Celexa studies, the Professional Affairs Department responded with letters that cited only positive data. The letters cited just one double-blind placebo-controlled trial on the use of Celexa to treat pediatric depression, Celexa Study 18. The letter never mentioned that there was another, negative double-blind placebo-controlled trial, Celexa Study 94404, which had shown an increased risk of suicidality among those taking Celexa that was almost three times higher than in the group taking placebo.

105. Several senior Forest executives – including Lawrence Olanoff (then Forest's Chief Scientific Officer and now its President), Ivan Gergel (Vice President of Clinical Development and Medical Affairs), and Amy Rubin (Director of Regulatory Affairs) – reviewed the letters before the Professional Affairs Department disseminated them. All of these senior Forest executives knew about the negative results of Celexa Study 94404.

106. Forest paid a medical writing firm to ghostwrite an academic article on Celexa Study 18, and Forest arranged to have the article published in the June 2004 issue of *The American Journal of Psychiatry*, with Dr. Wagner listed as the lead author. The article did not mention that the only other double blind, placebo-controlled trial on pediatric use of Celexa had shown no efficacy and had an incidence of suicide attempts and suicidal ideation among those taking Celexa that was almost three times higher than in the group taking placebo.

107. This carefully orchestrated, early dissemination of false information created a domino effect within the medial community. By broadly disseminating the results of Celexa Study 18 in a highly misleading and deceptive way while simultaneously suppressing the negative results of Celexa Study 94404, Forest created a perception within the medical community that Celexa was safe and effective for pediatric MDD. Forest pointed to the seemingly positive results of Celexa Study 18 and the lack of any negative marketing and the resulting indirect statements that spread within the medical community, that Celexa was effective in treating pediatric MDD.

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

109. By failing to disclose the Celexa Study 94404 results, which raised serious questions about the efficacy and safety of Celexa, while simultaneously promoting Celexa study 18, Forest told prescribing physicians a half-truth and thereby prevented them and the public form having all potentially available information when making important decisions about how to treat a serious medical condition in pediatric patients.

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

111. Forest's off-label scheme paid off handsomely and its success was vital to the prosperity of the company. Celexa and Lexapro constituted Forest's antidepressant franchise, which was the backbone of the company's growing fortunes. By July 2004, the proliferation of Celexa and Lexapro use in the pediatric population constituted a substantial percentage of Celexa and Lexapro sales. These two drugs accounted for 68%, 74%, 82% and 77% of the Forest's net sales for the fiscal years ending 2006, 2005, 2004 and 2003 respectively.

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

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

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

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

114. Forest knew that its off-label promotion for pediatric use was unlawful. Shortly before the FDA ordered the black box warning in September 2004, a Forest executive 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. That is the law, and we follow it." In fact, Forest had been illegally promoting pediatric use of Celexa and Lexapro throughout the preceding six years.

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

- "Discussed cx [Celexa] use in children…and results of Dr. Karen Wagner study [Celexa Study 18] regarding cx us 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 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 doing 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.

3. Paid Presenters Push the Pediatric Efficacy Message

116. In addition to a large well-trained sales force, Forest also employed numerous physicians whose sole purpose was to puppet marketing messages designed by Forest to disseminate false and misleading Celexa and Lexapro efficacy data in order to get physicians to prescribe the drugs to their pediatric patients. Forest maintained a list of "approved" promotional speakers, many of which were pediatric specialists. Forest sales representatives and

managers would organize promotional lunches and dinners on Celexa and Lexapro with these paid speakers to deliver a sales pitch to fellow doctors. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on pediatric use: the programs had titles such as "Adolescent Depression," Adolescent Treatment of Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment of 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 Adolescent," and "Treading Pediatric Depression." Forest management approved each of these programs.

117. From 1999 through 2006, one pediatric specialist, Dr. Jeffery 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, had 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 for the unapproved pediatric use. Between 2000 and 2006, Forest paid Dr. Bostic over $750,000 in honoraria for his presentations on Celexa and Lexapro.

4. Forest's Illegal Inducements to Physicians to Prescribe Celexa and Lexapro

118. Forest augmented its promotion efforts for the unproven indication through extensive payments and gifts to physicians to induce them to prescribe Celexa and Lexapro.

Forest's marketing department directed some of the kickbacks, such as honoraria for participation in advisory boards and in a large marketing study on Lexapro. Forest's sales representatives, often acting with the knowledge and encouragement of their managers, arranged for other kickbacks, such as restaurant gift certificates for physicians, lavish entertainment of physicians and their spouses, and grants to individual physicians.

5. "Advisory Boards" - a Pretext for Buying Goodwill (and Prescriptions)

119. In yet another component of Forest's company-wide program to push the use of Celexa and Lexapro for pediatric use by deceptive means, between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro which involved over 19,000 advisory board attendees that Forest called "consultants." As a "consultant" Forest paid each attendee an honorarium of $500.

120. Ostensibly, Forest paid physicians to attend these advisory boards to get their feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal company documents, Forest intended that the advisory boards would induce the attendees to prescribe more Celexa and Lexapro. Many of these advisory boards involved the deceptive promotion of Celexa and Lexapro for use in pediatric populations.

121. In a May 2000 proposal for a series of 44 Celexa advisory boards, a Forest contractor, Intramed, a division of Sudler & Hennesey Worldwide ("Intramed"), wrote that the advisory boards, each with 20 physician attendees, would "give Forest an opportunity to influence more physicians." Forest's marketing department approved this proposal. Later that year, Steve Closter, the Forest marketing executive who organized the advisory boards, wrote that the Celexa advisory boards begun in June 2000 had been successful and, as a result, "will become an even larger 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.

122. With the early success of the advisory board programs, the Forest sales force 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 "[t]here is no doubt that a program of this magnitude will increase Celexa market share. In 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."

123. In June 2002, Forest's two Vice Presidents of Sales sent 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 email to his District Managers stating that, "[w]ith 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 make [sic] maximize this opportunity!"

124. 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.

125. Forest monitored its return on investment ("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 analyses 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 SSRIs written by these physicians, 3.7% translates into almost 2000 new prescriptions on a yearly basis."

126. 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."

127. 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."

128. After 2003, Forest stopped conducting ROI analyses of advisory boards because of concerns about memorializing fraudulent and deceptive intent, but the company continued to use the same types of advisory board programs as a means of inducing doctors to prescribe Celexa and Lexapro. As a Forest 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 that they had come "up with 40 doctors that are either high Celexa writers or can be converted/persuaded to write Lexapro."

6. The EXCEED Study – a Useful Marketing Tool

129. 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).

130. In 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."

At the conclusion of EXCEED, Forest's marketing department planned to calculate the study's "ROI," *i.e.*, the number of prescriptions generated as compared against the cost of funding the study.

131. To the extent that EXCEED trial had a scientific purpose, it was secondary to the purpose of inducing participating physicians to prescribe Lexapro. Forest conceived the study as a promotional tool and then sought out company scientists "to discuss possible endpoints/outcomes to look at for our early usage trial." Forest hired Covance, a contract research organization, to conduct the study, but according to Covance's own study implementation plan, Covance, too, understood that "the primary goal of this trial is to provide experience to physicians." Similarly, Forest openly referred to the EXCEED trial as a "seeding study" in their internal communications.

132. Forest aimed the EXCEED study at 2,000 physicians, many of whom were specialists in pediatric care. Under the study protocol, each participating physician could enroll up to five (5) patients in the study, which would last eight (8) weeks and involve three (3) patient visits. After the first visit, the physician would fill out a one-page form with the patient's age, race, gender, and basic medical history, and Forest would pay the physician $50. After each of the next two (2) visits, the physician would fill out an additional page requiring the physician to write the date of the visit and to check one of seven (7) boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two (2) other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten (10) patients in the study, so that physicians could make up to $1,500.00 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to pre-study teleconference.

133. 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.

7. Preceptorships - Another Pretext to Buy Goodwill (and Prescriptions)

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

135. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out ROI forms to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify the cost to Forest. Senior Forest sales managers and headquarters staff reviewed and approved the completed preceptorship ROI forms. Many of these preceptorship payments were directed at pediatric specialist.

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

- "Dr. ____ is the managing partner of the ____ Psychiatric Group and is very influential among his colleagues in the ____ Hospital network. He currently averages @ 12 per week on 1" RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. _____."

- "Dr. ____ is the largest prescriber of SSRI's in a 3 state area…We are currently her first line SSRI. We must, however, continue to support her monetarily or this will not continue to be the case…We have to keep the pressure on to continue to receive the growth we are getting with Dr. _____."

- "Dr. _____ is my largest prescribing Celexa physician. He is a high maintenance target and doing round tables and preceptorships will help me to keep his business and to continue to grow his business."

- "2 different preceptorships Doc is 3rd ranked phys. in SSRI potential + bus had dropped. Needed his full attention."

- "Dr. _____ is my fourth larges SSRI writer…A preceptorship will provide opportunity for rapport and for future detail time and sales."

- "#1 physician in Territory … Dr. ___ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship."
- "This full day preceptorship will give me the opportunity to sell Celexa as a first line choice in doctor ___'s practice."
- "To influence doctor to Rx Celexa."

8. Lavish Entertainment and Gifts - Forget Pretext

137. During the period from 1998 through at least 2005, each Forest sales representative typically had a quarterly marketing budget of thousands of dollars to spend on physicians. As a Forest Regional Director put 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.

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

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."

- In September 2002, a sales representative gave a high-prescribing child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.

- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cap 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 Manger 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 rx lex [*i.e.*, prescribe Lexapro] 141 as long [sic] as we have fun and take care of him."

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

140. The effect of Forest's wrongful conduct was payment by Plaintiffs and members of the Classes for Celexa and Lexapro prescriptions that otherwise would not have been paid for and the payment of higher prices for Celexa and Lexapro than the drugs would have commanded absent the misrepresentations and fraud on the medical community.

K. Forest's Repeated Misrepresentations Caused Injury to Plaintiffs and the Classes

141. Forest's deceptive and misleading marketing scheme was calculated to ensure that Celexa and Lexapro was prescribed in great quantities by physicians for pediatric uses, despite the lack of FDA approval, with the knowledge of and active suppression of studies indicating safety concerns with adolescent patients. Forest knew that without their fraudulent scheme, consumers and third-party payors would not have paid for Celexa and Lexapro used in the treatment of depression and other psychiatric conditions in pediatric patients. Forest's promotion and marketing of Celexa and 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 was not entitled.

142. Plaintiffs and similarly situated Class Members bear the ultimate responsibility of paying for their members' prescriptions for Celexa and Lexapro.

143. PBMs prepare a "formulary," which is a list of the drugs that are approved for coverage by their third-party payor clients, such as Plaintiffs and Class Members. In order for a drug to be listed on the formulary, it must be assessed by the PBM for clinical safety, efficacy and cost effectiveness. Further, where a PBM finds that a drug has an advantage over competing drugs, that drug is given a preferred status on its formulary.

144. The level of preference on the formulary corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug – the higher the preference, the lower the co-payment, the more likely that drug will be purchased by a prescription plan's beneficiary in lieu of a cheaper or more cost effective alternative and *vice versa*. As such, the higher a drug's preference on the formulary, the more likely it is for a physician to prescribe that drug. This system is well known to pharmaceutical manufacturers, including Forest.

145. Due to the large number of drugs purchased through third-party payors, it is vital to a drug manufacturer's economic interests to have its products listed on as many formularies as possible.

146. By directly and falsely promoting Celexa and Lexapro for off-label uses and as safe and effective to treat depression and other psychiatric conditions in pediatric patients and actively suppressing and failing to timely disclose negative data and results of drug studies to avoid or dismiss any safety concerns raised by physicians and the medical community, Forest influenced PBMs to place Celexa and Lexapro on their formularies without any restrictions.

147. Through Forest's misleading drugs labels and the adulterated clinical studies for Celexa and Lexapro, Forest falsely promoted Celexa and Lexapro as safe and effective for depression and other psychiatric conditions in pediatric patients directly to PBMs in order to get Celexa and Lexapro placed on, or placed more favorably than its competitor drugs on the PBM formularies.

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

149. Therefore, Forest's failure to adequately inform consumers, third-party payors and those in the medical community of the negative data and study results indicating that Celexa and Lexapro was not proven as safe and effective for pediatric use, and their false and misleading promotion of Celexa and Lexapro's efficacy over other competing less expensive SSRI drugs, caused patients and third-party payors to pay for Celexa and Lexapro, which was neither safer nor more effective than other less expensive SSRIs drugs used to treat depression and other psychiatric conditions in pediatric patients.

V. CLASS ACTION ALLEGATIONS

150. Plaintiffs incorporate by reference all proceeding paragraphs as is fully set forth herein.

151. Plaintiffs bring this action on behalf of themselves and, under Rule 23 of the Federal Rules of Civil Procedure, as representatives of the proposed Classes defined as follows:

> ***Celexa Class***
>
> All persons or entities, in the United States and its territories, which purchased, paid, and/or reimbursed for some or all of the purchase price for the drug Celexa for use by a minor, for purposes other than resale, at any time during the period of 1998 through the present. This Class does not include those individuals who are seeking personal injury claims arising out of their purchase of Celexa.
>
> ***Lexapro Class***
>
> All persons or entities, in the United States and its territories, which purchased, paid, and/or reimbursed for some or all of the purchase price for the drug Lexapro for use by a minor, for purposes other than resale, at any time during the period of 2002 through the present. This Class does not include those individuals who are seeking personal injury claims arising out of their purchase of Lexapro.

152. The following persons or entities are excluded from the proposed Classes:

a. Forest and its officers, directors, management, employees, subsidiaries, or affiliates;

b. All persons or entities who purchased Celexa or Lexapro for purposes of resale or directly from Defendants or their affiliates;

c. Any co-conspirators; and

d. The judges in this case and any members of their immediate families.

153. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs believe the Classes include thousands of consumers and third-party payors.

154. Plaintiffs' claims are typical of the claims of the members of the Classes. Plaintiffs and all members of the Classes seek a refund or reimbursement of all amounts they have expended for the purchase of Celexa and Lexapro; and, all other ascertainable economic losses and such other relief as Plaintiffs and the Class Members are entitled to, including treble damages and reasonable attorneys' fees and costs.

155. Plaintiffs are represented by counsel competent and experienced in the prosecution of class actions and products liability litigation.

156. Plaintiffs will fairly and adequately protect and represent the interests of the Classes, whose interests are coincidental with, and not antagonistic to, those of the Classes. Accordingly, the interests of the Classes will be adequately protected and advanced.

157. Questions of law and fact common to the members of the Classes predominate over any questions affecting only individual members. These common questions of law and fact include, but are not limited to:

a. Whether Plaintiffs and the Class Members paid more for Celexa and Lexapro than for other equally or more effective drugs that were available at a cheaper price;

b. Whether Forest engaged in a comprehensive program of deceptive marketing in promoting the pediatric use of Celexa and Lexapro;

c. Whether Forest engaged in a conspiracy to promote the sales of and suppress adverse information about Celexa and Lexapro;

d. Whether, in marketing and selling Celexa and Lexapro, Forest failed to disclose the dangers and health risks to minors ingesting the drug;

e. Whether Forest failed to warn adequately of the adverse effects of Celexa and Lexapro for treatment of pediatric indications;

f. Whether Forest misrepresented in their advertisements, promotional materials and other materials, among other things, the safety and lack of dangers and health risks of Celexa and Lexapro;

g. Whether Forest knew or should have known that the ingestion of Celexa and/or Lexapro leads to increased risk of suicidal thinking and behavior (suicidality) in children and adolescents;

h. Whether Forest manufactured, marketed, distributed and sold Celexa and Lexapro notwithstanding their knowledge of the drug's dangerous nature;

i. Whether Forest knowingly omitted, suppressed and/or concealed material facts about the unsafe and defective nature of Celexa and Lexapro from government regulators, healthcare professionals, third-party payors, the medical community and/or the consuming public;

j. Whether Forest engaged in misleading and/or deceptive scheme of improperly marketing and selling Celexa and Lexapro for treatment of pediatric indications for which the drug was not lawfully approved;

k. Whether Forest engaged in a pattern or practice that directly caused Plaintiffs and the Class Members to pay for Celexa and Lexapro prescriptions that were non-medically necessary uses;

l. Whether Forest engaged in deceptive and/or misleading activity that directly caused Plaintiffs and the Class Members to pay for Celexa and Lexapro prescriptions that were for non-FDA approved uses;

m. Whether Forest engaged in deceptive and/or misleading activity that directly caused Plaintiffs and the Class Members to pay more for Celexa and Lexapro prescriptions than for other efficacious drugs that were available at a cheaper price;

n. Whether Forest engaged in deceptive and/or misleading activity with the intent to defraud Plaintiffs and the Class Members;

o. Whether Forest is liable to Plaintiffs and the Class Members for damages for conduct actionable under RICO;

p. Whether Forest is liable to Plaintiffs and the Class Members for damages for conduct actionable under various Consumer Protection Statues; and

q. Whether Forest unjustly enriched themselves by its acts and omissions, at the expense of Class Members.

158. These and other questions of law and/or fact are common to the Classes and predominate over any question affecting only individual Class Members.

159. The claims of the class representative are typical of the claims of the Classes in that the named class representative and members of the Classes each paid for the prescription

drugs Celexa and Lexapro or reimbursed members for the costs of the prescription due to the improper actions of Forest, as described herein.

160. Adjudicating the claims of the Class Members as a class action is superior to any other available methods because it allows for the fair and efficient adjudication of this controversy. Prosecution as a class action will eliminate the possibility of repetitious litigation and will permit a large number of similarly situated persons to adjudicate their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that would result from prosecuting numerous individual actions.

161. Proceeding as a class action is a superior method for fairly and efficiently adjudicating this controversy. There are no known circumstances presenting difficulties in management that would preclude maintenance as a class action. Furthermore, any potential difficulties in maintaining this action as a class action are greatly outweighed by the benefits of proceeding through the class mechanism — *i.e.*, providing persons and entities a method for pursuing claims that would not be practicable if pursued on an individual basis.

VI. CAUSES OF ACTION

COUNT I

Violation of 18 U.S.C. § 1962 (c) – Celexa and Lexapro Off-Label Marketing Enterprise

162. Plaintiffs incorporate by reference all proceeding paragraphs as is fully set forth herein.

163. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Celexa and Lexapro Off-label Marketing Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

164. The Celexa and Lexapro Off-label Marketing Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including its employees, agents and external consultants including but not limited to Lundbeck, Intramed, Covance, Lawrence Olanoff, Ivan Gergel, Amy Rubin, Dr. Karen Wagner, Dr. Jeffery Bostic and the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Forest to fraudulently market and promote Celexa and Lexapro as scientifically proven as safe and effective for pediatric uses. The Celexa and Lexapro Off-Label Marketing Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Celexa and Lexapro Off-Label Marketing Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of these entities, including Forest, is a "person" distinct from the Celexa and Lexapro Off-Label Marketing Enterprise.

165. Each of the Defendants, in concert with other participants in the Celexa and Lexapro Off-label Marketing Enterprise, created and maintained systematic links for a common purpose – to enable Forest to fraudulently represent that Celexa and Lexapro was scientifically proven as safe and effective for pediatric uses, while suppressing evidence to the contrary and improperly inducing physicians and others to increase pediatric prescriptions. Each of these entities received substantial revenue from the scheme, and these revenues were far greater than they would have been had the fraudulent acts not been undertaken. All participants were aware of the Forest's control over the activities of the Celexa and Lexapro Off-Label Marketing Enterprise, and each part of the enterprise benefited from the existence of the other parts.

166. The Celexa and Lexapro Off-Label Marketing Enterprise engaged in and affected interstate commerce, because, *inter alia*, the fraudulent activities described herein lead to the

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

167. Forest exerted control over the Celexa and Lexapro Off-Label Marketing Enterprise and management of the affairs of the Celexa and Lexapro Off-Label Marketing Enterprise.

168. Forest conducted and participated in the affairs of the Celexa and Lexapro Off-Label Marketing Enterprise through patterns of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud) and § 1952 (use of interstate facilities to conduct unlawful activity).

169. Forest's use of the mails and wires to perpetuate their fraud involved thousands of communications, including but not limited to:

a. communications with and among enterprise participants that led to the suppression and failure to timely disclose negative data and results of drug studies that called into question the safety and efficacy of Celexa and Lexapro;

b. communications with and among the enterprise participants that fraudulently misrepresented the efficacy and safety of Celexa and Lexapro amongst themselves and others;

c. communications with patients and Class Members, including Plaintiffs, inducing payments for Celexa and Lexapro by misrepresenting the safety and efficacy of Celexa and Lexapro;

d. receiving the proceeds in the course of and resulting from Forest's improper scheme;

e. transmittal and receipt of monies from consumers and third-party payors;

f. communications with and among the enterprise participants to conceal the fraud occurring by virtue of failing to disclose the results of negative studies;

g. communications with and among the enterprise participants to develop and implement the EXCEED trial;

h. communications with and among the enterprise participants to develop and implement the advisory board promotional strategy;

i. communications with and among the enterprise participants to develop and implement the ghostwriting publications strategy;

j. communications with and among the enterprise participants for the purpose of inducing doctors to become high prescribers through various forms of illegal remuneration; and

k. transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Celexa and Lexapro Off-Label Marketing Enterprise.

170. Forest knew that without their fraudulent scheme, consumer and third-party payors would not have paid for Celexa and Lexapro used in the treatment of depression and other psychiatric conditions in pediatric patients. At all times during the fraudulent scheme, Forest and the fraud participants had a legal and ethical obligation of candor to and honest dealing with consumers, third-party payors, physicians, and the medical community.

171. Forest's scheme was calculated to ensure that Celexa and Lexapro was prescribed in great quantities by physicians for pediatric uses, with the knowledge of and active suppression of studies indicating safety concerns with adolescents.

172. The conduct of the Celexa and Lexapro Off-Label Marketing Enterprise described above constituted "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Forest's decisions and activity in connection with the Celexa and Lexapro Off-Label Marketing Enterprise 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).

173. The above-described racketeering activities amounted to a common course of conduct intended to deceive and harm the FDA, physicians, the public, Plaintiffs and members of the Classes. Each such racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiffs and members of the Classes. Forest's racketeering activities were part of their ongoing business and constitute a continuing threat to the property of the Plaintiffs and members of the Classes.

174. Plaintiffs and members of the Classes have been injured in their property by reason of these violations in that Plaintiffs and members of the Classes paid hundreds of millions of dollars, if not billions, for Celexa and Lexapro that they would not have paid had Forest not engaged in this pattern of racketeering activity.

175. The injuries to Plaintiffs and members of the Classes were directly and proximately caused by Forest's racketeering activity.

176. By virtue of these violations of 18 U.S.C. § 1962(c), Forest is liable to Plaintiffs and the Classes for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

COUNT II

Violation of 18 U.S.C. § 1962 (d) – RICO Conspiracy

177. Plaintiffs incorporate by reference all proceeding paragraphs as is fully set forth herein.

178. 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."

179. Forest has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy was and is to conduct or participate in, directly or indirectly, the conduct of affairs of the Celexa and Lexapro Off-Label Marketing Enterprise described previously through a pattern of racketeering activity. Forest conspired with, *inter alia*, sales representatives, medical professionals, academics and other intermediaries to promote Celexa and Lexapro and suppress information about the drugs' true efficacy and safety in the pediatric population.

180. Forest and their co-conspirators engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, as described above.

181. The nature of the above-described acts, material misrepresentations, and omissions in furtherance of the conspiracy give rise to an inference that Forest and their co-conspirators 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 acts were and are part of an overall pattern of racketeering activity.

182. As a direct and proximate result of Forest and their co-conspirators overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs and members of the Classes were and continue to be injured in their business and property.

183. Plaintiffs and members of the Classes were injured in their property by reason of these violations in that Plaintiffs and members of the Classes paid hundreds of millions, if not billions, of dollars for Celexa and Lexapro that they would not have paid had Forest and their co-conspirators not conspired to violate 18 U.S.C. § 1962(c).

184. The injuries to Plaintiffs and members of the Classes were directly and proximately caused by Forest's racketeering activity, as described above. Had prescribers and patients known that Celexa and Lexapro were not clinically superior to placebo, no reasonable prescriber or patient would have submitted claims for reimbursement and Plaintiffs would not have allowed the claims to be reimbursed.

185. By virtue of these violations of 18 U.S.C. § 1962(d), Forest is liable to Plaintiffs and the Classes for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

COUNT III

Violation of Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1, *et. seq.*

186. Plaintiffs incorporate by reference all proceeding paragraphs as is fully set forth herein.

187. Plaintiffs brings this Count pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et. seq*.

188. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2 makes it unlawful to engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact.

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

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

191. As described herein, Forest deliberately engaged in deceptive and unlawful marketing in violation of 815 Ill. Comp. Stat. 505/2 by representing to Illinois consumers, prescribing healthcare professionals and third-party payors through deceptive promotion and the misleading drug labels, that Celexa and Lexapro were safe and effective in treating pediatric and adolescent MDD. These representations were materially false and misleading.

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

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

b. 510/2(7): Forest knowingly represented, through deceptive promotion and misleading drug labels, that Celexa and Lexapro were of a particular quality or standard, *i.e.*, capable of effectively treating pediatric and adolescent MDD, when in truth, Forest knew or should have known that neither Celexa or Lexapro were clinically effective at treating pediatric or adolescent MDD.

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

d. 510/2(12): Forest, through deceptive promotion and misleading drug labels, engaged in a practice that was misleading, false, or deceptive when it represented to Illinois consumers, prescribing healthcare professionals and third-party payors such as Plaintiffs that Celexa and Lexapro were clinically effective for pediatric and adolescent depression. These deceptive acts had a likelihood of confusing or misleading Illinois

consumers, prescribing healthcare professionals, third-party payors and the medical community.

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

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

195. Forest intended that Plaintiffs, the Classes and the medical community would rely on their materially deceptive practices and that Plaintiffs and members of the Classes would purchase or pay for Celexa and Lexapro as a consequence of the deceptive practices.

196. As a proximate result of Forest's deceptive and unlawful marketing practices, Plaintiffs and members of the Classes have suffered damages by purchasing or reimbursing for prescriptions of Celexa and Lexapro that they would not have paid had Forest not engaged in unfair and deceptive conduct in violation of 815 Ill. Comp. Stat. 505/1, *et. seq*.

197. As a direct and proximate result of Forest's wrongful conduct as alleged herein, Plaintiffs and members of the Classes are entitled to compensatory damages, treble damages, attorneys' fees and costs of this suit.

COUNT IV

Violation of New Mexico's Unfair Practices Act, N.M. Stat. § 57-12-1, *et seq.*

198. Plaintiffs incorporate by reference all proceeding paragraphs as is fully set forth herein.

199. Plaintiffs brings this Count pursuant to the New Mexico's Unfair Practices Act, N.M. Stat. § 57-12-1, *et seq.*

200. The New Mexico's Unfair Practices Act, N.M. Stat. § 57-12-1, *et seq.* makes it unlawful to engage in unfair or deceptive acts or practices in the conduct of any trade or commerce that includes the advertising, offering for sale or distribution of any services and any property and any other article, commodity or thing of value, including any trade or commerce directly or indirectly affecting the people of the State of New Mexico.

201. A business practice is unfair or deceptive under New Mexico law when it involves a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services or in the extension of credit or in the collection of debts by a person in the regular course of the person's trade or commerce, that may, tends to or does deceive or mislead any person.

202. Forest's comprehensive deceptive marketing program for Celexa and Lexapro, combined with its misleading drug labels, misled consumers and third-party payors about Celexa and Lexapro's safety and efficacy in treating pediatric depression. This conduct offends any notion of public policy and is truly unethical because it effectively promotes the use of a drug with known side effects but whose efficacy is lacking. Such conduct is particularly egregious when it is directed at a class of people who, by virtue of their age, are particularly vulnerable to malicious and predatory marketing schemes.

203. As described herein, Forest deliberately engaged in deceptive and unlawful marketing in violation of N.M. Stat. § 57-12-2, by representing to New Mexico consumers, prescribing healthcare professionals and third-party payors through deceptive promotion and the

misleading drug labels, that Celexa and Lexapro were safe and effective in treating pediatric and adolescent MDD. These representations were materially false and misleading.

204. In addition, Forest has committed, *inter alia*, the following unlawful and deceptive marketing practices pursuant to N.M. Stat. § 57-12-2:

a. 57-12-2(D)(5): Forest knowingly represented, through deceptive promotion and drug labels, that Celexa and Lexapro had a specific characteristic, use, or benefit that it did not have, *i.e.*, that Celexa and Lexapro was safe and effective for the treatment of pediatric and adolescent MDD.

b. 57-12-2(D)(7): Forest knowingly represented, through deceptive promotion and misleading drug labels, that Celexa and Lexapro were of a particular quality, standard, *i.e.*, capable of effectively treating pediatric and adolescent MDD, when in truth, Forest knew or should have known that neither Celexa or Lexapro were clinically effective at treating pediatric or adolescent MDD.

c. 57-12-2(D)(14): Forest, through deceptive promotion and misleading drug labels, engaged in a practice that was misleading, false, or deceptive when it represented material facts to New Mexico consumers, prescribing healthcare professionals and third-party payors such as Plaintiffs that Celexa and Lexapro were clinically effective for pediatric and adolescent depression. These deceptive acts had a likelihood of confusing or misleading New Mexico consumers, prescribing healthcare professionals, third-party payors and the medical community.

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

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

207. Forest intended that Plaintiffs, the Classes and the medical community would rely on their materially deceptive practices and that Plaintiffs and members of the Classes would purchase or pay for Celexa and Lexapro as a consequence of the deceptive practices.

208. As a proximate result of Forest's deceptive and unlawful marketing practices, Plaintiffs and members of the Classes have suffered damages by purchasing or reimbursing for prescriptions of Celexa and Lexapro that they would not have paid had Forest not engaged in unfair and deceptive conduct in violation of N.M. Stat. § 57-12-1, *et seq.*

209. As a direct and proximate result of Forest's wrongful conduct as alleged herein, Plaintiffs and members of the Classes are entitled to compensatory damages, treble damages, attorneys' fees and costs of this suit.

COUNT V

For Unfair and Deceptive Trade Practices Under Other State Consumer Protection Statutes

210. Plaintiffs incorporate by reference all proceeding paragraphs as is fully set forth herein.

211. Forest engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Forest's misrepresentations, unlawful schemes and courses of

conduct which induced Plaintiffs and members of the Classes to purchase Celexa and Lexapro through one or more unfair and/or deceptive acts and/or practices alleged herein.

212. The actions and failures to act of Forest, including the false and misleading representations and omissions of material facts regarding the risks and the off-label use(s) for Celexa and Lexapro and the above described course of fraudulent conduct and fraudulent concealment, constitute acts, uses, or employment by Forest of unconscionable commercial practices, deception, fraud, misrepresentations and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression, or omission of material facts in connection with the sale of merchandise of Forest in violation of the consumer protection statues.

213. Forest unfairly, unconscionably, and deceptively advertised, labeled, marketed, represented and sold Celexa and Lexapro to Plaintiffs and the Classes without disclosing the true risks and lack of efficacy in treating pediatric depression, through their comprehensive deceptive promotion program for Celexa and Lexapro combined with its misleading drug labels.

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

215. Physicians relied upon Forest's misrepresentations and omissions in prescribing Celexa and Lexapro to patients. Forest's misrepresentations and omissions caused Plaintiffs and members of the Classes to pay for Celexa and Lexapro.

216. Forest intended that Plaintiffs, the Classes and the medical and scientific community would rely on their materially deceptive practices and that Plaintiffs and members of

the Classes would purchase or pay for Celexa and Lexapro as a consequence of the deceptive practices, including Forest's off-label marketing and misrepresentations and omissions of material fact with respect to Celexa and Lexapro for pediatric use. Forest's deceptive representations and material omissions to Plaintiffs and the Classes were and are unfair and deceptive acts and practices. Plaintiffs and the Classes were deceived by Forest's misrepresentations.

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

218. As a proximate result of Forest's misrepresentations, Plaintiffs and members of the Classes have suffered an ascertainable loss, in an amount to be determined at trial, in that they paid millions, if not billions, of dollars for Celexa and Lexapro that they would not have paid had Forest not engaged in unfair and deceptive conduct. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Forest's unlawful conduct.

219. The unfair and deceptive acts and practices of Forest have directly, foreseeably and proximately caused or will cause damages and injury to Plaintiffs and members of the Classes.

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

221. By engaging in the foregoing conduct, Forest has violated the following state Unfair and Deceptive Trade Practices and Consumer Fraud laws:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Alaska by the Classes;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Arizona by the Classes;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code Ann. § 4-88-101, *et seq.* with respect to purchases of Celexa and/or Lexapro in Arkansas by the Classes;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of Celexa and/or Lexapro in California by the Classes;

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.* with respect to purchases of Celexa and/or Lexapro in Colorado by the Classes;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.* with respect to purchases of Celexa and/or Lexapro in Connecticut by the Classes;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code Ann. tit. 6, § 2511, *et seq.* with respect to purchases of Celexa and/or Lexapro in Delaware by the Classes;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code Ann. § 28-3901, *et seq.* with respect to purchases of Celexa and/or Lexapro in the District of Columbia by the Classes;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Florida by the Classes;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code Ann. §10-1-392, *et seq.* with respect to purchases of Celexa and/or Lexapro in Georgia by the Classes;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.* with respect to purchases of Celexa and/or Lexapro in Hawaii by the Classes;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.* with respect to purchases of Celexa and/or Lexapro in Idaho by the Classes;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Indiana by the Classes;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Kansas by the Classes;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of KY. Rev. Stat. Ann. § 367.110, *et seq.* with respect to purchases of Celexa and/or Lexapro in Kentucky by the Classes;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of LA. Rev. Stat. § 51:1401, *et seq.* with respect to purchases of Celexa and/or Lexapro in Louisiana by the Classes;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Maine by the Classes;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MD. Com. Law Code § 13-101, *et seq.* with respect to purchases of Celexa and/or Lexapro in Maryland by the Classes;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Massachusetts by the Classes;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Michigan by the Classes;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Minnesota by the Classes;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Rev. Stat. § 407.010, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Missouri by the Classes;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Montana by the Classes;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Nebraska by the Classes;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Nevada by the Classes;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in New Hampshire by the Classes;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J.S.A § 56:8-1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in New Jersey by the Classes;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of Celexa and/or Lexapro in New York by the Classes;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in North Carolina by the Classes;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*, with respect to purchases of Celexa and/or Lexapro in North Dakota by members of the Classes;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Ohio by the Classes;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. 15 § 751, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Oklahoma by the Classes;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Oregon by the Classes;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Pa. Cons. Stat. § 201-1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Pennsylvania by the Classes;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen Laws § 6-13.1-1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Rhode Island by the Classes;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*, with respect to purchases of Celexa and/or Lexapro in South Carolina by the Classes;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in South Dakota by the Classes;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Tennessee by the Classes;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Texas by the Classes;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Utah by the Classes;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451 *et seq.*, with respect to purchases of Celexa and/or Lexapro in Vermont by the Classes;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Virginia by the Classes;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Washington by the Classes;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*, with respect to purchases of Celexa and/or Lexapro in West Virginia by the Classes;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat § 100.18, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Wisconsin by the Classes; and

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. Ann § 40-12-101, *et seq.*, with respect to purchases of Celexa and/or Lexapro in Wyoming by the Classes.

222. As a direct and proximate result of Forest's wrongful conduct as alleged herein, Plaintiffs and members of the Classes are entitled to compensatory damages, treble damages, attorneys' fees and costs of this suit.

COUNT VI

Unjust Enrichment

223. Plaintiffs hereby incorporate by reference all proceeding paragraphs as is fully set forth herein.

224. As an intended and expected result of Forest's conscious wrongdoing as set forth in this Complaint, Forest profited and benefited from payments that Plaintiffs and members of the Classes made for Celexa and Lexapro.

225. In exchange for the payments they made for Celexa and Lexapro and at the time they made these payments, Plaintiffs and members of the Classes expected that the drug was a safe and medically effective treatment for the condition, illness, disorder, or symptom for which it was prescribed.

226. Forest voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and members of the Classes paid for

Celexa and Lexapro when they otherwise would not have done so and paid for the drug at a higher price than they would have paid but for Forest's wrongful conduct.

227. Forest should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Classes all unlawful or inequitable proceeds received by them. A constructive trust should be imposed upon all unlawful or inequitable sums received by Forest traceable to Plaintiffs and members of the Classes.

228. Plaintiffs and members of the Classes are entitled in equity to seek restitution of Forest's wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court and such relief as the Court deems just and proper to remedy Forest's unjust enrichment.

VII. JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury on all issues so triable.

VIII. DEMAND FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Classes, respectfully request that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes, and declare Plaintiffs the class representatives;

b. Enter joint and several judgments against Defendants in favor of Plaintiffs and the Classes;

c. Grant Plaintiffs and the Classes equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

d. Award Plaintiffs and the Classes damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

e. Award Plaintiffs and the Classes damages pursuant to 18 U.S.C. § 1964(c);

f. Award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees as provided by law;

g. Award Plaintiffs and the Classes prejudgment interest on all damages; and

h. Award Plaintiffs and the Classes all such other and further relief as may be just and proper under the circumstances.

Dated: March 13, 2014

By its attorneys,

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