UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHRISTOPHER R. GOBBLE, *et al.*,	**Civil Action No. 03-10395-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	**FILED UNDER SEAL**
Defendants.	
UNITED STATES OF AMERICA *ex rel.* JOSEPH PIACENTILE, *et al.*,	**Civil Action No. 05-10201-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC.,	
Defendant.	

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of the defendants, Forest Laboratories, Inc. ("Forest Labs"), and Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") (collectively, "Forest"). Over the course of more than half a decade, Forest illegally marketed two related antidepressant drugs, Celexa and Lexapro, for off-label use in pediatric patients when both drugs had been approved only for adult use. During much of that

time, Forest misled physicians by promoting the results of a positive study on pediatric use of Celexa while failing to disclose the results of a contemporaneous negative study for the same pediatric use. Forest also illegally paid kickbacks to physicians to induce them to prescribe the drugs. By knowingly and actively promoting these antidepressants for off-label pediatric use without disclosing the results of the negative pediatric study and by paying kickbacks, Forest caused false claims to be submitted to federal health care programs in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*.

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

2. The United States bases its claims on Forest causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1).

3. Within the time frames detailed below, Forest engaged in a fraudulent scheme to market and promote Celexa (citalopram) and Lexapro (escitalopram) off-label to treat depression and other psychiatric conditions in pediatric patients. Forest did so even though the Food and Drug Administration ("FDA") had not approved the drugs as safe and effective for any use in the pediatric population. In the case of Celexa, the FDA had specifically denied approval for any pediatric use.

4. In furtherance of its off-label marketing scheme, Forest disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety

and efficacy of Celexa and Lexapro in treating pediatric patients. At the same time that Forest was actively touting pediatric use of the drugs, the company failed to disclose the negative results of a large, placebo-controlled study that found Celexa no more effective than placebo for pediatric use and in which more patients taking Celexa attempted suicide or reported suicidal ideation than those taking only placebo. The negative data that Forest failed to disclose was among the data later considered by the FDA when mandating that Forest add a "black box" warning to both the Celexa and Lexapro labels for pediatric use.

5. In addition to its illegal off-label marketing scheme, Forest sought to induce physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment, and other valuable goods and services, all in violation of the federal anti-kickback statute, 42 U.S.C. § 3120a-7b(b) ("AKS").

6. As the direct, proximate, and foreseeable result of Forest's fraudulent course of conduct, as set forth above and herein, Forest caused thousands of false or fraudulent claims to be submitted to the federal health care programs for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use and/or were ineligible for payment as a result of illegal kickbacks.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345.

8. This Court may exercise personal jurisdiction over Forest pursuant to 31 U.S.C.

§ 3732(a) and because Forest transacts business in the District of Massachusetts.

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Forest has transacted business in this District.

III. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"); the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administers the Medicaid program; and the Department of Defense, which administers the TRICARE/CHAMPUS program ("TRICARE") (collectively, "federal health care programs").

11. Relator Christopher R. Gobble is a resident of Virginia and a former employee of Forest. In March 2003, Mr. Gobble filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

12. Relator Joseph Piacentile is a resident of New Jersey. On August 20, 2001, Mr. Piacentile filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

13. Defendant Forest Labs is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York. Forest Labs has a license from H. Lundbeck A/S ("Lundbeck"), a Danish company, to promote and sell Celexa and Lexapro in the United States.

14. Defendant Forest Pharmaceuticals is a wholly owned subsidiary of Forest Labs

with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals manufactures, distributes, and sells Forest prescription products in the United States.

IV. THE LAW

A. The False Claims Act

15. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government. 31 U.S.C. § 3729(a)(1).

16. The FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

17. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for

violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

18. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The statute was enacted in 1972; Congress strengthened it in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

19. The AKS prohibits any person or entity from offering, making, or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> * * *
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

20. Under the AKS, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to prescribe drugs for which payment may be made by federal health care programs.

21. The AKS not only prohibits outright bribes, but also prohibits any remuneration by a drug company to a physician that has as one of its purposes inducement of the physician to write prescriptions for the company's pharmaceutical products.

V. THE FEDERAL HEALTH CARE PROGRAMS

A. The Medicaid Program

22. The Medicaid program is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program and receives funding from the federal government, known as federal financial participation, based upon a formula set forth in the federal Medicaid statute.

23. Before the beginning of each calendar quarter, each state submits to CMS an

estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as actual provider claims are presented for payment). After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding (to reconcile the estimated expenditures to actual expenditures).

24. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

25. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

26. While federal drug coverage is an optional benefit available to the states, most states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

27. The Medicaid Rebate Statute generally prohibits federal financial participation for a covered outpatient drug unless there is a rebate agreement in effect with the manufacturer for that drug. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a state is generally required to cover that drug under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

28. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for

inclusion in any of the compendia" set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

29. A drug does not generally meet the definition of a "covered outpatient drug" if it is being prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. §§ 1396r-8(k)(2)(A), (k)(3).

30. Thus, even if a drug is FDA-approved for a certain indication, Medicaid ordinarily does not cover off-label uses that do not qualify as medically accepted indications. Many state Medicaid programs prohibit covering such uses. *See, e.g.*, 40-850-026 DEL. CODE REGS. § 3.5.4.1 (2008); IND. CODE § 12-15-35-4.5 (2008); N.J. ADMIN. CODE § 83C-1.14(1) (2008); N.M. CODE R. § 8.325.4 (2008).

B. The TRICARE Program

31. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

32. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

33. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. §199.4(g)(15)(i)(A)(Note). TRICARE will not knowingly provide reimbursement for off-label use if the prescriptions result from illegal off-label marketing.

VI. FOREST'S SCHEME

A. The Celexa And Lexapro Labels

34. Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRIs") drugs. Lundbeck developed both Celexa and Lexapro, which contains the active agent in Celexa, and subsequently licensed both drugs to Forest for marketing in the United States. Forest began selling Celexa in 1998. In 2002, with Celexa soon due to face generic competition, Forest began selling Lexapro.

1. The FDA Has Not Approved Celexa Or Lexapro For Pediatric Use.

35. In 1998, the FDA approved Celexa for the treatment of adult depression. The FDA never approved Celexa for treatment of any conditions other than adult depression, or for any pediatric use.

36. In 2002, the FDA approved Lexapro for the treatment of adult depression. In 2003, Lexapro received approval for treatment of Generalized Anxiety Disorder ("GAD") in adults. Lexapro has not been approved for any other conditions and was not approved for pediatric use.

37. The use of Celexa and Lexapro in pediatric patients is not supported by a citation included or approved for inclusion in any of the compendia. The use of Celexa and Lexapro in pediatric patients is not a "medically accepted" indication for those drugs.

38. If a manufacturer conducts pediatric clinical studies on a drug, a manufacturer may obtain an additional six months of patent exclusivity for the previously-approved, on-label

indications for that particular drug subject to certain FDA requirements. 21 U.S.C. § 355a. In such circumstances, the FDA issues a "Written Request" that details the studies that should be performed. 21 U.S.C. § 355a(c)(2)(A).

39. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa." 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.

40. On September 24, 1999, Forest submitted to the FDA protocols for two pediatric studies: 1) a double-blind, placebo-controlled pediatric study being conducted in Europe by Lundbeck (the "Lundbeck study"); and 2) a double-blind, placebo-controlled pediatric study to be conducted in the United States by Forest through University of Texas child psychiatrist Karen Wagner (the "Wagner study").

41. In mid-2001, the Wagner and Lundbeck studies were unblinded and their results were disseminated to senior Forest executives. The Wagner study was positive, *i.e.*, it indicated that Celexa was more effective than placebo in treating pediatric patients suffering from depression, but the Lundbeck study was negative, *i.e.*, it did not show Celexa to be any more effective than placebo in treating pediatric depression. Furthermore, in the Lundbeck study, 14 of the patients taking Celexa attempted suicide or reported suicidal ideation (*i.e.*, contemplation of suicide) compared to only 5 patients taking placebo. Under one statistical test, this result was "significant," and, under another statistical test, it was "borderline significant."

42. On April 18, 2002, Forest submitted the results of both the Lundbeck and Wagner studies to the FDA in support of requests for both a six-month extension of patent exclusivity

and a pediatric indication for Celexa. Forest's submission to the FDA was not public.

43. On July 15, 2002, the FDA granted Celexa six additional months of patent exclusivity for the on-label use of treating depression in adults.

44. On September 23, 2002, the FDA denied Forest's request for a pediatric indication for Celexa. The FDA concluded that the Lundbeck study "is a clearly negative study that provides no support for the efficacy of citalopram in pediatric patients with [major depressive disorder]."

2. The FDA-Mandated Black Box Warnings On The Celexa And Lexapro Labels

45. 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."

46. Later that year, the FDA directed the 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 children and 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). In addition, the FDA required SSRI manufacturers to state, in relevant part, that:

> The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in

> children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants.

47. The Lundbeck study on pediatric use of Celexa was one of the 24 trials considered by the FDA in mandating this warning.

48. Forest revised the Celexa and Lexapro labels in early 2005 to include the required black box warning and to state under each label's "Pediatric Use" subheading that "[s]afety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS-Clinical Worsening and Suicide Risk)." The Celexa label further stated that "[t]wo 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," while the Lexapro label stated that "[o]ne placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients."

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

50. To date, Forest has not obtained FDA approval for a pediatric indication for Celexa or Lexapro. Both the Celexa and Lexapro labels currently include black box warnings explicitly indicating that the safety and efficacy of the drugs in the pediatric population have not

been established.

B. Forest's Dissemination Of Half Truths As A Result Of Its Failure To Disclose The Results Of The Negative Lundbeck Study

51. Although Forest submitted the Lundbeck study 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 the Wagner study, thereby relaying the false impression that the only available pediatric data on Celexa was positive.

52. Although the Forest senior executives learned about the negative Lundbeck results in mid-2001, Forest failed for the next three years to disclose that negative data to, among others: its thousands of sales representatives who were detailing pediatric specialists; pediatric specialists whom it hired to give promotional speeches on Celexa and Lexapro; the members of its Executive Advisory Board of leading psychiatrists upon whom it ostensibly relied for advice concerning new data and upon whom it also relied to convey information to others; its own Professional Affairs Department, which it charged with disseminating "balanced" information in response to physician requests for available data on Forest drugs; or even its own pediatric researchers such as Dr. Wagner.

53. During this same time period, Forest took aggressive steps to publicize the positive results of the Wagner study. On August 27, 2001, Forest presented the Wagner study results to its Executive Advisory Board without making any mention of the contemporaneous negative Lundbeck results. Forest thereafter arranged for Dr. Wagner to present a poster summary of the Wagner study to various professional groups, including the American Psychiatric

Association, the American College of Neuropsychopharmacology, and the Collegium Internationale Neuro-Psychopharmalogicum. In conjunction with these presentations, Forest coordinated the "placement" of news stories about the positive Wagner data in numerous national and local media outlets.

54. 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 20 CME teleconferences that addressed the Wagner study results.

55. Forest's simultaneous failure to disclose the negative Lundbeck study results and wide publication of the positive Wagner study results caused Forest and its consultants to make false or misleading statements. For example, because not even Dr. Wagner was aware of the negative Lundbeck data, she never discussed that data in her many Forest-sponsored talks addressing the pediatric use of Celexa and Lexapro. Her slide presentations addressed negative studies on pediatric use of other SSRIs, but falsely indicated that there were no negative studies on the pediatric use of Celexa.

56. Forest's failure to disclose the negative Lundbeck results 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 Wagner 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 Lundbeck data.

57. During details to physicians, Forest's 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 Lundbeck data. Forest sales managers, also unaware of the Lundbeck data, directed the dissemination of these publications.

58. Forest had a Professional Affairs Department that responded to health care provider inquiries. 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 Lundbeck data 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 Wagner and Lundbeck 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, the Wagner Study. The letters never mentioned that there was another, negative, double-blind placebo-controlled trial, the Lundbeck study.

59. 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 Lundbeck data.

60. Forest paid a medical writing firm to ghost-write an academic article on the Wagner study, 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 the placebo.

61. On June 21, 2004, *The New York Times* published a news story titled "Medicine's Data Gap – Journals in a Quandry; How to Report on Drug Trials." The story featured *The American Journal of Psychiatry* article on the Wagner study, revealing the negative results of the Lundbeck study and noting that the Wagner article failed to mention them.

62. Three days after the story ran, Forest issued a press release acknowledging the existence of the Lundbeck study and its finding that Celexa "did not show efficacy versus placebo." That same day, Forest also disclosed the results of an earlier double-blind placebo-controlled study of Lexapro in children and adolescents. That study also failed to show efficacy in comparison to placebo.

63. By failing to disclose the Lundbeck study results, which raised serious questions about the efficacy and safety of Celexa, while simultaneously promoting the Wagner study,

Forest told prescribing physicians a half-truth and thereby prevented them and the public from having all potentially available information when making decisions about how to treat a serious medical condition in pediatric patients.

64. Forest's conduct regarding the Lundbeck study results was consistent with the way it handled prior negative study data on Celexa. Just a few months before the pediatric Lundbeck study was unblinded, senior executives from Forest and Lundbeck discussed whether publicly to disclose the negative results from a study of Celexa in a primary care population. The study included three groups: patients taking Lexapro, patients taking Celexa, and patients taking placebo. Although Lexapro showed efficacy versus the placebo in the study, Celexa did not. Minutes of a December 2000 meeting of senior Forest and Lundbeck executives show that Forest wanted to publicize only the Lexapro versus placebo results, while Lundbeck wanted the results from the entire study to be publicly disclosed. As Lundbeck executives noted a month earlier, "Forest made clear their concern over disclosing any data that could put Celexa in an unfavorable light." In May 2001, Lundbeck executives observed that "Forest are at the moment unwilling to release data where citalopram does not sufficiently surpass placebo." Forest ultimately prevailed over Lundbeck and, as it did later with Lundbeck's negative pediatric data, kept the negative Celexa versus placebo results confidential.

C. Forest's Fraudulent Course Of Conduct To Promote Celexa And Lexapro For Off-Label, Pediatric Use

65. To obtain FDA approval for a drug, a drug must be demonstrated to be safe and effective for each of its proposed uses. The approved uses for a drug are limited to those uses identified in the FDA-approved product label. *See* 21 U.S.C. § 355(a), (b). "Off-label" use

refers to the promotion of an approved drug for any purpose, or in any manner, other than what is described in the drug's FDA-approved labeling.

66. 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 approved for pediatric use and the science was, at best, inconclusive about the safety and efficacy of these drugs for pediatric use. Forest used its sales representatives to detail or target pediatric specialists; paid pediatric specialists to give promotional speeches to other physicians on pediatric use; selectively distributed publications on pediatric uses to pediatric specialists; misrepresented the safety and effectiveness of the drugs; and made extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses.

67. 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 the pediatric use of Celexa and Lexapro throughout the preceding six years.

68. 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. A specific component of this marketing scheme included the promotion of Celexa and Lexapro for pediatric indications.

69. From 1998 through the end of 2004, the lists of physicians whom Forest directed its sales representatives to target, 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 pediatric promotion. Examples of such notes include the following:

- "discussed cx [Celexa] use in children . . . and results of dr. karen wagner study regarding cx use for children and adolescents."
- "went over peds use, 0 drug interactions, less ae, less compliance issues for children, he is sold on that. closed on keeping cx first choice."
- "went over Celexa children, the invitation to the winery."
- "[doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!"
- "discuss lx [Lexapro] brief and what he [is] using dosing w children . . . reinforce safety for children."
- "Let him know some child psychs are using LX for children."
- "Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat the anxiety and depression and OCD."
- "dinner program [with child psychiatrist as speaker] at amato's with yale child study center."
- "focus on Lexapro efficacy at just 10mg..great choice for child/adolescents."
- "mainly sees children but always felt comfortable with CX & children - got his commitment to give [Lexapro] a fair clinical trial."

- "went over lxp use on children and efficacy."

Call notes such as these represent only some of the instances when sales representatives memorialized their illegal off-label promotion of Celexa and Lexapro. The call notes exemplify the tip of what was a much more pervasive and widespread off-label campaign.

70. Forest's headquarters office in New York maintained a list of "approved" promotional speakers that included numerous pediatric specialists. Forest sales representatives and managers identified speakers from these lists to organize promotional lunches and dinners on Celexa and Lexapro. 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 off-label pediatric use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Updates in Depression," "Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment Options in Depressive Disorders in Adolescents," "New Age Depression Treatment," "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," "Treatment of Depression," "Assessment and Treatments of Suicidal Adolescents," and "Treating Pediatric Depression." Forest management approved each of these programs.

71. From 1999 through 2006, one pediatric specialist, Dr. Jeffrey 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 off-label for pediatric use.

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

D. Forest's Illegal Inducements To Physicians To Prescribe Celexa And Lexapro

73. Forest augmented its off-label promotion efforts 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.

1. Advisory Boards

74. Between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro, with over 19,000 advisory board attendees that Forest called "consultants." Forest paid each "consultant" an honorarium of $500.

75. 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 induce the attendees to prescribe more Celexa and Lexapro.

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

77. 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 approximately January 2002, a marketing strategy slide deck given to Forest's chief executive, Howard Solomon, quoted a Regional Director stating that, "[w]ell planned Advisory Board meetings will be key to our efforts of reaching hesitant physicians."

78. 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 e-mail 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 can make [*sic*] maximize this opportunity!"

79. 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.

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

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

81. 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."

82. Three months later, in August 2001, the author of the ROI analysis reiterated to the Celexa marketing team that, "[o]ur 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."

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

2. The EXCEED Study

84. 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).

85. In the planning stages for EXCEED, a senior Forest marketing executive wrote

that the purpose of the study was to ensure a "fast uptake" for Lexapro. The overall Lexapro marketing plan, which was reviewed by the company's most senior executives, stated:

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

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.

86. To the extent the 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.

87. Forest aimed the EXCEED study at 2,000 physicians. Under the study protocol, each participating physician could enroll up to five patients in the study, which would last eight weeks and involve three 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 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 boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two 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 patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference.

88. 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.

3. Preceptorships

89. 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.

90. 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.

91. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out "Return on Investment (R.O.I.)" 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.

92. 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 1st RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. ___."

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

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

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

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

- "# 1 physician in Territory. . . . Dr. ___ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship."

- "This full day preceptorship will give me the opportunity to sell Celexa as a first-line choice in doctor ___'s practice."

- "To influence doctor to Rx Celexa."

Forest approved all of these preceptorship payment justifications.

4. Lavish Entertainment And Gifts

93. 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 it in an April 2006 memo to his sales team, "we have a ton of promotional money." Forest sales managers put pressure on their sales representatives to spend their entire marketing budgets.

94. 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. Both prior to and after 2003, Forest sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

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

- In September 2002, a sales representative gave a high-prescribing

child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.

- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.

- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.

- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.

- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."

- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.

- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would "always rxlex [*i.e.*, prescribe Lexapro] #1 aslong [*sic*] as we have fun and take care of him."

95. All of this spending was intended to induce physicians to prescribe Celexa or Lexapro.

VII. FALSE CLAIMS

96. As a result of Forest's fraudulent course of conduct, Forest caused the submission of false or fraudulent claims for Celexa and Lexapro to federal health care programs. These claims were not reimbursable because they were not covered for off-label pediatric use and/or

were ineligible for payment as a result of illegal kickbacks.

97. The chart set forth below identifies examples of false or fraudulent claims caused by Forest's off-label promotion. The chart includes: (a) the prescribing physician; (b) the number of promotional sales calls by Forest to each physician; (c) the number of pediatric Medicaid claims resulting from that physician; and (d) the amount paid for those pediatric claims by Medicaid.

CELEXA			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. A.	58	1927	$110,865
Dr. B.	70	977	$70,311
Dr. C.	133	871	$85,980
Dr. D.	58	777	$42,568
Dr. E.	33	586	$44,280
Dr. F.	50	589	$39,807
LEXAPRO			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. G.	257	1769	$197,052
Dr. H.	118	7790	$428,627
Dr. I.	76	4565	$251,378
Dr. J.	192	3219	$229,469
Dr. K.	296	2441	$252,879

98. The chart set forth below provides examples of false or fraudulent claims caused by Forest's illegal kickbacks to a physician, Dr. L. The chart identifies: (a) the year; (b) the type

of meeting or event Dr. L attended; (c) the amount paid to Dr. L; (d) the number of claims resulting from Dr. L; and (e) the amount paid for those claims by Medicaid.

Year	Type of Meeting or Event	Amount Paid	Claims	Medicaid Payment
2000	Advisory Boards	$500	197	$12,867
2001	Advisory Boards/Speaker Programs	$1,250	221	$14,646
2002	Advisory Boards/Speaker Programs/ Sponsorships	$2,500	367	$25,570
2003	Advisory Boards/Speaker Programs/Sponsorships	$10,250	302	$21,175
2004	Sponsorships	$500	272	$20,402

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

99. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

100. Forest knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use, and/or were ineligible for payment as a result of illegal kickbacks.

101. By virtue of the false or fraudulent claims that Forest caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION
(Unjust Enrichment)

102. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

103. The United States claims the recovery of all monies by which Forest has been unjustly enriched.

104. As a consequence of the acts set forth above, Forest was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Forest as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the damages sustained and/or amounts by which Forest was unjustly enriched or by which Forest retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

MICHAEL F. HERTZ
ACTING ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

Dated: February 13, 2009 By: 

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