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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and the STATES OF CALIFORNIA, DELAWARE, FLORIDA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MONTANA, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, TENNESSEE, TEXAS, VIRGINIA and the DISTRICT OF COLUMBIA EX REL. SHELLEY LAUTERBACH, Plaintiffs v. ORPHAN MEDICAL INC., JAZZ PHARMACEUTICALS INC. and DR. PETER GLEASON, Defendants.	C.A. No. 05 CV 0387 (SJF) (KAM) SECOND AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; CALIFORNIA STATE INSURANCE FRAUDS PREVENTION ACT [Cal. Ins. Code §1871 et. seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C.§1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann.§68.081 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat §175 et seq.]; ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT [740 Ill. Comp. Stat. §92]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [IC 5-11-55]; LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW [La. Rev. Stat. §437 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 §5 et seq.]; MONTANA FALSE CLAIMS ACT [Mont. Stat. Ann. 17-8-401 et seq.]; MICHIGAN MEDICAID FALSE CLAIMS ACT [MI Public Act 337]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Stat. Ann. §167:61 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. §27-2F-1 et seq.]; TENNESSEE FALSE CLAIMS ACT and TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §§4-18-101 et seq. and 71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.13 et seq.]

Plaintiff-Relator Shelley Lauterbach, through her attorneys Phillips & Cohen LLP and Jonathan A. Willens LLC, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of Tennessee, the State of Texas, the State of Virginia, and the District of Columbia (collectively "the States"), for her Complaint against defendants Orphan Medical Inc., Jazz Pharmaceuticals Inc. and Dr. Peter Gleason (collectively, "defendants"), alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent statements, records, and claims made and caused to be made by defendants Orphan Medical Inc. ("Orphan") and Dr. Peter Gleason and/or their agents, employees and co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq., and the false claims acts of the States set forth below.

2. Beginning in approximately 2003 and continuing through the present date, Orphan has systematically and illicitly placed commercial profits far above patient health and safety by illegally and aggressively promoting the drug Xyrem for treatment of "off-label" indications, i.e., medical conditions not approved for Xyrem treatment by the United States Food and Drug Administration ("FDA").

3. Xyrem is the drug commonly known as GHB. GHB is a controlled substance with

a history of abuse. It is a central nervous system depressant that has extremely dangerous risks associated with its use, including seizure, respiratory depression, and profound decreases in level of consciousness, with instances of coma and death.

4. Xyrem has been approved by the FDA for treatment of only one, very limited medical condition: the treatment of cataplexy (weak or paralyzed muscles) associated with narcolopesy (a neurological disorder that affects a person's ability to control sleep and wakefulness). Because the United States population suffering from narcoleptic cataplexy is extremely small, estimated to be between 20,000 and 50,000 patients, the profit potential from on-label Xyrem sales is very limited. To expand the profit potential, Orphan has resorted to a marketing strategy designed to promote Xyrem for numerous unapproved indications, including treatment of fatigue, fibromyalgia, non-specific sleep disorders, insomnia, pain, and psychiatric disorders. The market for these off-label conditions is huge.

5. As alleged below, Orphan's illegal off-label marketing and promotional campaign has combined (i) aggressive speaker events saturated with off-label messages, (ii) generous speaker fees to off-label prescribing physicians to induce them to disseminate the company's off-label message to other physicians; (iii) "unrestricted educational grants" to funnel illegal cash incentives and kickbacks to physicians as an inducement or reward for prescribing Xyrem for off-label purposes; and (iv) targeted sales calls on prescribing physicians by field representatives to reinforce the off-label message and translate it into increased Xyrem sales.

6. Defendant Dr. Gleason is the centerpiece of Orphan's aggressive off-label speaker program. He is the most frequent speaker on Orphan's national speaker's list, and has been paid hundreds of thousands of dollars to speak at hundreds of events. His talks are saturated with off-

label promotion of Xyrem. In his standard presentation, he promotes Xyrem for several off-label indications - including fibromyalgia, insomnia, non-specific sleep disorders, fatigue, and psychiatric disorders - and also explains how to defraud private and public healthcare insurers by falsifying the diagnosis on reimbursement claim forms in order to conceal the off-label nature of the prescription.

7. Orphan's off-label marketing campaign for Xyrem has been very successful, with sales of the drug more than doubling since the illegal campaign began. Most of the increase in sales has been fueled by off-label prescriptions that are a direct result of Orphan's illegal marketing practices complained of herein.

8. A significant portion of Xyrem off-label prescriptions are reimbursed by federal and state health insurance programs, including Medicaid, Medicare, Champus/Tricare, ChampVA, the Federal Employee Health Benefits Program, federal workers' compensation programs, and comparable state programs. These and other government-funded health programs have paid reimbursement claims for off-label Xyrem prescriptions that would not have been paid but for defendants' illegal practices. In this manner, defendants' illegal conduct has defrauded federal and state treasuries of substantial sums of money, in violation of the federal and state false claims acts.

9. The Federal False Claims Act ("FCA") was originally enacted during the Civil War, and was substantially amended in 1986. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's

behalf.

10. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

11. The FCA allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

12. In addition to violating the FCA, defendants' acts also violate the comparable provisions of the California False Claims Act, Cal. Govt Code §12650 et seq.; the California State Insurance Frauds Prevention Act, Cal. Ins. Code §1871 et. seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8 et seq.; the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92 et seq.; Indiana False Claims And Whistleblower Protection Act, Ind. Code 5-11-55 et seq.; Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 437 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; Michigan Medicaid False Claims Act. Mich. Public Act 337 et seq.; the Montana False Claims Act, Mont. Stat. Ann. 17-8-401 et seq. ; the Nevada False Claims Act,

Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Hampshire False Claims Act, N.H. Stat. Ann. §167:61 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 et seq. and the Tennessee False Claims Act, Tenn. Code Ann. §§4-18-101 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 et seq.

13. Based on these provisions, qui tam Plaintiff and Relator Shelley Lauterbach seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which defendants' misconduct has extended.

II. PARTIES

14. Plaintiff/Relator Shelley Lauterbach ("Relator") is a resident of Birmingham, Alabama. Since September 2002 until early 2005, she was employed by Orphan as a Specialty Sales Consultant. Relator was one of 36 Orphan Specialty Sales Consultants (hereafter referred to as "sales representatives") who are responsible for the marketing and sale of Xyrem. Relator has worked in sales in the pharmaceutical industry for over 14 years. Her former employers include Bristol Myers Squibb, Pfizer-Pharmacia, and Sanofi-Synthelabo.

15. Defendant Orphan Medical Inc. ("Orphan") is a Delaware corporation headquartered in Minnetonka, Minnesota. Orphan Medical Inc. acquires, develops, and markets pharmaceuticals for rare diseases treated by specialist physicians. The leading product for the company is Xyrem, which is approved for treatment of cataplexy associated with narcolepsy. Orphan Medical Inc.'s internet web site address is http://www.orphan.com.

16. Defendant Jazz Pharmaceuticals Inc. ("Jazz Pharma") is a Delaware corporation headquartered in Palo Alto, California. In 2005, Jazz Pharma acquired Orphan Medical Inc. and is, thus, a successor to liabilities incurred before its acquisition, as well as liable for illegal acts since the acquisition. For the remainder of this Complaint Jazz Pharma and Orphan will be referred to collectively as "Orphan."

17. Defendant Dr. Peter Gleason is a psychiatrist who practices in the Washington, D.C. area. Upon information and belief, he has an office in Annapolis, Maryland and resides in Maryland. Dr. Gleason is Orphan's leading speaker on its national speaker's list.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. In addition, 31 U.S.C. §3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in Counts 3, 5-8, and 10-21 of this Complaint. Jurisdiction over the state law claims asserted in Counts 4 and 9 is based on this Court's supplemental jurisdiction. Under 31 U.S.C. §3730(e), and under the comparable provisions of the state statutes listed in ¶ 12 above, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

19. Personal jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), as one or more of the defendants is found in, has or had an agent or agents, has or had contacts, and transacts or transacted business in this judicial District.

IV. APPLICABLE LAW

A. The FDA Regulatory Scheme

20. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

21. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

22. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

23. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered

to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

24. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

25. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

26. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

27. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA

have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

28. With regard to the first practice - disseminating written information - the FDAMA permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

29. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held,

and whether the audience is selected by the sales and marketing department of the company. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

30. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, i.e., the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

31. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed by federal and state health care programs.

1. The Medicaid Program

32. Medicaid is a public assistance program providing for payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

33. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

34. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. §1396r-8(k)(3). A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute.

Id. §1396r-8(k)(6).

35. During the time period relevant to this Complaint, the off-label uses of Xyrem promoted by Orphan were neither listed in the labeling approved by the FDA nor included in any of the drug compendia specified by the Medicaid statute. Consequently, when prescribed for off-label uses, Xyrem is not a Medicaid-covered outpatient drug and is not eligible for Medicaid reimbursement. Reimbursement claims submitted to Medicaid for off-label Xyrem prescriptions that were the result of illegal promotional activities of Orphan constitute false or fraudulent claims for reimbursement.

2. Medicare Program

36. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program.

37. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 USC §1396r-8(k) (as described in paragraphs 29 and 30 above).

38. The first stage of the Medicare program, from May 2004 through December 2005, permits Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

39. In addition, low income beneficiaries, defined as those whose incomes are not more than 135 percent of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualify for a $600 credit (funded by Medicare) on their drug discount card for 2004 and again for 2005.

40. Starting in January 2006, the Part D of the Medicare Program provides subsidized drug coverage for all beneficiaries. Low income individuals receive the greatest subsidies.

3. Other Government-Funded Health Care Programs

41. In addition to Medicaid, the federal and state governments reimburse a portion of the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Champus/Tricare, ChampVA, the Federal Employees Health Benefit Program, federal workers' compensation programs, and comparable state programs.

42. Reimbursement claims submitted to these programs for off-label Xyrem prescriptions that were the result of illegal promotional activities of Orphan constitute false or fraudulent claims for reimbursement.

C. The Anti-Kickback Statute

43. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

44. The Anti-Kickback statute prohibits any person or entity from 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 under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or

recommend drugs that may be paid for by Medicaid, Medicare, or any other federal health care program.

45. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician which has as one of its purposes inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

46. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violate the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,372 (Dec. 19, 1994). Among the improper practices cited by the Inspector General are drug companies' payments to physicians where the payment appears to be based on the volume of business the doctor can generate for the drug company. Id. at 65,376

47. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, Medicare, and other government health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law.

48. In a number of states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

49. In sum, either pursuant to provider agreements, claims forms, or other manner, providers who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

V. BACKGROUND

A. The Limited Scope Of The FDA's Approval of Xyrem

50. In July 2002, the FDA approved Xyrem (pronounced "Zyrem") as an oral solution for treatment of one, and only one, medical condition: cataplexy associated with narcolepsy. Narcolopsy is a neurological disorder that affects a person's ability to control sleep and wakefulness. Cataplexy, a symptom of narcolepsy, is a sudden loss of muscular control and weakness usually triggered by emotions such as amusement, anger or excitement.

51. The effects of cataplexy range from dropping of the jaw and slumping of the head, to buckling of the legs and even collapse of the whole body. These effects can last for a few seconds or up to many minutes. The FDA estimates that narcoleptic cataplexy affects approximately 20,000 to 50,000 individuals in the United States.

52. The active chemical ingredient in Xyrem is sodium oxybate, commonly known as gamma hydroxybutyrate or GHB. GHB is a central nervous system depressant. Because of public health and safety concerns associated with the use of GHB, the FDA banned the sale of GHB in the 1990s. When the FDA subsequently approved Xyrem in 2002 for treatment of cataplexy associated with narcolopesy, the FDA explained its previous ban on GHB as follows:

> In the early 1990s, GHB was marketed as a dietary supplement for many claimed purposes, including inducing sleep, releasing growth hormone, enhancing sexual activity and athletic performance, and relieving depression. It also gained favor as a recreational drug, and was used for date rape, because of its intoxicating effects.

> Many serious adverse events, including deaths, were reported with the use and misuse of the GHB containing products. As use increased, so did the adverse event reports. That prompted FDA to make several public announcements alerting consumers to the dangers surrounding GHB and similar products. . . . [and led the FDA] to prevent their sale to consumers and any further illnesses or deaths.

"Xyrem (Sodium Oxybate) Questions and Answers," FDA Center for Drug Evaluation and Research, published July 17, 2002, reprinted at www.fda.gov/cder/drug/infopage/xyrem.

53. Because of these safety concerns, when the FDA approved Xyrem in July 2002 for treatment of narcoleptic cataplexy, the FDA required Orphan to include a "black box" warning on the product insert that accompanies every sale of Xyrem. The required warning, which is in bold letters at the top of the Xyrem product insert, states in pertinent part:

> **!WARNING: Central nervous system depressant with abuse potential. Should not be used with alcohol or other CNS depressants. Sodium oxybate is GHB, a known drug of abuse. Abuse has been associated with some important central nervous system (CNS) adverse events (including death). Even at recommended doses, use has been associated with confusion, depression and other neuropsychiatric events. Reports of respiratory depression occurred in clinical trials. . . . Important CNS adverse events associated with abuse of GHB include seizure, respiratory depression and profound decreases in level of consciousness, with instances of coma and death.**

54. The FDA reiterated the risks associated with use of Xyrem in FDA publications timed to coincide with the agency's approval of Xyrem for the single indication described above. In the FDA's "Medication Guide," the agency explained:

> Xyrem can cause serious side effects including trouble breathing while asleep, confusion, abnormal thinking, depression, and loss of consciousness. Tell your doctor if you have any of these problems while taking Xyrem.
>
> The active ingredient in Xyrem is gamma-hydroxybutyrate (GHB), a chemical that has been abused (misused). Abuse can cause serious medical problems, including trouble breathing, seizures (convulsions), loss of consciousness, coma, and death. Abuse of Xyrem could also lead to dependence, craving for the medicine, and severe withdrawal symptoms.

"Xyrem (Sodium Oxybate) Oral Solution Medication Guide," FDA Center for Drug Evaluation and Research, published July 17, 2002, reprinted at www.fda.gov/cder/drug/infopage/xyrem.

55. The FDA also implemented a number of extraordinary measures to ensure that Xyrem is not improperly used. For example, the FDA authorized only one, centralized pharmacy to distribute the drug. That pharmacy is Express Scripts, located in St. Louis, Missouri. Prescribers and patients can only obtain the product through that single source. Furthermore, before the pharmacy can send Xyrem to patients, the FDA requires the pharmacy to verify that the patient has been provided with information on the safe and effective use of the drug and that the patients has read the information.

56. Concern over the misuse of GHB led Congress to pass the Date-Rape Drug Prohibition Act of 2000 ("Date-Rape Act"), which placed GHB in a category of drugs that are the most strictly regulated by the federal Controlled Substances Act. Under the Date-Rape Act, anyone who sells, distributes, or gives Xyrem to anyone else, or uses Xyrem for purposes other than what it was prescribed for, can be imprisoned for a term of up to 20 years and fined.

57. Xyrem was approved by the FDA with "orphan drug" status, which is available for products that treat "rare diseases." A "rare disease" is defined as one that affects patient populations of 200,000 or fewer. Sponsors of drugs with orphan drug status receive federal benefits that include seven-year marketing exclusivity, tax credit for clinical research associated with the product, and research design assistance by the FDA

58. Because Xyrem is the only drug on the market approved for treatment of cataplexy associated with narcolopesy, Orphan can charge patients a very high price for the drug. It costs approximately $300 to $500 for a monthly supply.

59. Xyrem's closest competitor is Provigil, manufactured by Cephalon, Inc. However, Provigil is only approved for treating one of the symptoms of narcolepsy, excessive daytime sleepiness, and does not treat the symptom of cataplexy.

B. Orphan's Sales and Marketing Organization

60. Orphan's sales and marketing organization for Xyrem is divided into four regions, each of which is divided into several sales territories. Orphan has 36 individual sales representatives, each assigned a separate territory.

61. Relator Shelley Lauterbach is one of the 36 Xyrem sales representatives. Her territory covers Alabama and Tennessee, within the Southeast Region. David Tucker is the Regional Manager for the Southeast Region and is Relator's immediate boss.

62. Orphan's four Regional Managers report to the Vice President of Marketing, Pam Stahl. The Vice President of Marketing reports to the President of Marketing, Mark Perrin. The President of Marketing reports to the Chief Executive Officer, John Bullion.

63. Strategic decision-making concerning the marketing of Xyrem is centralized in Orphan's corporate headquarters in Minnesota. From that central office, Orphan dictates strategy and policies applicable to all of the regions and sales territories throughout the country.

64. Orphan sales representatives receive incentive-based compensation that includes an annual salary, plus a commission. The sales representative's commission is determined by the number of new patients on Xyrem that he or she enrolls each quarter, regardless of whether the patient is prescribed Xyrem for off-label or on-label treatments, and regardless how long the patient stays on the drug.

VI. Orphan Aggressively Markets Xyrem For Off-Label Treatments

A. Internal Orphan Marketing Strategy For Xyrem Is Driven By Lucrative Off- Label Markets

1. The Inception Of Orphan's Off-Label Marketing Strategy

65. Relator was recruited and hired by Orphan in September 2002, two months after Xyrem was approved for sale by the FDA. Relator was hired to join the Orphan sales force devoted to the promotion and sale of Xyrem.

66. Shortly after being hired, Relator and other Xyrem sales representatives were trained for two weeks in Minnesota on the disease state of narcoleptic cataplexy, the rare disorder for which Xyrem was approved. In October 2002, Orphan launched the drug on the market.

67. Orphan's initial marketing efforts were strictly legal, focused on physicians who treat cataplexy associated with narcolepsy. The physicians who treat this disorder are (i) pulmonologists, (ii) neurologists, and, more rarely (iii) psychiatrists who specialize in sleep medicine. Orphan's marketing strategy targeted these specialties.

68. Sales of Xyrem grew slowly over the first few quarters as the sales representatives promoted Xyrem for its indicated use. Modest sales were not surprising, since the patient population suffering from narcoleptic cataplexy is so small, between 20,000 and 50,000.

69. In 2003, however, Orphan's marketing strategy changed, and the company began aggressively promoting Xyrem's off-label uses. It was clear that the company had shifted its focus to non-FDA approved indications in order to increase revenues. Relator was told that management wanted to sell the company, and that in order to make it a more attractive acquisition target, it was necessary to show increased sales revenues.

70. The potential market for off-label uses of Xyrem - for treatment of fatigue, fibromyalgia, non-specific sleepiness, insomnia, pain, and psychiatric disorders - is huge. Orphan

management knew that if these markets could be tapped, Xyrem sales could be substantially increased. The company decided to pursue this strategy notwithstanding the fact that it is blatantly illegal, and jeopardizes public health and safety.

2. Orphan Management Instructed Sales Representatives in Off-label Promotion at a National Sales Meeting in January 2004.

71. At Orphan's National Sales Meeting in Nashville, Tennessee in January 2004, the Xyrem sales representatives received completely new directives from the company. Although the company's formal policy forbade promotion of Xyrem for off-label uses, company officials verbally communicated a different message to the sales force, namely: increase Xyrem sales whenever and wherever possible, whether off-label or on-label.

72. In the general sessions of the national meeting, the home office officials stressed the importance of keeping internal records clean. They told the sales representatives that all physician call records in their computers should contain information about the promotion of Xyrem for approved indications only, and that their business plans should include only information about legal activities. The sales representatives were instructed to carefully monitor their records so as to prevent any documentation of off-label activity that could subject the company to legal liability.

73. In addition, Relator's manager, David Tucker, recommended that the sales representatives attempt to collect as many Medical Information Request Forms as possible from physicians to whom they promoted the drug off-label, so as to make it appear that the physician had initiated the request for information regarding Xyrem's off-label uses.

74. Following the general sessions, the meeting broke into private sessions for each of the four regions. At the private session for the Southeast Region, Regional Manager Tucker told

the sales representatives (including Relator) that they were all hired to "get the business" however they could get it, and that they all had sold products off-label before, so there was no reason for them to object now. As long as they were not caught, he said, everything would be fine.

75. Tucker told the group about a speaker, Dr. Peter Gleason, a psychiatrist from the Washington, D.C. area, who would come and "work magic" in their territories. The clear implication was that Dr. Gleason would "work magic" by promoting Xyrem off-label in their territories.

76. Tucker also told the representatives that they should promote Xyrem for fibromyalgia in rheumatology offices and pain clinics, and stated that representatives who could not "think outside of the box" of cataplexy would never make their quotas and would not be around for long. Fibromyalgia is a chronic disorder characterized by widespread pain and fatigue. It is not an approved indication for Xyrem. (Several months after the national meeting, Orphan submitted a Investigational New Drug Application ("IND") to the FDA requesting permission to begin a clinical study of the effect of Xyrem on fibromyalgia patients. The clinical study is currently in its initial stages. After the study is concluded, Orphan will decide based upon the results whether to file a Supplemental New Drug Application ("SNDA") with the FDA requesting approval of Xyrem for the treatment of fibromyalgia. In the meantime, fibromyalgia remains an unapproved indication.)

77. At the meeting, Tucker informed the audience about an abstract of an article by Dr. Martin Scharf published in the Journal of Rheumatology in 2003 entitled, "The Effects Of Sodium Oxybate On Clinical Symptoms And Sleep Patterns In Patients With Fibromyalgia" (hereafter referred to as the "Scharf abstract"). The article discusses a clinical study of the effect

of sodium oxybate (Xyrem) on patients with fibromyalgia. Only 18 patients completed the study, and one of these could not be included in the results because of insufficient data. Relator is informed and believes that medical authorities do not consider such a small sample scientifically significant, and therefore conclusions concerning the efficacy of Xyrem in the treatment of fibromyalgia cannot be drawn from the study.

3. On Several Occasions in 2004, Orphan's Manager Instructed Her To Promote Xyrem Off-label

78. On February 16 and 17, 2004, Relator's Manager, David Tucker, came to Birmingham, Alabama to work with Relator in her territory. He took Relator to a local coffee shop and explained how things with the company had "changed" since she had been out on maternity leave. He informed Relator that sales representatives' quotas had increased substantially over the prior year, and that it would be necessary to begin promoting Xyrem "out of the box" of the approved indication, narcoleptic cataplexy, in order to reach the quota. He told Relator that management was interested in selling the company and wanted to increase sales revenue in order to make the company more attractive to suitors.

79. Relator was uncomfortable with this conversation and the new "direction." She continued to promote Xyrem primarily for its one approved indication, despite the fact that her sales numbers lagged behind the other sales representatives in her region.

80. On June 28, 2004, Relator received a telephone call from her manager. Tucker was angry and irritated and said that he had recently received a negative performance review. He told Relator that her sales numbers were making him look bad and that he would be coming to Birmingham to work with her in her territory on July 6 and 7.

81. During the telephone conversation on June 28, and during Tucker's visit to Birmingham on July 6 and 7, Tucker gave Relator several suggestions on how to increase Xyrem sales in her territory. Tucker told Relator to arrange speaking events in her territory for several doctors that are paid to speak on behalf of Orphan, and who are known to promote the off-label uses of Xyrem. Tucker told her to arrange speaking events for Dr. Peter Gleason, Dr. David Knapp, and Dr. Vernon Pegram, Phd, among others.

82. Acting upon Tucker's instructions, Relator did arrange for Dr. Gleason, Dr. Knapp and Dr. Pegram to speak in her territory. As described in more detail in the following section below, each of these speakers presented lectures that heavily promoted Xyrem for treatment of unapproved indications. Dr. Gleason promoted Xyrem for treatment of fibromyalgia, fatigue, non-specific sleep disorders, insomnia, and psychiatric disorders; Dr. Knapp promoted Xyrem for treatment of fibromyalgia; and Dr. Pegram promoted Xyrem for treatment of fibromyalgia and pain. See discussion below.

83. After Relator reluctantly followed Tucker's instructions and arranged these off-label speaking events - arranged under implicit threat of termination if she did not do so - her new patient enrollment doubled. Previously, in the second quarter of 2004, when Relator only promoted Xyrem for its on-label indication, Relator's total new patient enrollment was 15 patients. In the third quarter of 2004, after Drs. Gleason, Knapp and Pegram spoke in her territory, her new patient enrollment increased to 30 patients. Part of this increase was due to off-label prescriptions.

84. Even that two-fold increase was still short of the company's aggressive quota imposed on its Xyrem sales representatives. When Relator first began working for Orphan, the

quota for new patient enrollment was 9 patients per quarter per representative. By the end of 2004, the quota was in the range of 70 patients per quarter. Given the limited on-label market, the new quota could only be reached by aggressively promoting the off-label uses of Xyrem, which Relator was not comfortable doing.

85. On December 15, 2004, David Tucker returned to Birmingham to meet with Relator. On that date, he presented her with a letter stating, inter alia, that Relator's employment would be terminated unless she enrolled 23 new Xyrem patients by the end of December (at the time, Relator had enrolled one new patient for the month), and 25 new patients in the month of January. Relator told Tucker him there was not that much narcoleptic cataplexy business in her territory, and he responded, "do what you need to do in order to get the business. I've given you the plan – it's up to you whether or not to do it." The unmistakable meaning in Tucker's comment was that Relator must aggressively promote Xyrem off-label, or be fired.

86. This attitude reflects corporate policy at Orphan. Orphan's quota system forces its sales representatives to promote Xyrem for off-label purposes, or be fired.

B. Orphan Utilizes A Variety Of Illegal Practices To Aggressively Promote Xyrem For Off-Label Treatments

87. Relator's experiences described above are not unique to her territory; her experiences reflect a company-wide policy to promote Xyrem for unapproved indications. That policy is driven by the much larger market potential for Xyrem's off-label uses than for its single on-label use. Orphan's company-wide off-label marketing strategy relies upon a variety of illegal practices, including the following:

1. Orphan Uses Speaker Programs To Promote Off-Label Uses Of Xyrem Directly To Prescribing Physicians

88. Orphan has developed an aggressive speaker program to take its off-label message directly to physician-prescribers of Xyrem.

89. There are two prongs to Orphan's speaker program. First, on the national level, Orphan relies heavily on one doctor, defendant Dr. Peter Gleason, who is paid by Orphan to give hundreds of talks around the country promoting Xyrem off-label. Secondly, on the local and regional level, Orphan's strategy is to identify physicians who prescribe Xyrem off-label, and then persuade them with lucrative speaker fees to give talks promoting Xyrem's off-label uses to colleagues in their own area or neighboring areas. Relator has been present at several of these talks, which are described in greater detail below.

90. Orphan's paid speaker program blatantly violates the federal prohibition against off-label promotion by drug manufacturers. In addition, Orphan's payments to physician-speakers violate the Anti-Kickback statute by rewarding the physicians for prescribing Xyrem off-label and by inducing the physicians to recommend the drug's off-label uses to other physicians. Claims for reimbursement to government health care program for these off-label and kickback-induced sales are false and fraudulent claims in violation of the federal and state False Claims Acts.

a. Dr. Peter Gleason

91. Dr. Peter Gleason is a psychiatrist who practices in the Washington, D.C. area. He has been utilized more than any other speaker on Orphan's national speaker's list. Orphan has paid him hundreds of thousands of dollars in speaker's fees for hundreds of speaking engagements. In Dr. Gleason's presentations, he promotes Xyrem for treatment of a number of off-label indications, including fibromyalgia, insomnia, excessive daytime sleepiness, fatigue, and psychiatric disorders. Dr. Gleason also seriously minimizes the health risks of taking Xyrem, and

also recommends high dosages without scientific basis. Dr. Gleason is in enormous demand by Xyrem sales representatives because he generates off-label sales whenever he speaks in a territory.

92. Relator found out first-hand why Dr. Gleason is in such heavy demand when he came to Relator's territory on October 4, 2004 to speak at a Continuing Medical Education ("CME") program sponsored by Orphan. Relator had scheduled this event at the suggestion of her manager, David Tucker. During Tucker's visit to Birmingham in July 2004, see ¶75 above, Tucker told Relator to use Dr. Gleason as often as possible in order to increase Xyrem sales in her territory.

93. Dr. Gleason's October 2004 lecture in Relator's territory took place at Bottega's Restaurant in Birmingham, Alabama. Ostensibly the program was organized by Health Science Corporation ("HSC"), a CME program provider. HSC is funded by an "unrestricted educational grant" from Orphan. Based on Relator's experience working with HSC, it is entirely under the influence and control of Orphan. Following standard practice, the venue for the October 2004 event and the speaker were selected by Relator, the sales representative for the territory where the program was held. HSC provided Relator with invitations to send to physicians of Relator's choosing. In addition, HSC sent invitations to physicians listed on a database provided by Orphan. Although Dr. Gleason's speaker's fee was paid by HSC (the standard fee for an evening lecture is $1,000), Relator is informed and believes that the funds for the fee were provided by Orphan through its grant to HSC.

94. In attendance at the October event were approximately 10 physicians. The invitation described the lecture as a talk on narcolepsy and excessive daytime sleepiness ("EDS") associated with narcolepsy. Relator also attended the lecture.

95. During the lecture, without solicitation by anyone in the audience, Dr. Gleason boldly promoted Xyrem for fatigue, non-specific EDS, and most intensively for fibromyalgia - all of which are off-label indications.

96. Dr. Gleason handed out a study entitled,"Growth Hormone Deficiency in Fibromyalgia," and explained to the audience that Xyrem increases growth hormone and therefore is effective in the treatment of fibromyalgia. Dr. Gleason also handed out the Scharf abstract and cited it as evidence that sodium oxybate (Xyrem) is effective in the treatment of fibromyalgia.

97. Dr. Gleason also explained how to handle insurance reimbursement for off-label prescriptions of Xyrem. Dr Gleason stated that the prescribing physician should falsify the diagnosis on the reimbursement claim form. He stated that prescribing physician should not provide the insurance code for the off-label indication for which the drug is prescribed because the insurance company will reject the claim; instead, Dr. Gleason handed out the billing codes for diagnoses such as (i) non-specific EDS and (ii) narcolepsy (without cataplexy), which he stated were more likely to pass scrutiny and be reimbursed. (Dr. Gleason elaborated upon this scheme to defraud insurance payors in a January 2005 lecture, see ¶ 96f below).

98. Although Dr. Gleason's October 2004 lecture was represented to be a non-promotional, independent CME lecture, it was, in truth, entirely under the control and influence of Orphan's sales and marketing division. The event failed virtually every test of independence required of a legitimate CME event. This was one of the most blatant examples of a company

using a CME event for off-label promotion that Relator had ever seen in her 14 years as a pharmaceutical representative.

99. Dr. Gleason returned to Relator's territory for a non-CME lecture sponsored by Orphan on January 5, 2005. Federal law imposes even stricter limitations on the content of purely promotional events, i.e., non-CME events, since the speaker is openly appearing as an agent of the sponsoring company, and therefore the speaker's statements are directly attributable to the company. At a promotional event, federal law strictly prohibits a drug company, or anyone acting on its behalf, from disseminating information concerning off-label uses of a drug unless there is an unsolicited request for that information. (Even when there is an unsolicited request, written information concerning off-label uses cannot be provided unless it has previously been submitted to the FDA.)

100. The January 5, 2005 event was organized by Relator at the suggestion of her Regional Manager, David Tucker, who also attended the event. The lecture took place in Birmingham, Alabama at the Daniel George Restaurant at approximately 7 pm.

101. Relator and her manager, David Tucker, drove Dr. Gleason to the event. During the drive, they discussed the best way to handle insurance reimbursement claims for off-label Xyrem prescriptions. Dr. Gleason and Tucker noted that there is nothing on the prescription form that requires a particular diagnosis, and that in the majority of cases the insurers are paying for off-label prescriptions without any diagnosis provided. In light of this success rate, Dr. Gleason cautioned against "giving too much information." In the event insurers questioned the omission of diagnosis information, Gleason further advised that doctors code the off-label use as diagnosis code 307.44 - EDS non-specific - even if it was a misstatement of the actual diagnosis.

102. Dr. Gleason suggested that doctors try sending the prescription forms for non-cataplexy diagnoses in without a diagnosis, and if it is questioned to try "EDS non-specific." For example, Dr. Gleason advised that a fibromyalgia diagnosis should be characterized as "EDS non-specific" on the prescription form.

103. In addition to Relator and Tucker, the attendees for this program were:

Dr Robert Doeckel, pulmonologist, Sleep Disorders Center of Alabama

Dr Adams, pulmonologist, Sleep Disorders Center of Alabama

Dr Don Cornelius, pain management specialist, Doleys Pain Center, Montclair Hospital

Dr Eslami, neurologist, Shelby Hospital

Dr Eslami's wife, Mary

Dr Paul LaRussa, psychiatrist, Renaissance Center Psychiatry, Alabaster, Alabama

104. During the lecture, without any prompting or questions from the audience, Dr. Gleason promoted Xyrem for a variety of off-label indications. Following is a brief synopsis of Dr. Gleason's blatant off-label promotion of Xyrem during the lecture:

a. Dr. Gleason began by promoting Xyrem for treatment of fibromyalgia. He stated that the fibromyalgia patients treated with Xyrem experienced dramatic improvements. Dr. Gleason also referenced the Scharf study on fibromyalgia, and provided copies of the article to the physicians to take home.

b. Dr. Gleason next promoted Xyrem for treatment of excessive daytime sleepiness (EDS), another unapproved use of Xyrem. Dr. Gleason referenced a published study concerning treatment of EDS that involved a head to head study between Xyrem and Provigil. Dr. Gleason's commentary on the study was misleading. He stated simply

that Xyrem did "better than Provigil." In fact, the study shows that while Xyrem only slightly outperformed Provigil, it was the *combination* of Xyrem and Provigil that had the most significant positive outcome. Dr. Gleason did not reference this outcome nor provide a copy of the study. Dr. Gleason left the audience with the clear impression that Xyrem is effective for treatment of EDS.

c. Dr. Gleason then proceeded to promote Xyrem for the treatment of insomnia and fatigue. There is no published data on Xyrem's safety or efficacy in treating these off-label indications. Dr. Gleason stated that he provides patients suffering from insomnia and fatigue with 3 grams of Xyrem at bedtime, then another 3 grams a few hours later - a dosing regimen invented by Dr. Gleason for treatment of these off-label indications.

d. Later, one of the pulmonologists in the audience asked Dr. Gleason whether he performs sleep studies on his insomnia patients before treating them with Xyrem. Dr. Gleason replied that he generally does not. The significance and danger in this response lies in the fact that of the millions of Americans who suffer from insomnia, a significant percentage have a condition known as "sleep apnea." Sleep apnea is characterized by interrupted breathing patterns at night, which causes poor sleep. If Xyrem, which is a central nervous system depressant, is provided to an individual with sleep apnea, it can potentially kill the individual or cause severe respiratory distress requiring emergency room treatment and intubation. Thus, the Xyrem product label contains a specific warning concerning these risks:

> Sodium oxybate is a CNS depressant with the potential to impair respiratory drive, especially in patients with already compromised

> respiratory function. In overdoses, life threatening respiratory depression has been reported. . . .
>
> Caution should be observed if Xyrem is prescribed to patients with compromised respiratory function. Prescribers should be aware that sleep apnea has been reported with a high incidence (even 50%) in some cohorts of narcoleptic patients.

If Dr. Gleason's off-label message - that Xyrem is effective as a general treatment for insomnia - is widely disseminated (as Relator believes it has been), it could seriously jeopardize public health and safety.

e. Dr. Gleason next proceeded to misinform his audience that there have been no incidences of diversion of Xyrem (referencing the fact that Xyrem is GHB, a controlled substance). In fact, there have been cases of diversion, of which Orphan is well aware since it has become involved in the ensuing investigations.

f. Near the conclusion of his talk, Dr. Gleason described how to defraud private and public healthcare insurers by getting them to pay for off-label prescriptions of Xyrem. A member of the audience asked Dr. Gleason a question about insurance reimbursement. Dr. Gleason explained how the prescribing physician should fill out the insurance claim form. He stated that the physician should not provide the insurance code for the off-label indication for which the drug is prescribed because the insurance payor company will reject the claim. Instead, according to Dr. Gleason, the physician should falsify the diagnosis on the claim form by using the code for "non-specific EDS," which is more likely to pass scrutiny. Dr. Gleason handed out "sleep" billing codes and suggested that doctors seek reimbursement using code 307.44 - the code for excessive daytime sleepiness. He further explained to physicians present that using billing code 307.44 has a

good chance of being approved by the "high school students" who work for payors, but that the codes for fatigue, insomnia or depression would likely be denied.

g. Dr. Gleason also briefly discussed how he uses Xyrem for the treatment of bipolar disorders and depression, additional off-label uses of the drug.

105. Relator is informed and believes that Dr. Gleason promotes Xyrem in a similar manner at all of his speaking engagements on behalf of Orphan. Relator has spoken with several other Xyrem sales representatives who confirmed that Dr. Gleason promoted Xyrem for off-label uses in lectures in their territories.

106. Orphan records show that Dr. Gleason was paid to speak at 118 promotional events in 2004, for which he was paid $73,750 in speaker fees. In addition to these promotional events, Dr. Gleason spoke at a large number of the estimated 250 Orphan-sponsored CME events in 2004. Relator does not have access to a list of the CME events or the speakers, but Relator is informed and believes that Dr. Gleason spoke at more than half of the events, for which he would have earned an estimated $150,000 in additional speaker fees, paid out of funds provided by Orphan to HSC.

107. Following is a list of Dr. Gleason's speaking engagements at Orphan promotional (non-CME) events in 2004:

LOCATION	DATE	SPEAKER FEE ($)
Office of Dr. Jorge Raichman, Houston, TX	1/8/2004	250.00
Prince Frederick, MD	1/15/2004	300.00
Cooper Aerobics Center, Dallas, TX	1/19/2004	1,250.00
Dr. Jones Office, Richardson, TX	1/20/2004	650.00
Dr. Balachandran Office, Houston, TX	1/21/2004	350.00
Ronald Garb & Associates, Houston, TX	1/21/2004	750.00

Café Annie, Houston, TX	1/21/2004	1,250.00
Gleason Office	1/28/2004	750.00
Office of Dr. Harmon, Santa Cruz, CA	1/26/2004	500.00
Santa Cruz, CA	1/26/2004	1,250.00
Psychiatry Office, Mountain View, CA	1/27/2004	500.00
Walnut Creek, CA	1/27/2004	1,250.00
Lifetree Clinic, Salt Lake City, UT	1/29/2004	1,000.00
Calvert Psychiatric Assoc., Prince Frederick, MD	2/9/2004	250.00
Syracuse Psychiatry, Syracuse, NY	2/3/2004	500.00
Office of Dr. Wadeson, Clinton, MD	2/10/2004	750.00
Group of psychiatrists, Washington, DC	2/5/2004	N/A
Psychiatric Associates, Orange Park, FL	2/16/2004	750.00
Del Fescois, Orlando, FL	2/16/2004	750.00
Sleep Center, Ormond Beach, FL	2/19/2004	1,250.00
Sleep Disorder Ctr of Central TX	2/19/2004	250.00
Santa Barbara, CA	3/1/2004	350.00
Santa Barbara, CA	3/1/2004	350.00
Los Angeles, CA	3/2/2004	1,250.00
New York, NY	2/13/2004	2,450.00
No location listed	2/19/2004	250.00
Irvine Medical Center, Irvine, CA	3/2/2004	750.00
Calvert Psychiatry, Seattle, WA	3/8/2004	2,500.00
Boulder, CO	3/4/2004	750.00
Boulder, CO	3/4/2004	1,250.00
Office of Gregory Wilets, Greenwood Village, CO	3/5/2004	750.00
MCU Sleep Lab, MidlothianVA	3/11/2004	1,250.00
Washington, DC	3/26/2004	250.00
St. Luke's Sleep Center, Allentown, PA	3/10/2004	750.00
Washington, DC	3/25/2004	350.00
Pulmonary & Critical Care, Murrieta, CA	3/29/2004	350.00
Cenitel Area Sleep Center, Alexandria, VA	3/31/2004	750.00

Rehab Hospital of RI	4/12/2004	250.00
Dr. Wallington's Office, West Hartford, CT	4/15/2004	350.00
Prime Health Care, Glastonbury, CT	4/15/2004	350.00
Paragon Health Care, Kensington, CT	4/15/2004	350.00
Norwich Neurology Associates, Norwich, CT	4/15/2004	750.00
Danbury Hospital	4/26/2004	250.00
Rockville, MD	5/6/2004	250.00
New London, CT	4/15/2004	750.00
Office of Dr. Singson, Wilmington, DE	4/22/2004	750.00
Office of JJ Storlazzi, Wilmington, DE	4/22/2004	450.00
Havenwyck Hosp., Dr. Daddagh Auburn Hills, MI	4/27/2004 a.m.	750.00
Dr. Anderson & Bernstein, Farmington Hills, MI	4/27/2004 p.m.	750.00
Rochester, MI	4/28/2004 a.m.	750.00
Farmington Hills, MI	4/28/2004 noon	750.00
Rehab Hospital of CT, Hartford, CT	5/11/2004	250.00
Jefferson Hosp, Dr. Borrero Office, Clairton, PA	6/21/2004	750.00
Dr. Lori Calabrese	6/24/2004	250.00
Office of Rolando Sausa, New York, NY	5/13/2004 a.m.	450.00
Office of Frederick Busch, New York, NY	5/13/04 noon	450.00
Office of Silvia Hofligen, New York, NY	5/13/04 1pm	450.00
Office of Philip Miskin, New York, NY	5/13/04 2pm	450.00
Office of Susan Lacks, Washington, DC	5/17/2004	750.00
Orellana Institute, Grand Rapids, MI	5/20/2004	750.00
Alpha Neurology, Staten Island, NY	5/17/2004	750.00
Office of Robert Bransfield, Red Bank, NJ	5/18/2004	450.00
Office of Rajkumar Singh, Freehold, NJ	5/18/2004	450.00
Office of Patricia Falivena, Denville, NJ	5/18/2004	450.00
Office of Sylvain Junger, Denville, NJ	5/18/2004	450.00
Office of Lisa Cannon, Ho Ho Kus, NJ	5/19/2004	450.00
Office of Eileen Sweeney, Staten Island, NY	5/19/2004	450.00
Office of Emmanual/Paul Hriso, Bayonne, NJ	5/19/2004	450.00

Behavioral Medicine Associates, Naples, FL	6/16/2004	750.00
Dr. F. Scott Perrino	6/14/2004	1,500.00
Office of Dr. Kevin Balter, Encino, CA	6/7/2004	450.00
Dr. William Rickles, Chaya Venice, CA	6/8/2004	450.00
Office of Dr. John Lee, Pittsburg, PA	6/21/04 3pm	450.00
Office of Dr. Terence Stare, Pittsburg, Pa	6/21/04 4pm	450.00
Office of Dr. Lawrence Solte, Akron, OH	7/27/2004	750.00
Drs Carabeth & Lorant, San Luis Obispo, CA	6/25/2004	250.00
Arthritis & Pain Center, Clearwater, FL	6/16/2004	450.00
Hardy Ctr. For Functional Medicine, Hingham, MA	7/29/2004	750.00
Dr. Rahim Shafa, Milford, MA	8/17/2004	750.00
Office of Dr. David Mazur, Grand Rapids, MI	8/3/2004	750.00
Dr. Lawrence Probes, Grand Rapids, MI	8/3/04 8am	750.00
Sr. H. Barry Miller, Hollywood, FL	6/17/04 12pm	750.00
Miami , FL	6/17/04 6:30pm	1,500.00
Dr. Melanie Rosenblatt, Pompano Beach, FL	6/18/2004	750.00
West Coast Family Medicine, Madeira, FL	6/30/2004	750.00
North Miami Beach, FL	6/30/2004	1,500.00
Office of Michael Farina-Woodbury, San Juan, PR	7/1/2004	250.00
Savannah Neurological, Savannah, GA	7/14/2004	750.00
Midlands Neurology, Columbia, SC	7/29/2004	1,500.00
Our Lady of Lourdes Sleep Center, Lafayette, LA	5/24/2004	750.00
Baton Rouge Psychiatry Assoc.	5/24/2004	1,500.00
Southwest Sleep Center, Middlebury Hts, OH	7/12/2004	1,000.00
Santa Fe, NM	8/5/2004	1,500.00
Advantage Health Center, Myrtle Beach, SC	11/16/2004	1,500.00
Medical Univ. of SC, Charleston, SC	8/30/2004	1,500.00
Office of Dr. Jefferson Davis, Santa Fe, NM	8/5/2004	450.00
Dr. Young, Rochester, MI	8/24/2004	450.00
Dr. Torregosa, Dearborn, MI	8/24/2004	750.00
Office of Dr. James Thrasher, Myrtle Beach, SC	8/23/2004	1,000.00

Office of Dr. Gonzales, Dallas, TX	8/31/2004	250.00
Jeffrey Lieberman, Decatur, GA	9/27/04 12pm	750.00
Northwest Behavioral Medicine, Atlanta, GA	9/27/04 6:30pm	1,000.00
Dr. Denise Troy Curry, Kirkwood, MO	8/16/2004	1,500.00
Office of Dr. Georgia Jones, Washington, MO	8/18/2004	750.00
Office of Dr. Gerald Weiss,	9/9/2004	250.00
Office of Dr. Susan Nilson,	10/4/2004	250.00
Muskegon Psychiatric, Grand Haven, MI	8/25/2004	1,000.00
Office of Tim Lieske, Lincoln, NE	9/8/2004	450.00
KCOM-Neurobehavioral Sciences, Kirksville, MO	9/7/2004	750.00
Regions Hospital, St. Paul, MN	9/16/2004	650.00
Minnesota Sleep Institute, Edina, MN	9/16/04,5:30pm	1,000.00
Park Nicollet Pulm Dept., St. Louis Park, MN	9/17/2004	450.00
Mpls.Clinic of Neurology-Southdale, Edina, MN	9/17/04 @12pm	750.00
Hinsdale Ctr. for Integrative Med. Hinsdale, IL	9/17/2004	250.00
Sleep Disorder Center Of VA, Glen Allen, VA	11/5/2004	1,250.00
Chesapeake Bay Society, Glen Allen, VA	11/5/2004	750.00
VOMA Virginia Beach, VA	10/2/2004	750.00
University Hospital, Syracuse, NY	9/29/2004	450.00
TOTAL:	118 Events	$73,500.00

108. Relator is informed and believes that off-label sales of Xyrem increased in every territory where Dr. Gleason spoke as a result of the off-label content of his talk.

109. Orphan's management is well aware that Dr. Gleason's standard presentation promotes Xyrem off-label and encourages the fraudulent billing of Xyrem prescriptions. Orphan's regional managers have all heard Dr. Gleason speak many times and continue to encourage their Xyrem sales representatives to use Dr. Gleason as frequently as possible. For example, after David Tucker attended Dr. Gleason's blatantly off-label presentation in Birmingham on January 5,

2005, he encouraged Relator to bring him back to speak in her territory as often as possible. In fact, not "using Dr Gleason" is considered by Orphan management as a dereliction of a sale representative's duty to promote Xyrem sales in his or her territory.

110. According to an Orphan scheduler, Dr. Gleason is almost fully booked with Orphan speaking engagements for the next year. For the first three months of 2005, for example, Orphan records show that Dr. Gleason is scheduled to speak at 45 Orphan promotional events, as follows:

LOCATION	DATE	SPEAKER FEE ($)
Diva's, Toledo, OH	3/11/2005	1,500.00
Emerils, Atlanta, GA	2/18/2005	1,500.00
Charleston Neurology, Charleston, SC	2/21/2005	750.00
Austin, TX	1/12/2005	1,000.00
San Antonio Psychiatry Assoc, San Antonio, TX	2/9/2005	1,000.00
Aldo's restaurant, San Antonio, TX	2/9/2005	1,000.00
Medical Univ. of South Caroline, Mt. Pleasant, SC	2/17/2005	1,000.00
Office of Dr. Barry Rozantine, Savannah, GA	2/21/2005	1,500.00
Office of Dr. David McNeil, Skokie, IL	2/22/2005	450.00
Office of Dr. R. Elliot, Lexington, KY	1/26/2005	750.00
Office of Dr. Mark Wright, Lexington, KY	1/26/2005	450.00
Lexington, KY	1/26/2005	1,500.00
Norwich Psychiatric Center, Norwich, CT	1/27/2005	650.00
Office of Dr. Kippels, Dallas, TX	2/2/2005	650.00
Arthritis Center of North Texas, Dallas, TX	2/3/2005	650.00
Southeast Lung and Critical Care, Savannah, GA	2/22/2005	1,500.00
Eugene McDermott Ctr. for Pain Mgmt, Dallas, TX	1/5/2005	450.00
Office of Dr. Lee, Pittsburgh, PA	1/20/2005	450.00
Office of Dr. Kambhampati, Pittsburgh, PA	3/15/2005	450.00
Pain & Headache Center of Newport Beach, CA	1/18/2005	650.00

Grossmont Hospital/Neurology Dept., La Mesa CA	1/27/2005	650.00
Queens Medical Center/Sleep Center, Honolulu, HI	2/4/2005	650.00
Kapiolani Medical Center, Neur. Assoc., Aiea, HI	2/25/2005	650.00
First Medical Group, Dept of Pulmonary, Nashville, TN	1/3/2005	650.00
Samson Hospital Sleep Disorders Ctr.,Glasgow, KY	1/4/2005	650.00
Bowling Green, KY	1/18/2004	1,000.00
Cadillac Pulmonology, Cadillac, MI	2/24/2005	1,000.00
Michigan Soc. Respiratory Care, Grand Rapids, MI	3/23/2004	1,000.00
Office of Dr. Hasrollah Eslami, Birmingham, AL	1/5/2005	1,000.00
Orlando, FL	1/12/2005	1,500.00
Private Office, New Smyrna Beach, FL	1/13/2005	750.00
Mary Jenkins Behavioral Ctr, North Charleston, SC	1/11/2005	750.00
Charleston Pulmonary, Charleston, SC	3/8/2005	1,000.00
Office of Dr. Gonzalez, Dallas, TX	1/26/2005	250.00
The Kohn Group Clinic, McHenry, IL	1/10/2005	750.00
Private Office, Jacksonville, FL	1/13/2005	1,500.00
Office of Dr. Davis, Los Angeles, CA	1/6/2005	250.00
Office of Dr. Saifuddin, Los Angeles, CA	1/31/2005	250.00
Huntington Memorial Sleep Lab, Pasadena, CA	2/2/2005	not listed
VA Pulmonary Department, Los Angeles, Ca	2/7/2005	450.00
Office of Dr. Adbel Malek, Pasadena, CA	2/7/2005	450.00
Office of Dr. John Spangler, Pasadena, CA	2/28/2005	450.00
Office of Dr. Jack Lindheimer, California	1/20/2005	250.00
Office of El Gabalawi, CA	1/24/2005	250.00
Arroyo Chop House, Los Angeles, CA	1/13/2005	450.00
	Total:	$34,400

111. In addition to these events, Relator is informed and believes that Dr. Gleason is also scheduled to speak at a number of CME events sponsored by Orphan during the same time period.

112. Relator does not have access to Orphan payment records to determine whether, in addition to speaker fees, there are additional Orphan payments to Dr. Gleason, such as speaker training fees, consulting agreements, etc. Further investigation is necessary to determine the existence or extent of such payments.

b. Dr. Martin Scharf

113. Dr. Martin Scharf is a sleep specialist who practices in Cincinnati, Ohio. He has had an extensive relationship with Orphan Medical. He was the lead investigator who co-authored the one and only published article that evaluates the use of sodium oxybate (Xyrem) in patients with fibromyalgia. See ¶71 supra.

114. Relator arranged for Dr. Scharf to speak at an Orphan-sponsored CME event in Birmingham on April 27, 2004. Like the CME event featuring Dr. Gleason described in ¶¶ 86-92 above, this event, ostensibly organized by HSC, was under the influence and control of Orphan. Orphan marketing and sales personnel chose the venue, the speaker, and many of the invitees. Relator did not handle payment of the speaker fee for this event, but Relator is informed and believes that, following standard practice, HSC would have paid Dr. Scharf approximately $1,000 for this lecture, from funds provided by an Orphan grant.

115. Relator attended Dr. Scharf's lecture, which was held over dinner at the Copper Grill Restaurant in Birmingham. There were approximately eight physicians at the dinner. At one point during his lecture, Dr. Scharf stated, "I'm going straight off-label." Dr. Scharf then proceeded to discuss the efficacy of Xyrem in treatment of fibromyalgia, citing his own research and article.

116. Dr. Scharf has been paid to speak at a number of CME events as well as non-CME events sponsored by Orphan. Relator is informed and believes that Dr. Scharf promotes Xyrem

for treatment of fibromyalgia in all of the talks he gives at these events. Orphan records show that Dr. Scharf was paid to speak at the following non-CME events in 2004:

LOCATION	DATE	SPEAKER FEE ($)
Cincinnati, OH	1/8/2004	1,000.00
Medical Univ. of S. Carolina, Charleston	1/29/2004	1,500.00
TriState Sleep Disorder Ctr, Cincinnati, OH	2/17/2004	1,000.00
The Medical Group, Michigan City, IN	2/18/2004	1,000.00
Maryview Hospital	2/10/2004	1,500.00
Dallas, TX	3/4/2004	1,500.00
Mercy Hospital, Miami, FL	3/9/2004	1,500.00
Dr. Harney's Office, Richardson, TX	3/24/2004	1,000.00
Johns Hopkins, Baltimore, MD	4/14/2004	1,500.00
Cottage Hospital, Santa Barbara, CA	4/22/2004	1,000.00
Office of Dr. Mark Kosins, San Clemente, CA	4/23/2004	650.00
Des Moines, IA	5/20/2004	1,500.00
Office Dr. Ethan Bickelhaupt, Topeka, KS	6/14/2004	1,000.00
Office of Dr. Gary Fink, N. Charleston, SC	6/22/2004	1,000.00
Charleston Pulmonary, Charleston, SC	6/22/2004	1,500.00
Dr. Jadai, St. Clair Shores, MI	6/28/04 @12pm	500.00
Office of Dr. Marcus, Dearborn, MI	6/28/04 @2pm	500.00
Office of Dr. Buzzard, W. Bloomfield, MI	6/28/04 @4pm	500.00
Troy, MI, overnight	6/28/2004	1,500.00
	Total:	$21,150

117. In addition to the above events, Dr. Scharf was also paid to give several CME dinner lectures for Orphan. Relator does not have access to the CME records that would show the dates of Dr. Scharf's CME lectures or the amounts paid to him for those lectures. However, Relator is informed and believes that they are roughly equivalent in numbers to the non-CME events.

c. Dr. Vernon Pegram, PhD

118. Vernon Pegram, Phd, is a sleep medicine specialist affiliated with Montclair Hospital in Birmingham, Alabama. When Relator's manager, David Tucker, was working with Relator in Birmingham during the week of July 6th, 2004, he instructed Relator to visit Dr. Pegram in order to ask him to give two lectures in her territory promoting Xyrem for the off-label treatment of fibromyalgia. Tucker suggested that Relator schedule the lectures at rheumatology practices or pain clinics that have a relationship with Dr Pegram. Rheumatology practices and pain clinics do not treat cataplexy or narcolepsy but do treat fibromyalgia.

119. Since Dr. Pegram is affiliated with Montclair Hospital, Relator asked him to give one lecture at a pain clinic and another in a rheumatology office affiliated with the hospital. Dr. Pegram agreed to do the lectures for a fee of $1,000 per lecture.

120. The talks were held on August 19 and 20, 2004. Relator was present for both talks. The August 19th talk was held at the office of rheumatologist Dr. Doug Bell. Dr Pegram spoke with Dr. Bell for approximately 15 minutes promoting the efficacy of Xyrem for treatment of fibromyalgia. Dr. Pegram also provided Dr. Bell with a copy of the abstract of the Scharf study concerning Xyrem treatment in 18 fibromyalgia patients. There were no other physicians present. Dr. Pegram was paid $1,000 for this brief encounter.

121. At the second talk, held on August 20, Dr. Pegram promoted Xyrem's efficacy in improving body pain and fibromyalgia to Dr. Doley and Dr. Columbia from the Doleys Pain Clinic at Montclair Hospital. Dr. Pegram provided both physicians with copies of the Scharf abstract. Dr. Pegram was paid $1,000 for this talk.

122. Relator was later chastised by her manager for not scheduling these off-label promotional talks earlier in the year since "your sales were so low."

d. Dr. F. Scott Perrino

123. Dr. F. Scott Perrino is an Internal Medicine Physician in the Tampa, Florida area. At an Orphan sales meeting for the Southeast Region in July 2004, Relator was told by several representatives in the Southeast Region that Lori Hammill, the representative in Tampa, had found a "gold mine," named Dr. Perrino, who wrote Xyrem off-label "hand over fist." Relator was told that Hammill and other representatives had great success boosting Xyrem sales by paying Dr. Perrino to give lectures to physicians in their areas.

124. Relator is informed and believes that Dr. Perrino's talks are devoted to promoting various off-label uses of Xyrem, Dr. Perrino's practice is in Internal Medicine. Internal Medicine physicians do not typically treat patients with narcolepsy, much less cataplexy associated with narcolepsy; therefore, Dr. Perrino would not be qualified to speak on the one approved use of Xyrem.

125. Orphan records show that Dr. Perrino was paid to speak on the following occasions in 2004:

LOCATION	DATE	SPEAKER FEE ($)
Tampa, FL	4/22/2004	500.00
Tampa, FL	4/28/2004	500.00
Tampa, FL	5/3/2004	500.00
Tampa, FL	5/17/2004	1,000.00
Dr. F. Scott Perrino	6/3/2004	1,000.00
Dr. G. Wheeler, Tampa, FL	7/6/2004	1,000.00
Hardeep Singh, MD, Tampa, FL	8/18/2004	1,000.00
Cheryl Carbicce, Tampa, FL	9/18/2004	650.00
Miami, FL	9/29/2004	1,500.00
James Jenkins, Charleston, SC	10/11/2004	1,500.00
Not listed	10/20/2004	1,500.00

Ft. Lauderdale, FL	12/13/2004	1,500.00
Private Practice, Homestead, FL	12/15/2004	650.00
	Total:	$12,800

126. The speaker fees paid to Dr. Perrino reflect Orphan's practice of identifying individual physicians who prescribe Xyrem off-label, and then paying that individual to speak about the off-label benefits of Xyrem to colleagues in his or her area or in neighboring areas.

e. Dr. David Knapp

127. Dr. David Knapp is a rheumatologist in Nashville, Tennessee. He has several patients on Xyrem for fibromyalgia. Orphan pays him to give lectures in which he promotes Xyrem for treatment of fibromyalgia.

128. In Relator's telephone conversation on June 28, 2004 with her manager, David Tucker, in which Tucker criticized Relator's sales performance, see ¶74 supra, Relator asked what she could do to improve her sales. Tucker responded that she should contact Dr. David Knapp and arrange to have him speak in her territory. Tucker instructed Relator to set up a dinner lecture, and invite rheumatologists, pain management physicians, and anyone else who treats fibromyalgia.

129. Following that conversation, Relator immediately contacted Michael Thomas, the Orphan sales representative in Nashville that calls on Dr Knapp, and made arrangements for Dr. Knapp to come to Birmingham to speak.

130. Dr. Knapp came to Birmingham for two lectures, on August 26 and August 27, 2004. Relator was present at both lectures. At the August 26th lecture, Dr. Knapp promoted Xyrem for fibromyalgia, chronic pain, and as a weight loss/appetite suppressant - all off-label indications - to the following providers in Relator's territory: Dr. Cornelius from the Doleys Pain

Clinic; Dr. Hakim from the Greystone Fibromyalgia Clinic; nurse practitioner Faith Pearce from the Greystone Fibromyalgia Clinic; and Dr. Gordon Kirschberg, a neurologist who treats fibromyalgia at the Brookwood Medical Center. At the August 27th lecture, Dr. Knapp promoted Xyrem for fibromyalgia to Dr Wynn Chatham, a rheumatologist at the University of Alabama rheumatology clinic. Dr. Knapp was paid $1,000 for the August 26 event (a dinner meeting) and $650 for the August 27th one-on-one talk.

131. As part of his standard presentation, Dr. Knapp uses a power point presentation that contains a slide promoting the use of sodium oxybate (i.e., Xyrem) in patients with fibromyalgia. The slide presentation cites the Scharf study and states, inter alia, that sodium oxybate reduces symptoms of pain and fatigue in patients with fibromyalgia.

132. In addition to the August events, Dr. Knapp spoke at lectures in Relator's territory on June 3, 2004 (Antioch, Tennessee) and June 22, 2004 (Nashville, Tennessee). He was paid $650 for each of these two events. These lectures were attended by another representative. Relator is informed and believes that Dr. Knapp promoted Xyrem for fibromyalgia in these lectures. Since Dr. Knapp is a rheumatologist, he is qualified to speak on the topic of fibromyalgia but not on the topic of narcolepsy.

f. Dr. Idan Sharon

133. In December 2004, Todd Courtney, a Xyrem sales representative in the New York area, told Relator about Dr. Idan Sharon. According to Courtney, Dr. Sharon is a New York physician who writes prescriptions for Xyrem off-label. Courtney stated that he has used Dr. Sharon as a paid speaker in the New York area to promote Xyrem's use in the treatment of several off-label indications, including fibromyalgia, excessive daytime sleepiness, psychiatric

disorders, and movement disorders. According to Orphan records, Orphan paid Dr. Sharon to speak on the following occasions in Courtney's territory in 2004:

LOCATION	DATE	SPEAKER FEE ($)
New York, NY	5/18/2004	1,500.00
New York, NY	6/8/2004	1,500.00
New York, NY	6/30/2004	1,500.00
New York, NY	7/30/2004	1,500.00
New York, NY	8/12/2004	1,500.00
New York, NY	8/26/2004	1,500.00
	Total:	$9,000

g. Dr. George Juetersonke

134. In December 2004, Amy Neb, a Xyrem sales representative located in Colorado, told Relator about Dr. George Juetersonke, who practices medicine in Colorado Springs, Colorado. Neb told Relator that Dr. Juetersonke prescribes Xyrem for fibromyalgia and insomnia, and that she trained him to be an effective speaker who promotes Xyrem for these off-label indications to other physicians. According to Orphan records, Orphan paid Dr. Juetersonke to speak on at least the following occasions in 2004:

LOCATION	DATE	SPEAKER FEE ($)
Biaggi's Ristorante, Colorado Springs, CO	4/29/2004	650.00
Office of Dr. T. Higginbotham, Colo. Sprgs,CO	9/1/2004	250.00
Office of Dr. Kippels, Dallas, TX	9/20/2004	450.00
The Boulder Cork, Boulder, CO	10/14/2004	1,000.00
Cool River Café, Greenwood Village, CO	10/14/2004	750.00
	Total:	$3,100

h. Dr. Manoj Waikar

135. In December 2004, Dan Pardi, the Xyrem sales representative who covers the San Francisco territory, told Relator that he developed Dr. Manoj Waikar, who prescribes Xyrem off-label, to be an effective speaker on behalf of Orphan. According to Pardi, Dr. Waikar's talks have helped to persuade other physicians in the San Francisco area to prescribe Xyrem off-label. Orphan records show that Orphan paid Dr. Waikar to speak on at least the following occasions in Pardi's territory in 2004:

LOCATION	DATE	SPEAKER FEE ($)
Office of Dr. Ann Bogan, San Francisco, CA	6/23/2004	500.00
Office of Dr. Richard Lannon, San Francisco CA	9/27/2004	450.00
Gardner Family Clinic, Palo Alto CA	10/4/2004	650.00
Private Practice Dr., San Francisco CA	10/19/2004	450.00
	Total:	$2,050

i. Dr. David Harris

136. Dr. David Harris is a Pain Management and Rehabilitation Medicine specialist. In December 2004, Linda Lossman, the Orphan sales representative who covers Texas, told Relator that she talked Dr. Harris into treating his fibromyalgia patients with Xyrem, and then offered him money to speak on behalf of Orphan to other physicians in his speciality. According to Lossman, Dr. Harris' lectures helped increase off-label sales of Xyrem in her territory. Company records show that Orphan paid Dr. Harris to speak on at least the following occasions in Lossman's territory in 2004:

LOCATION	DATE	SPEAKER FEE
Austin, TX	5/18/2004	$ 500
Austin, TX	6/8/2004	$ 500
Austin, TX	6/15/2004	$ 500
Austin, TX	8/31/2004	$ 750

Total: $2,250

j. Dr. Ward Dean

137. Dr. Ward Dean is an outspoken advocate for GHB. He has written a book promoting the benefits of GHB, entitled, "GHB the Natural Mood Enhancer." All of the uses of GHB that Dr. Dean advocates are off-label uses of Xyrem. Orphan records show that Lori Hamill, the Orphan sales representative in Tampa, Florida, utilized Dr. Dean as a speaker at least once in her territory. According to the records, Orphan paid Dr. Dean $1,000 to speak at a dinner on May 20, 2004 to one physician: Dr Mark Kanzler of Orlando, Florida. Hamill later expressed to Relator the need to keep Dr. Dean's activities "under the radar" because of his outspoken advocacy of Xyrem's off-label uses.

k. Dr. Scott Bell

138. When Relator's manager visited Relator in July 2004 to discuss her sales performance, he instructed Relator to put together a round table discussion in Montgomery, Alabama that would be moderated by Dr. Scott Bell. Dr. Bell is an alternative medicine physician who has put many patients on Xyrem for off-label uses. This program has not yet occurred as of the filing of this Complaint but is listed in Relator's 2005 "Business Plan" that was reviewed and approved by Tucker.

2. Targeting Specialties That Do Not Treat Narcoleptic Cataplexy

139. A large number of Orphan's paid promotional lectures are given at institutions and specialty practices that do not treat narcoleptic cataplexy, the only FDA-approved indication for Xyrem. Narcoleptic cataplexy is treated by pulmonologists, neurologists, and, more rarely, psychiatrists who specialize in sleep medicine. Orphan has paid speakers to present Xyrem promotional lectures at other specialty practices, such as pain clinics, rheumatology practices,

and internal medicine clinics, where the contemplated use of Xyrem is off-label (including treatment of fibromyalgia, fatigue, insomnia, and non-specific sleep disorders)..

140. Following are a few representative examples of institutions or practices that only treat conditions that are not approved for treatment with Xyrem, but where Xyrem promotional lectures took place in 2004:

INSTITUTION	DATE
Rehab Hospital of R.I.	April 12, 2004
Greenwood Internal Medicine Associates	May 6, 2004
Iowa Pain Management Institute	May19, 2004
Rehab Associates of Indiana-Indianapolis, IN	June 28, 2004
Arthritis and Pain Center, Clearwater Florida	June 16, 2004
West Coast Family Medicine	June 30, 2004
Dr. Doug Bell-Rheumatology Associates, Birmingham AL	August 19, 2004
Doleys Pain Clinic-Birmingham, AL	August 20, 2004
University of Alabama Rheumatology, Birmingham AL	August 27, 2004
Alvarado Rheumatology, San Diego CA	August 30, 2004
Headache and Pain Institute, Newport Beach CA	September 30, 2004

141. Orphan management is well aware of and encourages the targeting of these institutions for Xyrem sales promotion. Every speaking event that is scheduled must receive the prior approval of a regional sales manager. Orphan's internal procedure requires the sales representative to submit a request for the event - which includes the name of the speaker, the venue, and the intended invitees - on a request form that is sent to the regional sales manager, who must approve it before the event can take place.

3. Orphan's Xyrem Off-Label Message Was Taken Directly to Prescribing Physicians Through Frequent Office Visits by Sales Representatives

142. Orphan sales representatives attend every speaking event and are well aware of the off-label claims made by the speakers. Regional sales managers also frequently attend the off-label speaking events. The sales representatives follow up the events with in-office visits to the physician-invitees, to reinforce the strong off-label message in the presentations and to promote the use of Xyrem for such non-approved indications.

143. As noted above, Orphan's quota system requires its Xyrem sales force to promote the drug for off-label treatments. It is widely understood throughout every level of the company that the sales quota imposed on the representatives could not possibly be reached without promoting Xyrem for unapproved indications. To reach the quota, Orphan regional managers actively encourage the Xyrem sales representatives to make in-office visits to specialty practices that treat fibromyalgia, fatigue, insomnia and other off-label indications but that do not treat Xyrem's only on-label indication, narcoleptic cataplexy.

144. Relator's sales colleagues acknowledge that they promote Xyrem off-label. Indeed, one candidly acknowledged to her that she could not make her sales quota by limiting promotion to on-label indications, and estimated that eight out of ten of her prescriptions are off-label. Relator is informed and believes that this comment is representative of the experience of a large number of Xyrem sales representatives.

4. Orphan Engages In A Variety Of Other Off-Label Promotional Activities To Increase Xyrem Sales

a. Offering "Unrestricted Educational Grants" To Physicians As A Financial Inducement or Reward For Prescribing Xyrem Off-Label

145. In July 2004, Relator's manager, David Tucker, encouraged Relator to identify physicians' offices that had the potential to generate off-label business and offer them an "unrestricted educational grant" to develop a small "study" involving Xyrem treatment for off-

label indications. Tucker suggested, for example, giving $2,000 grants to doctors who agreed to put six fibromyalgia patients on Xyrem for a specified period of time.

146. The "study" suggested by Tucker was not contemplated as a rigorous clinical investigation. Rather, it was a marketing strategy to essentially buy off-label prescriptions by offering physicians financial incentives to put patients on Xyrem. Such grants are often referred to as "seeding trials." A seeding trial is a drug company-financed study in which, instead of providing free drug for use in the trial, the company provides the physician with the funds to purchase the drug. On the company's books, total sales revenue increases, which is particularly important for a company, such as Orphan, that is interested in enhancing its value in the eyes of potential corporate suitors.

147. Although Relator did not participate in this suggested activity, she is informed and believes that there have been such "grants" given by Orphan to physicians around the country, and in particular in those areas where sales appear to be extremely robust. Since the purpose of the payments is to directly promote off-label sales of Xyrem, it is a blatantly illegal business practice.

b. Promising Referrals In Exchange For Off-Label Promotion

148. Another ploy used by Orphan to promote off-label Xyrem sales involves promising patient referrals. As noted above, a key facet of Orphan's off-label promotional strategy is to identify physicians who prescribe Xyrem off-label and then enlist the physicians' assistance in persuading other doctors to do likewise. The most common method used by Orphan to enlist the assistance of the off-label prescribing physicians is to offer them lucrative speaker fees, as described above.

149. Another incentive offered by Orphan is the promise of referral business. Relator was informed by Orphan sales representative Linda Lossman that she uses this method to persuade off-label prescribers to speak on behalf of Orphan. (Of course, these speakers are also given speaker fees). Offering anything of value - whether speaker fees or the promise of referral business - to induce physicians to promote off-label sales of Xyrem violates both the prohibition on off-label marketing and the Anti-Kickback statute.

c. Other Off-Label Promotional Activities

150. In addition to the off-label promotional activities alleged above, Relator is informed and believes that Orphan engages in other off-label promotional practices, the specifics of which Relator is presently unaware. This belief is based on (I) the pattern and practice of conduct described above and (ii) the fact that Orphan management has established a corporate climate that tolerates and encourages off-label promotion of Xyrem. As further off-label promotional practices are identified, Relator will seek leave to amend this Complaint accordingly.

VII. ORPHAN BUSINESS PRACTICES ALSO DEFRAUD PRIVATE INSURERS

151. In addition to the state false claims acts cited in paragraph 12 above, the states of California and Illinois have enacted Insurance Fraud Prevention Acts that permit Relator to bring a qui tam action to recover for fraudulent claims submitted to *private* insurance companies in those states. See Counts IV and IX below.

152. Although this Complaint has focused on the impact of Orphan's practices on the federal and state governments, these practices also defraud private insurance companies that reimburse prescription drugs. The practices alleged herein are systematic, nationwide practices that defraud private insurance companies in every state where defendants conduct business, including the states of California and Illinois.

VII. RELATOR WAS THE SUBJECT OF RETALIATION

153. As alleged above, Orphan imposed a strict sales quota requirement on its sales representatives. In or about early 2004, Orphan raised its sales quotas significantly. Given Xyrem's extremely limited on-label indication, the sales quotas could only be achieved through off-label promotion.

154. Indeed, as described above ¶78-86, Relator's Manager, David Tucker, instructed her to promote Xyrem off-label under implicit threat of termination if she did not increase her new patient enrollment.

155. As Relator grew increasingly uncomfortable with Orphan's marketing practices, she began investigating the extent of the illegal conduct alleged in this complaint. Among other things, Relator engaged in numerous discussions about Orphan's practices with other company sales representatives to confirm the depth and nation-wide scope of the illegality.

156. Orphan became aware of relator's investigation, and by letter of late 2004 or early 2005, ordered Ms. Lauterbach that she must stop contacting her colleagues and discussing the company's marketing and off-label promotion practices. She was also told by Orphan that she would be severely disciplined - up to and including termination - if she did not stop. As a result of her investigation in furtherance of this False Claims Act action and unwillingness to engage in illegal promotion, Ms. Lauterbach was terminated by Orphan in early 2005.

Count I
False Claims Act 31 U.S.C. §§3729(a)(1) and (a)(2)

157. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

158. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

159. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

160. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

161. Each prescription that was written as a result of defendants' illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, illegally-induced prescriptions, or prescriptions with false diagnosis codes submitted to a federal health insurance program represents a false or fraudulent claim for payment.

162. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by numerous separate entities, across the United States. Relator has no control over or dealings with such entities and has no access to the records in their possession.

163. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

164. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

Count II
False Claims Act 31 U.S.C. §3730(h)

165. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

166. Beginning in 2004 and continuing to the date of filing this Complaint, Relator has taken actions to investigate the allegations set forth herein; to set the stage for the initiation of this lawsuit; and to assist undersigned counsel in the preparation of the instant Complaint, and in preparing to disclose defendant's fraudulent scheme to the appropriate governmental officials.

167. These actions were fully lawful, and are protected actions of Relator pursuant to 31 U.S.C. § 3730(h), the federal False Claim Act's anti-retaliation action.

168. On information and belief, Relator was fired, in whole or in part, because Orphan learned of her federally protected efforts with respect to this False Claims Act lawsuit.

Count III
California False Claims Act
Cal Govt Code §12651(a)(1) and (2)

169. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

170. This is a claim for treble damages and penalties under the California False Claims Act.

171. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

172. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

173. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

174. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

175. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count IV
California Insurance Frauds Prevention Act
California Insurance Code § 1871.7

176. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 156 above as though fully set forth herein.

177. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as "the Act"). The Act provides for civil recoveries against persons who violate the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code §1871.7(b).

178. Subsection (e) of Cal. Ins. Code §1871.7 provides for a qui tam civil action in order to create incentives for private individuals who are aware of fraud against insurers to help disclose and prosecute the fraud. Cal. Ins. Code §1871.1(e). The *qui tam* provision was patterned after the Federal False Claims Act, 31 U.S.C. §§3729-32, and the California False

Claims Act, Cal. Gov't Code §§12650 et seq. Subsection (a) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who "knowingly employ runners, cappers, steerers, or other persons . . . to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer." Subsection (b) of Cal. Ins. Code §1871.7 permits any interested person to bring a civil action in the name of the State of California for violation of Penal Code sections 549 or 550.

179. Section 549 of the California Penal Code provides criminal penalties for anyone who:

> solicits, accepts, or refers any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether, the individual or entity . . . intends to violate Section 550.

180. Section 550 of the Penal Code prohibits the following activities, among others:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * * * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.
>
> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.
>
> * * * * * *
>
> (b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:
>
> (1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an

> insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

181. By virtue of the acts described in this Complaint, defendants violated Cal. Ins. Code §1871.7(a) by knowingly employing runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that were the basis for claims against private insurers in the State of California.

182. By virtue of the acts described in this Complaint, defendants violated California Penal Code §549 by soliciting, accepting, or referring business to or from individuals and entities with the knowledge that, or with reckless disregard for whether, the individuals or entities intended to violate California Penal Code §550.

183. By virtue of the acts described in this Complaint, defendants knowingly presented or caused to be presented, false or fraudulent claims for health care benefits, in violation of Penal Code §550(a).

184. By virtue of the acts described in this Complaint, defendants also concealed and/or failed to disclose information that would have affected the rights of patients and/or pharmacies to receive reimbursement for Xyrem prescriptions, in violation of Penal Code §550(b).

185. By virtue of these violations of California Penal Code §§549 and 550, defendants violated California Insurance Code §1871.7(b).

186. Each prescription that was written as a result of defendants' illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal

inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a health insurer represents a false or fraudulent claim for payment.

187. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

188. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continue to pay the claims that would not be paid but for defendants' unlawful conduct.

189. The California State Government is entitled to receive three times the amount of each claim for compensation submitted by defendants in violation of Cal. Ins. Code §1871.7. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count V
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1) and (2)

190. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

191. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

192. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

193. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

194. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

195. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

196. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VI
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

197. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

198. This is a claim for treble damages and penalties under the Florida False Claims Act.

199. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

200. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

201. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

202. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

203. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VII
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

204. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

205. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

206. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

207. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

208. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid

and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

209. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

210. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VIII
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1), (2)

211. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

212. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

213. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

214. By virtue of the acts described above, Pharmacia knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

215. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

216. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

217. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count IX
Illinois Insurance Claims Frauds Prevention Act
740 Ill. Comp. Stat. §92

218. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 156 above as though fully set forth herein.

219. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92/1 et seq. ("Illinois Insurance Fraud Act").

220. Subsection 5(a) of the Illinois Insurance Fraud Act provides for a civil cause of action for any person who commits the crime of insurance fraud or who knowingly offers or pays "any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer." 740 Ill. Comp. Stat. §92/5(a).

221. Pursuant to 720 Ill. Comp. Stat. §5/46-1 of the Illinois Criminal Code, a person commits the offense of insurance fraud when he or she:

> knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company . . . .

720 Ill. Comp. Stat. §5/46-1(a).

222. Subsection 15(a) of the Illinois Insurance Fraud Act provides for a qui tam civil action in order to create incentives for private individuals to disclose and prosecute violations of

the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. §92/15(a).

223. By virtue of the acts described in this Complaint, defendants committed the following acts, or aided and abetted the commission of the following acts, in violation of the Illinois Insurance Fraud Act:

(a) defendants knowingly offered or paid remuneration directly or indirectly, in cash or in kind, to induce other persons to procure clients or patients to obtain services or benefits under a contract of insurance or that would be the basis for a claim against an insurer, in violation of 740 Ill. Comp. Stat. §92/5(a); and

(b) defendants knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat. §92/5(b) and 720 Ill. Comp. Stat. §5/46-1(a).

224. Each prescription that was written as a result of defendants' illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a health insurer represents a false claim for payment.

225. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

226. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continue to pay the claims that would not be paid but for defendants' unlawful conduct, and have been damaged thereby.

227. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by defendants in violation of 740 Ill. Comp. Stat. §92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count X
Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5-2(b)(1) and (2)

228. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

229. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

230. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

231. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

232. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

233. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

234. The State of Indiana is entitled to the maximum penalty of at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XI
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §437 et. seq.

235. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 156 above as though fully set forth herein.

236. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

237. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

238. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

239. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Louisiana State Government.

240. Each prescription that was written as a result of defendants' illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for

reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

241. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

242. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

243. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

244. Additionally, the Louisiana State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XII
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1), (2)

245. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

246. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

247. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

248. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

249. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

250. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

251. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIII
Michigan Medicaid False Claims Act
Mich. Public Act 337

252. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

253. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

254. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

255. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

256. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

257. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

Count XIV
Montana False Claims Act
Mont. Gen. Laws 17-8-403 (1)(a) and (b)

258. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

259. This is a claim for treble damages and penalties under the Montana False Claims Act.

260. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

261. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

262. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid

and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

263. By reason of the defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

264. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XV
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a), (b)

265. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

266. This is a claim for treble damages and penalties under the Nevada False Claims Act.

267. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

268. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

269. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

270. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

271. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVI
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(a), (b), and (e)

272. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 156 above as though fully set forth herein.

273. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

274. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

275. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

276. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Hampshire State Government.

277. Each prescription that was written as a result of defendants' illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for

reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

278. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

279. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

280. By reason of the defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

281. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVII
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-2F-1 et seq.

282. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

283. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

284. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

285. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

286. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

287. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

288. The State of New Mexico is entitled to the maximum penalty allowed by law for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVIII
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

288. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

290. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

291. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

292. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

293. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

294. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

295. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIX
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

296. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

297. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

298. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

299. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

300. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used defendants' illegal off-label marketing practices and illegal inducements.

301. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

302. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1), (2)

303. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

304. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

305. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

306. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

307. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

308. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

309. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XX
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §1-1188.14(a)(1), (2)

310. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

311. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

312. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

313. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

314. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

315. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

316. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Prayer

WHEREFORE, Relator prays for judgment against the defendants as follows:

1. that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the counterpart provisions of the state statutes set forth above;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment against defendants in an amount equal to three times the amount of each claim for compensation submitted by defendants in violation of Cal. Ins. Code §1871.7, plus a civil penalty of $10,000 for each violation of Cal. Ins. Code §1871.7(b);

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. §68.082(2);

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

9. that this Court enter judgment against defendants in an amount equal to three times the amount of each claim for compensation submitted by defendants in violation of 740 Ill. Comp. Stat. §92, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §92;

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus a civil penalty of at least $5,000 for each violation of IC 5-11-55;

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana s has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437;

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of MI Public Act 337;

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mont. Stat. Ann. 17-8-401;

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I;.

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-2F-4;

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(1);

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §2-308.14(a);

22. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

23. that Relator be awarded all costs of this action, including attorneys' fees and expenses;

24. that Relator recover two times her back pay, plus interest, lost as a result of the defendant's retaliatory discharge;

25. that Relator be reinstated;

26. that Relator recover special damages suffered as a result of defendant's retaliatory discharge; and

27. that Relator recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: February 17, 2006

JONATHAN A. WILLENS, LLC

By: _____

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