UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, et al., ex rel. [under seal] Plaintiffs, v. [under seal], Defendants	C.A. No. 1: 03-cv-10641 (J. Gertner). FIFTH AMENDED COMPLAINT

FILED IN CAMERA AND UNDER SEAL

Erika A. Kelton
PHILLIPS & COHEN LLP
2000 Massachusetts Ave NW
Washington, D.C. 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Howard M. Brown (B.B.O. # 547948)
BARTLETT HACKETT FEINBERG PC
155 Federal St., 9th Floor
Boston, MA 02110
Tel: (617) 422-0200
Fax: (617) 422-0383

Attorneys for [under seal]

Erika A. Kelton
PHILLIPS & COHEN LLP
2000 Massachusetts Ave NW
Washington, D.C. 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Howard M. Brown (B.B.O. # 547948)
BARTLETT HACKETT FEINBERG PC
155 Federal St., 9th Floor
Boston, MA 02110
Tel: (617) 422-0200
Fax: (617) 422-0383
Attorneys for Qui Tam Plaintiffs

UNITED STATES DISTRICT COURT
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UNITED STATES OF AMERICA EX REL. THOMAS GERAHTY and MATTHEW BURKE Plaintiffs, v. GLAXOSMITHKLINE PLC and SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE Defendants	) C.A. No. 1: 03-cv-10641 (J. Gertner))) FIFTH AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; COLORADO MEDICAID FALSE CLAIMS ACT [Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*]; CONNECTICUT FALSE CLAIMS ACT [2009 Ct. P.A. 5]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. §1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 et seq.]; GEORGIA FALSE MEDICAID CLAIMS ACT [Ga. Code Ann. §49-4-168 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.]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [Ind. Code Ann. §5-11-5.5-1 et seq.]; LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW [La. Rev. Stat. §437 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 §5 et seq]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp. Laws § 400.601 et seq]; MONTANA FALSE CLAIMS ACT [Mont. Code Ann. §17-8-401 et seq.];NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Rev. Stat. Ann. §167.61 et seq.]; NEW JERSEY FALSE CLAIMS ACT [N.J. Stat. § 2A:32C-1 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. §27-2F-1 et seq.]; NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. §187 et seq.]; NORTH CAROLINA FALSE CLAIMS ACT [NC Gen. Stat. § 1-605 et seq.]; OKLAHOMA MEDICAID FALSE CLAIMS

ACT [Okla. Stat. Tit. 63 §5053 et seq.]; RHODE ISLAND FALSE CLAIMS ACT [R.I. Gen. Laws § 9-1.1 et seq.]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. '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.]; WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT [Wis. Stat. § 20.931 et seq]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.13 et seq.]

FILED IN CAMERA
AND UNDER SEAL

JURY TRIAL DEMANDED

Plaintiffs Thomas Gerahty and Matthew Burke, through their attorneys Phillips & Cohen LLP and Bartlett Hackett Feinberg PC, on behalf of the United States of America, the State of California, the State of Colorado; the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, 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 Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Virginia, the State of Wisconsin, and the District of Columbia (collectively "the States and the District of Columbia"), for their Complaint against defendants GlaxoSmithKline PLC and SmithKline Beecham Corp. d/b/a GlaxoSmithKline allege based upon personal knowledge and relevant documents, as follows.

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America, the States and the District of Columbia arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by

defendants GlaxoSmithKline PLC and SmithKline Beecham Corp. d/b/a GlaxoSmithKline (collectively "Glaxo") and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et seq., as amended ("the FCA" or "the Act").

2. As set forth below, Glaxo's acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5, et seq.; the Connecticut False Claims Act, 2009 Ct. P.A. 5; 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 Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168 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; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §5-11-5.5-1 et seq.; the 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.; the Michigan False Claims Act, Mich. Comp. Laws § 400.601 et seq; the Montana False Claims Act, Mont. Code 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. Rev. Stat. Ann. §167.61 et seq.; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-1 et seq.; the New York False Claims Act, N.Y. State Fin. §187 et seq.; the North Carolina False Claims Act, NC Gen. Stat. § 1-605 et seq.; the Oklahoma Medicaid false Claims Act, Okla. Stat. tit. 63 §5053 et seq.; the Rhode Island False Claims Act, RI Gen. Laws §9-1.1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 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.; the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 et seq.

3. Since at least the late 1990s, it has been Glaxo's practice to systematically and illegally promote numerous prescription drugs for off-label indications. Among the prescription drugs Glaxo has promoted for off-label uses are Wellbutrin SR, Valtrex, Zofran, Lamictal, Advair, and Imitrex. Additionally, Glaxo has extensively marketed Advair for medically unnecessary treatments, contrary to prevailing standards and federal recommendations for asthma care.

4. In addition to and in support of its off-label marketing efforts, Glaxo offered and made substantial financial inducements to providers to encourage them to prescribe Glaxo drugs, and/or to switch from competitor products. As alleged below, Glaxo disguised physician inducements as consulting fees for "special advisory boards," payments for "reprint mastery training," "preceptorships," and speaking fees, among other things. Among the prescription drugs Glaxo promoted with illegal inducements are Wellbutrin SR, Valtrex, Imitrex, Lamictal and Advair, at least.

5. At least since the late 1990s, Glaxo has illegally promoted Wellbutrin SR – an antidepressant medication – for off-label indications. Wellbutrin SR has a single, FDA-approved indication – i.e., depression. As alleged below, Glaxo mounted a national marketing campaign to promote Wellbutrin SR for a broad range of unapproved uses from weight loss to chronic fatigue syndrome. Glaxo's improper marketing of Wellbutrin SR has been immensely profitable. In a mere four and a half years Wellbutrin SR was transformed into one of Glaxo's crown jewels,

with sales revenues that more than quadrupled.

6. Glaxo has also illegally promoted Lamictal for off-label treatments. Lamictal's on-label indications are for use as an adjunctive therapy in the treatment of partial seizures in adults and pediatric patients over 2 years of age, and for use in treating the generalized seizures of Lennox-Gastaut syndrome in adult and pediatric patients. In 2003, Lamictal was approved for use in treating Bipolar I Disorder. Glaxo has impermissibly promoted Lamictal as a treatment for Bipolar Disorders generally, and for Bipolar I Disorder well in advance of its approval, as well as for neuropathic pain and pain management.

7. Likewise, Glaxo has aggressively promoted Valtrex off-label (i) for the suppression of genital herpes in HIV-infected patients; (ii) the treatment of cold sores; and (iii) the prevention of herpes transmission – many years in advance of receiving FDA approval for those indications in mid-2003 and late 2002. Glaxo also improperly promoted Valtrex for the off-label treatment of Bell's palsy, multiple sclerosis, mononucleosis, and chicken pox among other uses.

8. Glaxo further disregarded federal law by promoting Zofran for off-label use. Zofran's on-label indications are limited to use in preventing post-operative nausea and vomiting and in preventing nausea and vomiting associated with certain enumerated types of cancer chemotherapy and radiotherapy. Although Zofran is a "Pregnancy Category B" drug, and there are "no adequate and well-controlled studies in pregnant women," Glaxo improperly promoted Zofran as an anti-nausea treatment for morning sickness in pregnant women.

9. Glaxo's improper marketing scheme also extends to its blockbuster drug Advair. Although federal guidelines limit use of Advair's "combination therapy" to individuals with

moderate and severe asthma, Glaxo made, and continues to make, a concerted effort to market Advair for patients with mild asthma. Such treatments are medically unnecessary and Glaxo's promotion has false and fraudulent claims for payment to be submitted to, and paid by, federal and state healthcare programs.

10. Advair's single on-label indication was for the treatment of asthma in individuals over 12 years old until 2003, when Advair 250/50 ("Advair 250") was approved for treating chronic obstructive pulmonary disease ("COPD") associated with chronic bronchitis. In April 2004, Advair was approved for use in children over 4 with asthma, and who are symptomatic on inhaled corticosteroid therapy alone. Notwithstanding the absence of FDA approval and serious questions concerning Advair's safety, Glaxo actively promoted the drug for pediatric and COPD treatments years in advance of any approval for those uses, including at the highest dose – Advair 500/50 ("Advair 500"). Moreover, even after Advair 250 was approved for treatment of COPD, Glaxo continued to focus much of its COPD marketing efforts on promoting Advair 500, a higher, more expensive, and riskier dosage, which the FDA had explicitly refused to approve for treatment of COPD.

11. Finally, Glaxo's illegal practices also reach Imitrex, its popular migraine drug. As detailed below, Glaxo's marketing of Imitrex heavily relied on promotion through illegal financial inducements and off-label promotion of Imitrex for an entire spectrum of headaches – not just migraines.

12. For ease of reference, Wellbutrin SR, Valtrex, Zofran, Imitrex, Advair and Lamictal will be referred to collectively as "the Glaxo prescription drugs" for the remainder of this Complaint.

13. As a direct result of Glaxo's improper practices, federal and state health insurance programs including, but not limited to, Medicaid, MediCal, CHAMPUS/TRICARE, CHAMPVA and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement of off-label uses of the Glaxo prescription drugs that would not have been paid but for the defendants' illegal business practices.

14. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986 and 2009. Congress amended the Act in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments 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 legal resources to prosecuting fraud on the Government's behalf.

15. The Act 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.

16. The Act 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 Act 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.

17. Based on these provisions, qui tam plaintiffs seek through this action to recover damages and civil penalties arising from Glaxo's making or causing to be made false or fraudulent records, statements and/or claims in connection with its knowing off-label marketing of prescription drugs. Although Glaxo did not directly submit claims for prescription drugs to federal and state health insurance programs, it knew that its illegal off-label marketing practices and illegal inducements would cause the submission of thousands of claims to these health programs for prescriptions that were not eligible for program reimbursement.

II. PARTIES

18. Plaintiff/relator Thomas Gerahty is a resident of Baltimore, Maryland. Mr. Gerahty was employed by Glaxo as a Senior Marketing Development Manager for Pennsylvania, western New York and southern New Jersey.

19. Plaintiff/relator Matthew Burke is a resident of Moorestown, New Jersey. Mr. Burke was employed by Glaxo from 1986 to 2003.

20. Defendant GlaxoSmithKline plc ("GSK") is a public limited company, incorporated under English law, with headquarters in Brentford, England. It has operational headquarters in Research Triangle Park, North Carolina and in Philadelphia, Pennsylvania. GSK is one of the world's leading pharmaceutical companies, with approximately seven percent of the pharmaceutical market. As of the initial filing of this action, GSK employed approximately 100,000 people worldwide, about 44,000 of whom have roles in sales and marketing, which represents one of the largest sales force in the pharmaceutical industry.

21. Defendant SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("GlaxoSmithKline") is a Pennsylvania corporation with headquarters in Philadelphia. It is the United States subsidiary of GSK.

22. Until 2000, Glaxo was two separate corporate entities – Glaxo Wellcome plc ("GW") and SmithKline Beecham plc ("SKB"). GW and SKB each had United States subsidiaries, Glaxo Wellcome Inc ("GW Inc.") and SmithKline Beecham Corp. ("SKB Corp."), respectively. In 2000, GW and SKB merged to create the new corporate entity GlaxoSmithKline plc. In addition, GW Inc. and SKB Corp. also merged, with SKB Corp. as the surviving entity. In 2001, SKB Corp. filed to do business under the "fictitious name" GlaxoSmithKline. As a result of the merger transactions, GlaxoSmithKline plc and GlaxoSmithKline are responsible for liabilities resulting from the acts or omissions of GW, SKB and GW Inc. that occurred prior to the 2000 merger transaction.

III. JURISDICTION AND VENUE

23. 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. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

24. This Court has personal jurisdiction and venue over the defendants pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, or transact or have transacted business in the District of

Massachusetts.

25. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendants can be found in and transact or have transacted business in the District of Massachusetts. At all times relevant to this Complaint, defendants regularly conducted substantial business within the District of Massachusetts, maintained employees and offices in Massachusetts and made significant sales within Massachusetts. In addition, statutory violations, as alleged herein, occurred in this district.

IV. BACKGROUND

26. Glaxo is one of the largest – and most profitable – pharmaceutical companies in the world. It manufactures a wide range of prescription products including, inter alia, drugs for the treatment of central nervous system, respiratory, cardiovascular, and gastro-intestinal disorders, as well as cancer treatments. Among the prescription drugs manufactured by Glaxo are Wellbutrin SR, Valtrex, Zofran, Lamictal, Advair, and Imitrex – all of which are the subject of this Complaint.

27. Glaxo pharmaceutical sales and marketing are organized by therapeutic area. Wellbutrin SR, Lamictal, Valtrex, Imitrex and Advair sales and marketing efforts are undertaken by Glaxo's Central Nervous System ("CNS") Division. During the period at issue, Stan Hull has been the Senior Vice President of Glaxo's CNS Division, and thus has supervised the marketing and sales activities concerning these prescription drugs. Zofran sales and marketing are conducted by Glaxo's Oncology Division ("Oncology"), which is headed by Kevin Lokay, Vice President of Oncology. Until approximately late 2001, Advair's sales and marketing were conducted by Glaxo's Respiratory Division, headed by Jim Daly. In or about early 2002,

Glaxo's Respiratory Division was combined with its CNS Division, headed by Mr. Hull.

28. In the United States, Glaxo's sales and marketing are undertaken through 14 regions, each of which is organized into numerous sales districts. Approximately 7,000 sales representatives are engaged in promoting the Glaxo prescription drugs at issue. Each Glaxo sales representative reports to a District Sales Manager, who in turn reports to a Regional Vice President. Each region also has an assigned Marketing Development Manager who serves as a liaison between Glaxo's sales and marketing arms, and between Glaxo headquarters and the field.

29. Glaxo sales representatives receive incentive-based compensation that includes an annual salary, plus a quarterly bonus. An individual sales representative's bonus is determined by his/her performance in the relevant market and whether s/he satisfies or surpasses targets for quarterly market share change. Accordingly, the more prescription drug sold by a Glaxo sales representative or prescribed by a provider in his or her territory, the higher his or her compensation will be. In addition, Glaxo's sales organizations offer additional incentives such as Hawaiian vacations for winners of periodic sales challenges. See Exhibit 1. (Exhibits are included electronically on the CD attached to this Complaint.)

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

30. 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.

31. 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.

32. 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).

33. 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) & ©. 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).

34. 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.

35. 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.

36. 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) & ©.

37. 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.

38. With regard to the first practice – disseminating written information – the FDAMA only 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.

39. 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, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

40. 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, the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

41. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

1. The Medicaid Program

42. Medicaid is a public assistance program providing for payment of medical expenses for low-income 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.

43. 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. 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).

44. 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). During the time period relevant to this Complaint, the off-label uses of Wellbutrin SR promoted by Glaxo were not eligible for reimbursement from Medicaid because the drug's off-label uses were neither listed in the labeling approved by the

FDA nor included in any of the drug compendia specified by the Medicaid statute.

2. Other Federal Health Care Programs

45. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/ TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

46. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, e.g.,TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

47. During the time period relevant to this Complaint, the off-label uses of Wellbutrin SR promoted by Glaxo did not qualify for reimbursement under any of the various federal health care programs.

3. The Anti-Kickback Statute

48. 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.

49. 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, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, or other federal health care program.

50. 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.

51. 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 violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General are drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. Id.

52. Compliance with the Anti-Kickback law is a precondition to participation as a

health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal 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. In Massachusetts and a number of other 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.

53. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians 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.

VI ALLEGATIONS

A. Glaxo Extensively Promoted Wellbutrin SR For Off-Label Treatments

54. One of Glaxo's leading prescription drug products is an antidepressant named Wellbutrin SR (sustained release) which was introduced to market in the mid-1990s. It was preceded to market and FDA approval by Wellbutrin IR (immediate release), which was introduced December 1985. Wellbutrin XL was approved in August 2003 as a once-daily alternative to Wellbutrin SR for the treatment of depression.

55. Wellbutrin SR has only one on-label indication – i.e., the treatment of depression in patients 18 years of age and older. A diagnosis of depression is defined as (1) depressed mood

or (2) loss of interest or pleasure, and at least five of the following symptoms are present during a two week period and represent a change in previous behavior – depressed mood, markedly diminished interest or pleasure in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, and a suicide attempt or suicide ideation.

56. Wellbutrin SR is contraindicated in patients with, inter alia: a seizure disorder; a current or prior diagnosis of bulimia or anorexia; in patients undertaking an abrupt discontinuation of alcohol or sedatives. Indeed, Wellbutrin IR (which contains the same active agent as Wellbutrin SR) was withdrawn from the market for approximately three years because of seizure concerns.

57. Wellbutrin SR is unique among antidepressants. Its active pharmacological agent – bupropion – is classified as a dopamine reuptake blocking compound, and works by increasing levels of the chemical neurotransmitters dopamine and norepinephrine.

58. Wellbutrin SR's primary competitors include Paxil, Prozac, Zoloft, Effexor and Celexa, among others. These antidepressants are categorized as selective serotonin reuptake inhibitors ("SSRIs").

59. SSRIs are, by far, the most popular antidepressants and represent the vast majority of the antidepressant market share. Because Wellbutrin SR and the SSRIs have the same single on-label indication – depression – they are direct competitors. Wellbutrin SR and the SSRIs, however, have different side effect profiles. In its on-label use in treating depression, Wellbutrin SR has been found to have less impact on weight gain and sexual function than the SSRIs.

60. Glaxo may properly distinguish Wellbutrin SR and the SSRIs on the basis of their respective side effect profiles in the treatment of depression. It is, however, illegal for Glaxo to promote Wellbutrin SR for treatment of SSRI-induced side effects, for the treatment of co-morbidities, or for the treatment of any condition other than the drug's single, FDA-approved on-label depression indication.

61. A co-morbidity is a disorder that may appear with other separate disorders. It is a separate and distinct indication and is properly treated as such. Although a disorder may tend to appear with another disorder, a drug may not be promoted to treat a co-morbid disorder unless it is specifically FDA-approved for that indication. Thus, an antidepressant may not be promoted as a treatment for a "co-morbid" disorder that may sometimes afflict a depressed individual, unless the drug is specifically approved by the FDA for that indication.

62. Likewise, an antidepressant may not be promoted to treat the side effects of other anti-depressants (as opposed to the underlying depression) unless specifically approved by the FDA for the treatment of those side effect indications.

63. Since its introduction, Wellbutrin SR has suffered from a significant marketing hurdle. Surveys conducted by or on behalf of Glaxo have consistently shown that the drug is not perceived as an effective treatment for depression – Wellbutrin SR's only on-label indication. See Exhibit 2, 3 and 4.

64. Beginning in or about 1999, Glaxo initiated efforts to surmount this obstacle through the systematic and rigorous off-label promotion of Wellbutrin SR. The results were hugely profitable. In 1999, Wellbutrin SR revenues were approximately $590 million, and in 2000 its revenues jumped to nearly $800 million. In 2001, they again increased to approximately

$1.1 billion and again in 2002 to approximately $1.6 billion. In 2003, at the time of filing the initial complaint in this action, Wellbutrin SR revenues are on track to exceed $2.1 billion.

65. Since implementing its off-label promotion of Wellbutrin SR, Glaxo's sales of the drug have increased between approximately 35 and 45 percent each year.

66. As alleged below, Glaxo's off-label marketing and promotional campaign combined aggressive speaker and "special issue" board events saturated with off-label messages, with targeted sales calls on prescribing physicians by field representatives to reinforce the off-label messages and translate them into increased drug sales.

67. Further, Glaxo utilized paid "reprint mastery training" and "preceptorships" and to disseminate off-label uses of Wellbutrin SR. In addition, Glaxo impermissibly influenced CME program content to further promote off-label uses of Wellbutrin SR.

68. As detailed below, Wellbutrin SR's commercial success is the result of Glaxo's impermissible and illegal off-label marketing campaign. As a direct result of Glaxo's illegal practices, federal government health insurance programs have been induced to reimburse claims for prescriptions that they otherwise would not have.

1. The Internal Glaxo Marketing Strategy For Wellbutrin SR Was Driven By Lucrative Off Label Markets

69. Beginning in mid-1999, Glaxo's national marketing strategy for the Wellbutrin SR brand recognized that its off-label uses could provide potentially large gains in sales and revenues for the drug. Prior to 1999, the Wellbutrin brand struggled to overcome concerns that the drug elevated risk of seizure. Glaxo surmounted that hurdle, however, by incorporating strong off-label messages into its promotion of Wellbutrin SR.

70. As alleged below, Glaxo's off-label promotion of Wellbutrin SR was opportunistic, and targeted especially marketable areas of concern for individual health and quality of life – e.g., enhancing sex life, improving weight and body image, addressing substance addictions and managing attention issues. In the United States, these areas represent multi-billion dollar markets every year.

71. In 1999, Glaxo instituted "Operation Hustle" – a national sales campaign. In meetings with national sales and marketing force in approximately 17 cities around the country, Glaxo introduced a new approach to selling Wellbutrin SR. See Exhibits 5, 5 and 7.

72. Rather than only focusing on Wellbutrin SR's on-label indication – i.e., depression – Glaxo's "Operation Hustle" campaign also addressed other, distinct disorders that are not FDA approved indications for Wellbutrin SR. In particular, Glaxo instructed its sales force to promote norepinephrine and dopamine, the neurochemical-agents that Wellbutrin SR acts to increase, as effective in treating certain "co-morbid" disorders. Specifically, Glaxo told its sales representatives that increasing levels of norepinephrine could address attention deficit/hyperactivity disorder ("ADHD"), addiction withdrawal syndrome, anxiety associated with depression, and such anxiety disorders as post-traumatic stress syndrome, panic disorder, social phobia, and generalized anxiety disorder. See Exhibits 5, 6, 7 and 8. See also Exhibit 9 (acknowledging, among other things, that Wellbutrin is "not indicated for anxiety disorders" though represents that its efficacy is equivalent to SSRIs in anxious depressed patients). Similarly, Glaxo advised its sales force that increasing levels of dopamine could address ADHD, craving, addiction, chronic fatigue syndrome, and cognitive dysfunction. See Exhibits 10, 11 and 12. In its promotional efforts, Glaxo particularly emphasized those disorders addressed by

increasing dopamine levels.

73. The message in Glaxo's "Operation Hustle" campaign was clear. Wellbutrin SR, by acting to increase levels of norepinephrine and dopamine, could be used to treat a substantially broader range of indications than mere depression. Glaxo represented that Wellbutrin SR's norepinephrine and dopamine combination was effective for numerous distinct and separate indications – from ADHD and addictions to chronic fatigue syndrome, craving and cognitive disorders.

74. Notwithstanding these claims, Glaxo did not seek FDA approval for these additional indications or any indications other than depression. Glaxo's expansive representations about the efficacy of and treatment options with Wellbutrin SR were based mainly on theoretical and speculative surmise rather than thorough, controlled scientific studies.

75. Although Glaxo characterized ADHD, addiction withdrawal syndrome, anxiety associated with depression, the anxiety disorders of post-traumatic stress syndrome, panic disorder, social phobia, and generalized anxiety disorder, craving, chronic fatigue syndrome, and cognitive dysfunction as "co-morbid disorders," they are all discrete diagnoses and indications, each of which has FDA-approved drugs for their treatment. As alleged above, Wellbutrin SR is not FDA-approved for any of these indications.

76. Over the next year of Operation Hustle, Wellbutrin SR's sales grew by 34 percent, to nearly $800 million.

77. In April of 2000, Glaxo developed another strategic plan for the Wellbutrin SR brand. That plan recognized that the recent sales successes of Wellbutrin SR over the past year were due to the "heavy promotion of new indications" as well as its side effect profile. See

Exhibit 13. Glaxo also acknowledged that, while Wellbutrin SR's usage for depression had grown by 20 percent, its use for "other" indications had grown by nearly 60 percent. Id. "Other" indications include all the distinct disorders identified in "Operation Hustle."

78. In 2000, Glaxo's marketing plan continued to identify sales opportunities in non-depression indications including ADHD, anxiety, lethargy and bi-polar disorders. In addition, Glaxo advocated the use of Wellbutrin SR in combination with other anti-depressants to treat the SRI-induced side effects such as weight gain and sexual dysfunction. See Exhibit 13, 14, 15 and 16. Internally, Glaxo recognized that "add ons" to SSRIs were a very strong sales opportunity for the brand. See Exhibit 13.

79. By 2000, SSRI prescriptions represented as much as 90 percent of all antidepressant prescriptions. Marketing surveys consistently showed that Wellbutrin SR was regarded as a less effective treatment for depression than the SSRIs. Promoting Wellbutrin SR as an "add on" to treat SSRI side effects would allow Glaxo to greatly expand its market, without having to overcome the strong perception that Wellbutrin SR was ineffective for its single on-label indication.

80. As an "add on" treatment to SSRIs, Wellbutrin SR was thus promoted not for the depression indication, but rather to control patients' weight and to enhance their sex life. Weight control and sex life enhancement are not FDA-approved indications for Wellbutrin SR.

81. At the same time that Glaxo identified "add on" treatment as a strong "strategic option" for Wellbutrin SR, the company also acknowledged internally that there was an "unknown proof of [the] concept" that Wellbutrin SR was an effective and safe treatment for SSRI side effects. See Exhibit 13. Nevertheless, Glaxo's brand strategy advocated increasing

the use of Wellbutrin SR as an "add on" therapy for those using SSRIs as a first line antidepressant.

82. The off-label strategy worked. Less than a year later, Glaxo acknowledged that Wellbutrin SR's "use for treatment of antidepressant induced sexual dysfunction has increased due to product positioning," and that it was a "product of choice for adding . . . patients who experience sexual dysfunction or efficacy poop-out." See Exhibit 17.

83. In 2001, Glaxo's off-label strategy expanded once again. That year, the results of small clinical studies funded by Glaxo were released. The studies all concluded that Wellbutrin SR was an effective treatment for weight loss in nondepressed patients, and that Wellbutrin SR might be an effective treatment for hypoactive sexual desire disorder ("HSDD") in nondepressed women. See Exhibits 17, 18, 19, 20, 21 and 22. Although the Glaxo-funded studies were small and preliminary, Glaxo actively incorporated the early results into its Wellbutrin SR marketing strategy, recognizing that strategic opportunities existed for Wellbutrin SR's use as a weight loss aid and in treating sexual dysfunction in non-depressed patients. See also Exhibit 23 (summarizing Wellbutrin clinical studies underway in mid-2002, which included trials for use of Wellbutrin in treating seasonal affective disorder, adult ADHD, obesity in the nondepressed, hypo-sexual desire disorder, lethargy and adolescent depression).

84. Glaxo saw potential revenue gains from utilizing for promotional purposes the early clinical data on weight loss and HSDD in nondepressed populations, and integrated the material into its strategic approach for Wellbutrin in 2002. Accordingly, Glaxo's internal 2002 strategy plan for Wellbutrin SR indicated that the company would utilize putatively "nonpromotional" materials to market Wellbutrin SR. As Glaxo stated: "Through non-

promotional means (medical information letters, publications, etc.) optimize use of strong clinical data for prevalence of antidepressant induced sexual dysfunction, comparison vs key competitors in depressed and non-depressed patients for weight loss and HSDD (hyposexual desire disorder)." See Exhibit 17.

85. As alleged in the next section, Glaxo's Wellbutrin SR promotional strategy and off-label message were taken directly to the prescribing physicians through aggressive speaker programs, so-called "advisory" boards, and frequent visits to physicians by sales representatives. And, as stated above, Glaxo's strategy for Wellbutrin SR has been enormously successful. Revenues for the drug have grown from about $450 million in 1998 to $1.6 billion in 2002. In 2003, revenues are on pace to exceed $2.1 billion. See also Exhibit 24 (2003 Plan of Action presentation showing Wellbutrin annual revenue growth between 30 and 42 percent).

2. Glaxo Used Speaker Programs To Improperly Promote Off-Label Uses Of Wellbutrin SR Directly To Prescribing Physicians

86. Glaxo's overall marketing strategy for Wellbutrin SR utilized an aggressive speaker program to take its off-label message directly to physician prescribers of Wellbutrin SR. To evade federal off-label marketing prohibitions, Glaxo structured these programs so that they would appear to be events where putatively "independent" speakers and/or consultants presented their own materials and views about Wellbutrin SR. See e.g., Exhibit 25 (2003 Wellbutrin Operating Plan which notes that "key tactical drivers for 2003 are samples, professional and educational events . . .").

87. There were two central components to Glaxo's promotional campaign. First, Glaxo created a national speaker program – Peer Review of Intimacy and Depression ("PRIDE")

– to elevate and drive the "off-label" for Wellbutrin SR. The PRIDE program was also supplemented by local and regional speaker programs, which very frequently used the same PRIDE speakers. See Exhibits 26 and 29.

88. Second, as alleged below, Glaxo utilized hundreds – if not thousands – of "special advisory boards" as another forum for instructing prescribing physicians as to Wellbutrin SR's off-label uses. In addition, Glaxo utilized paid "reprint mastery," "preceptorship" and Glaxo-controlled CME programs to promote off-label and as a vehicle for financial inducements.

89. Glaxo's PRIDE Program was the linchpin of its initial off-label campaign. PRIDE was launched in or about late 1999 or early 2000, and it quickly showed a favorable impact on new prescriptions of Wellbutrin SR. Indeed, during the period at issue, PRIDE dinner programs yielded an approximate 280 percent return on investment. See Exhibits 27 and 31.

90. Comparable "on-label" dinner speaker programs conducted by Glaxo have a return on investment of approximately 20 to 120 percent.

91. From the program's inception, Glaxo has conducted many thousands of PRIDE events. In 2002 alone, for example, Glaxo scheduled approximately 2,000 PRIDE events. In addition, Glaxo supplemented its PRIDE campaign by conducting thousands of local speaker events to promote Wellbutrin SR. See Exhibits 28, 29 and 2. Glaxo also conducted numerous PRIDE teleconferences with similar off-label representations. See Exhibits 30, 31, 32, 33 and 34.

92. Glaxo's PRIDE program events featured speakers who had particularly strong off-label messages. Because Glaxo representatives attended every PRIDE program event and obtained copies of the presentations, the company was well aware of the off-label content of the

speaker programs. Indeed, it was those PRIDE speakers with strong off-label claims who were invited to speak most frequently.

93. Speakers were typically compensated $2,000 to $3,000 for the approximately one hour program. Because many of the speakers traveled the country making virtually identical presentations at each location, no (or extremely little) additional preparation time was necessary. Each payment and any other form of compensation to the speakers and presenters at these events constituted a reward or kickback for the recipients' advocacy and promotion of the off-label uses of Wellbutrin SR.

94. Among the PRIDE speakers most frequently used by Glaxo are: Dr. James Pradko, Dr. James Hudziak, Dr. Norman Sussman; Dr. Anita Clayton, Dr. Jeffrey Green and Dr. Sarah Atkinson. See Exhibits 35 and 36. See also Exhibit 37. In hundreds of programs every year, these particular speakers made PRIDE presentations saturated with off-label representations. Drs Pradko and Hudziak, in particular, promoted Wellbutrin SR's off-label use at hundreds of Glaxo PRIDE programs and local speaker events every year, and received as much as $500,000 or more annually in compensation from Glaxo for promoting Wellbutrin SR. See Exhibits 38 and 39.

95. Physicians were targeted for invitations to attend PRIDE events based on their prescribing strength. See e.g., Exhibit 40. In advance of the dinner, physicians' prescribing practices were reviewed and high prescribers were invited, particularly if the trend of their Wellbutrin SR prescriptions was falling rather than rising. The PRIDE event was seen as a means of directly boosting or reinforcing their Wellbutrin SR prescriptions.

96. Information about off-label uses of Wellbutrin SR was proactively provided to

event attendees by the "national" PRIDE speakers. Dr. James Pradko was utilized by Glaxo more frequently than any other PRIDE speaker – although Dr. James Hudziak was a close second. Dr. Pradko was also hired by Glaxo to present at sales representatives training sessions - both initial and "advance" sales training – and was repeatedly invited to present at Glaxo's Wellbutrin SR National Speaker Training Meetings. See Exhibits 41, 42, 21 and 43. Dr. Pradko, whose specialty is family practice, was also appointed to Glaxo's National Advisory Board.

97. Dr. Pradko traveled to every Glaxo sales region to present his standard presentation – "The Neuroreceptor Basis of Initial Antidepressant Choice." In 2002, Pradko made this presentation at 156 PRIDE events, as well as approximately 165 local speaker events and "special issue boards." See Exhibit 44. In 2002 alone Glaxo compensated Dr. Pradko approximately $600,000 for these various speaking engagements.

98. Pradko's presentation was permeated with off-label representations and claims about Wellbutrin SR. See Exhibits 45, 46, 47, 48 and 49. Indeed, Dr. Pradko's off-label representations far outnumbered his comments about its on-label indication. Among other claims, Dr. Pradko represented that Wellbutrin SR could be used for weight loss; attention deficit disorder in pediatric patients; chronic fatigue syndrome; marital dysfunction; erectile dysfunction; addictions and chemical dependencies; attention disorders; sleep disorders and to restore REM levels of sleep; to restore libido and a healthy sex life; low energy in anxious patients; treatment of pregnant women; and, as an "add-on" to treat SRI side effects such as "poop out", sexual dysfunction and weight gain.

99. Many of Dr. Pradko's claims are directly contrary to Wellbutrin SR's prescribing information. For example, Dr. Pradko asserted that he put all of his pregnant patients on

Wellbutrin SR and further claimed that the FDA said that it is safest in pregnancy. This representation is directly contrary to the drug's prescribing information, which specifically cautions that it "should be used during pregnancy only if clearly needed" and that "there are no adequate or controlled studies in pregnant women."

100. In addition, Dr. Pradko's claims concerning Wellbutrin SR use in treating sleep disorders are called into question by labeling information that cautions that in placebo-controlled trials between 11 and 16 percent of patients receiving Wellbutrin experienced insomnia. Similarly, Pradko's claims advocating use of Wellbutrin SR in pediatric patients are contrary to the drug's FDA approval only for patients over the age of 18. Glaxo's prescribing information further warns that the safety and effectiveness of Wellbutrin SR in pediatric patients is not established.

101. Other PRIDE speaker presentations were similarly saturated with off-label treatment claims. In standard presentations that were delivered hundreds of times at Glaxo PRIDE and local speaking events, Dr. James Hudziak advocated using Wellbutrin SR for a wide range of off-label treatments including ADHD, addictions, obesity, weight reduction in the "chubby," and bi-polar disorders. See Exhibits 41, 50, 51, 52, 42, 53, 11, 54 and 59.

102. Dr. Norman Sussman's standard PRIDE presentation likewise incorporated representations that Wellbutrin SR promotes weight loss, including in nondepressed patients. Dr. Sussman also advocated using Wellbutrin SR to treat ADHD, smoking cessation, SRI side effects and chronic fatigue syndrome. Sussman further claimed that Wellbutrin SR increases REM level sleep, provides a more restful sleep, and that it is useful in treating Parkinson's patients. See Exhibits 41, 60 and 55. All of these claims go well beyond the FDA label.

103. Although Wellbutrin SR is specifically contraindicated for patients with seizure disorders and/or eating disorders, Dr. Sussman made claims that either improperly minimized or contradicted the drug's FDA-approved labeling. In particular, Dr. Sussman represented that Wellbutrin SR's seizure rates were either equivalent to or less than the rates seen with SSRIs, even though no head-to-head trials have established comparative seizure rates. See Exhibit 55.

104. Dr. Sussman also suggested that Wellbutrin SR could be used to treat patients with eating disorders, even though the drug's labeling information provides a specific contraindication for use by eating disorder patients because of seizure risk. Sussman minimized that risk and advocated instead that patients suffering from eating disorders merely supplement their Wellbutrin SR with Topamax, an anti-seizure medication. See Exhibit 55.

105. Drs. Sarah Atkinson and Anita Clayton also represented that Wellbutrin SR promoted weight loss in the nondepressed, among other things. See Exhibits 56, 57, 58, 42, 59 and 60. Similarly, Dr. Jeffrey Green presented Wellbutrin SR as a treatment for cocaine and alcohol addictions, as well as for ADHD. See Exhibits 61, 62 and 69. In doing so, Dr. Green, like Dr. Sussman and others, improperly minimized Wellbutrin SR's FDA-required seizure risk labeling by suggesting that the drug's seizure risk was less than certain SSRI's even though no head-to-head clinical trials have been conducted.

106. Glaxo representatives attended every PRIDE speaking event and were well aware of the off-label claims made by putatively "independent" consultants. Leading speakers such as Drs. Pradko, Hudziak, Sussman, Clayton and Atkinson spoke dozens of times a year and were highly sought after by Glaxo for promotional events. By actively and frequently employing the speakers with full knowledge of the content of their presentations, Glaxo fully adopted their off-

label claims.

107. Indeed, Dr. James Pradko's off-label message was expressly adopted by Glaxo. Not only did Dr. Pradko appear and present at Glaxo sales training sessions, but on March 23, 2000, Pradko's standard presentation was copied and provided to every sales representative responsible for promoting Wellbutrin SR. As alleged above, Dr. Pradko's presentation is permeated with off-label claims concerning Wellbutrin SR.

108. In addition, Glaxo actively promoted Dr. Pradko's off-label message. Hundreds, if not thousands, of audiocassette tapes of Dr. James Pradko's standard lecture were purchased by Glaxo through regional sales budgets, and were actively distributed by Glaxo sales representatives when calling on prescribing physicians. The cassette tapes are priced at approximately $20 each and added to Dr. Pradko's already substantial additional compensation by Glaxo. See Exhibit 63. Glaxo's payments to Dr. Pradko for these tapes constituted a reward or kickback by Glaxo to Dr. Pradko in exchange for his advocacy and promotion of the off-label uses of Wellbutrin SR.

109. Glaxo sales representatives distributed the Pradko tape liberally to reinforce the strong off-label message and to promote the use of Wellbutrin SR for such non-approved indications as ADHD, combination therapy for SRI side effects, weight control, sexual dysfunctions, cocaine or alcohol addictions. Glaxo sales representatives distributed hundreds, if not thousands, of Dr. Pradko's tapes on sales calls to prescribing doctors.

110. For example, Glaxo sales representatives provided the Pradko tape to the following physicians, among many hundreds of others. In some cases, Glaxo sales representatives provided multiple copies of the tape to the same physician.

Dr. Jeffrey Krotenberg of Lake Mary, Florida - November 15, 2000

Dr. Owen Sheekey of Vineland, New Jersey - February 26, 2001

Dr. Sarah Morris of Long Branch, New Jersey - March 13, 2001

Dr. Karen Bowles of Philadelphia, Pennsylvania - April 18, 2001

Dr. Young Kim of Brownstown Township, Michigan - May 7, 2001

Dr. Ashok Jain of Murrysville, Pennsylvania - May 24, 2001

Dr. Scott Lance of Ashland, Kentucky - June 1, 2001

Dr. Patricia Lapkin of Ashland, Kentucky - June 1, 2001

Dr. Uzma Ehtesham of Pikeville, Kentucky - June 21, 2001

Dr. William Matthew of Pikeville, Kentucky - June 21, 2001

Dr. Jay Narola of Pikeville, Kentucky - June 21, 2001

Dr. Richard Minnihan of Wausau, Wisconsin - June 27, 2001

Dr. Douglas Keagle of Darby, Pennsylvania - July 31, 2001

Dr. Matthew Meyer of Madison, Wisconsin - August 13, 2001

Dr. Amita Talati of Voorhees, New Jersey - August 23, 2001

Dr. Malgorzata Piszcz-Connelly of Millville, New Jersey - September 10, 2001

Dr. Elmer Harden of Riverdale, Georgia - October 9, 2001

Dr. Donna Scott of Newnan, Georgia - October 17, 2001

Dr. Geraldine Yarne of Tucson, Arizona - November 7, 2001

Dr. Mark Bernstein of Montgomeryville, Pennsylvania - November 13, 2001

Dr. Cira Amenta of Souderton, Pennsylvania - November 29, 2001

Dr. Jane Gallant of Fountainville, Pennsylvania - November 29, 2001

Dr. Carla Patton of Fountainville, Pennsylvania - November 29, 2001

Dr. Priscilla Benner of Pennsburg, Pennsylvania - November 30, 2001

Dr. Cory Krueger of Lansdale, Pennsylvania - November 30, 2001

Dr. Richard Lorraine of Harleysville, Pennsylvania - November 30, 2001

Dr. Cletus Carvalho of Hazard, Kentucky - December 5, 2001

Dr. John Schremly of Corbin, Kentucky - December 5, 2001

Dr. Jonathan Cowen of Lansdale, Pennsylvania - December 14, 2001

Dr. Terry Vondrak of Tucson, Arizona - December 14, 2001

Dr. Rafael Tortosa of New Providence, New Jersey - February 15, 2002

Dr. James Hutchins of Somerville, New Jersey - February 22, 2002

Dr. Stefan Lerner of Bridgewater, New Jersey - March 14, 2002

Dr. Vincent Colon of Watchung, New Jersey - March 15, 2002

Dr. John Titus of Phillipsburg, New Jersey - March 15, 2002

Dr. Dong Moon of Dayton, Ohio - April 30, 2002

Dr. Martha Tymeson of Dayton, Ohio - April 30, 2002

Dr. Roddy Ingraham of Rocky Face, Georgia - May 28, 2002

Dr. Sandra Wiederhold of Richland, Michigan - June 12, 2002

Dr. Susan Seidler of Westerly, Rhode Island - June 13, 2002

Dr. Leopoldo Covarrubias of Battle Creek, Michigan - June 21, 2002

Dr. Amy Doorley of Portsmouth, Rhode Island - July 16, 2002

Dr. Ralph La Guardia of Mansfield Center, Connecticut - July 23, 2002

Dr. Mary Krolik of New Orleans, Louisiana - August 28, 2002

Dr. Benjamin Monato of Sterling Heights, Michigan - August 29, 2002

Dr. Russell Brubaker of Muskegon, Michigan - September 3, 2002

Dr. Mazhar Munir of Grand Rapids, Michigan - September 3, 2002

Dr. Bisel Brikho of Lathrup Village, Michigan - September 4, 2002

Dr. Herbert Brennan of East Greenwich, Rhode Island - September 6, 2002

Dr. Michael Fusillo of Allegan, Michigan - September 9, 2002

Dr. Philip Haines of Grand Rapids, Michigan - September 10, 2002

Dr. Edward Roberts of Detroit, Michigan - September 10, 2002

Dr. Marwan Tabbara of Three Rivers, Michigan - September 10, 2002

Dr. Susan Yoder of Three Rivers, Michigan - September 10, 2002

Dr. Rebecca Santiago of Highland, Michigan - September 11, 2002

Dr. Sanker Jayachandran of Munster, Indiana - September 12, 2002

Dr. Joan Kuric of Munster, Indiana - September 12, 2002

Dr. David Henley of New Castle, Indiana - October 2, 2002

Dr. Randall Christenson of Grand Rapids, Michigan - October 4, 2002

Dr. Juvvala Reddy of Rochester Hills, Michigan - October 4, 2002

Dr. Vincent Colon of Watchung, New Jersey - October 14, 2002

Dr. Gerardo Moreira of El Paso, Texas - October 15, 2002

Dr. Kenneth Kron of Rochester Hills, Michigan - October 22, 2002

Dr. Puthenparampil Vijayakumaran of Wayne, Michigan - October 29, 2002

Dr. Jun Cho of Westland, Michigan - October 31, 2002

Dr. Melanie Kates of Fairport, New York - November 5, 2002

Dr. Pamela Marini of Clifton Springs, New York - November 5, 2002

Dr. Becca Mcnamara of Clifton Springs, New York - November 5, 2002

Dr. Joel Shamaskin of Rochester, New York - November 8, 2002

Dr. Rochelle Barrone of Webster, New York - November 8, 2002

Dr. Kelly Chura-singh of Crawfordsville, Indiana - December 4, 2002

Dr. Teri Schwarz of Morgan City, Louisiana - December 10, 2002

Dr. Stanley Russell of Brandon, Mississippi - December 11, 2002

Dr. Richard Gerhardstein of Port Washington, Wisconsin - January 6, 2003

Dr. Carol Robinson of Saint Louis, Missouri - January 16, 2003

Dr. Kimberly Davis of Monette, Arkansas - January 24, 2003

111. In addition to proactively distributing the Pradko tape to prescribing physicians, Glaxo sales representatives also actively discussed and reviewed the content of PRIDE speaker presentations. The purpose was to promote particular off-label uses identified in the presentations and/or to reinforce the PRIDE speakers' off-label message. Glaxo, thus, adopted the presentations of so-called "independent" PRIDE program speakers in its direct promotion and sales to prescribing physicians.

112. It was Glaxo's general practice to select speakers based in large part on the content of their presentations and whether they advocated use of Wellbutrin SR off-label.

Doctors were at times told that they would not be asked to speak if they did not convey the message Glaxo wished. In addition, because speakers received generous compensation, doctors often actively sought speaker programs and offered to bias their presentations in favor of Glaxo drugs in return for a speaking invitation.

113. For example, in December 2000, Dr. Thomas Lauer of High Point North Carolina discussed his availability to speak for Glaxo. According to sales representative notes, he did not "mind prostituting himself out for about $750 a pop," and would talk for Glaxo "if the price is met." In January 2001, a Glaxo representative noted the need to be frank with Dr. Lauer "and tell him that unless he gives a better message, he will not talk for us."

114. Similarly, Dr. Brian Park (formerly of Boston) expressed interest in lecturing for Glaxo. According to a sales representative note, he wanted to be Glaxo's "whore," and was anticipating downsizing his hours and was "looking for a way to make up the difference."

115. Likewise, Glaxo candidly discussed its promotional expectations from Dr. Charles DeBattista's speaking programs. Glaxo's representative told Dr. DeBattista that they "would not spend company money" on him if he did not support Wellbutrin SR as a first line drug. Similarly, when Glaxo-trained speaker Dr. Robert Moreines of Westfield, New Jersey asked for an increase in his speaking honorarium to $1500 a presentation in December 2001, was told that first he needed to prescribe Wellbutrin SR "first line in all cases."

3. Glaxo Immersed Its Sales Force In Information Concerning Off-Label Uses And Tested Their Proficiency In Off-Label Information

116. Glaxo's Wellbutrin SR sales force was also actively encouraged to promote the drug for off-label treatments. From the time of their introductory sales training and throughout

their tenure with the company, Glaxo bombarded its sales force with information concerning off-label treatments with Wellbutrin SR.

117. Among other things, Dr. James Pradko provided his standard presentation - The Neuroreceptor Basis of Initial Antidepressant Choice - at new representatives' sales training. As alleged above, Dr. Pradko's presentation incorporates numerous off-label claims about Wellbutrin SR. Before Glaxo sales trainees had been fully instructed about Wellbutrin SR's on-label indications, prospective sales representatives were instructed about the drugs off-label opportunities. See Exhibit 64.

118. In addition to requiring new-hires' attendance at Dr. Pradko's presentation, in March 2000 every Glaxo sales representative handling Wellbutrin SR also received a personal copy of Pradko's standard presentation, replete with off-label claims. Id.

119. Further, Glaxo stressed to its sales force that Wellbutrin SR promoted weight loss in non-depressed patients and also treated sexual dysfunction in non-depressed patients. For example, in October 2000 all members of Wellbutrin SR Field Sales Teams received copies of an article posted on Salon.com concerning Wellbutrin SR's sex-enhancing effects. See Exhibit 65.

120. The article discussed the use of Wellbutrin SR (a) as an "add on" to treat SSRI-induced sexual problems; (b) for erectile dysfunction in nondepressed men; (c) for sexual dysfunction in the nondepressed; and (d) for sexual dissatisfaction in nondepressed women. See Exhibits 73 and 74.

121. Glaxo sales representatives were barraged with information concerning the use of Wellbutrin SR to promote weight loss in the nondepressed. Sales representatives were provided with multiple copies of the results of numerous Glaxo-funded studies on weight loss in the

nondepressed. For example, on June 27, 2001, Glaxo distributed a memorandum to all its Wellbutrin SR sales force concerning new clinical data on the drug's impact on weight loss in non-depressed obese patients. See Exhibit 20 and 66. Other materials on weight loss in the nondepressed distributed by Glaxo include: "Bupropion for Weight Loss: An Investigation of Efficacy and Tolerability in Overweight and Obese Women," K. Gadde, et al; "Buproprion SR Significantly Enhances Weight Loss When Used With A Moderate-Intensity Lifestyle Intervention," J. Anderson et al.; "Effects of Bupropion SR on Body Weight," K. Fujioka; "A Study Of Bupropion SR Compared To Placebo In Obese Adults With Mild To Moderate Depressive Symptoms," abstract, A. K. Jain, et al. See Exhibits 67, 68, 69, 70, 71, 72, 73, 74, 84, 75, 76, 77, 78, 79 and 80, attached. See also Exhibits 81 and 82.

122. Indeed, Glaxo interrupted an "all hands" sales force meeting on migraine treatment, "Migraine University," in mid-2001 so that a live presentation could be made by Dr. Ken Fujioka on his just-released results of Wellbutrin SR's impact on body weight in the nondepressed.

123. In addition, in late 2001 and early 2002, all Glaxo sales representatives handling Wellbutrin SR were required to take a mandatory written "knowledge certification" on the off-label weight data concerning nondepressed patients. See Exhibits 83, 94 and 84. Sales representatives were also tested on their verbal mastery of the off-label material. Similar tests were conducted for the use of Wellbutrin SR to treat ADHD, and other off-label treatments. See Exhibits 85 and 84.

124. Glaxo's emphasis on various off-label uses translated into direct promotion to prescribing physicians by the company's sales representatives. Although Wellbutrin SR is not

FDA-approved for patients under the age of 18, for example, Glaxo required that sales representatives visit pediatricians and child psychiatrists to market Wellbutrin SR. Every quarter, sales representatives were given "optimal frequency" lists that identified the number of visits each representative was required to make on a particular doctor in that three month period. The number of visits ranged from one to ten per doctor, and depended on the particular physician's prescribing activities.

125. Child psychiatrists and pediatricians were among those specialties targeted by Glaxo for marketing Wellbutrin SR. Sales representatives were required to visit certain pediatricians and child psychiatrists as many as ten times in a three month period. Indeed, on their sales calls Glaxo representatives actively promoted Wellbutrin SR for such off label indications as ADD/ADHD, and pediatric depression - neither of which were approved indications for the drug.

126. The following examples are representative of Glaxo's Wellbutrin SR off-label promotional efforts directed at pediatricians and child psychiatrists.

a. On November 27, 2001, Dr. David Hernandez of Santa Barbara, California was "updated" on the use of Wellbutrin for ADHD.

b. On January 1, 2000, a Glaxo sales representative advised Dr. Paul Fleiss of Los Angeles, California on prescribing information for the use of Wellbutrin SR for his ADHD patients.

c. On January 12, 2000, a Glaxo sales representative reviewed the use of Wellbutrin SR to treat ADHD with Dr. Negar Ghafouri of Manhattan Beach, California.

d. On December 3, 2001, a Glaxo sales representative advised Dr. Denice Cook of Tinley Park, Illinois on the use of Wellbutrin for treating depression, ADD and ADHD in children.

e. On July 3, 2002, a Glaxo sales representative "talked up" the success and popularity of off-label use of Wellbutrin SR to treat ADHD to Dr. Thu Thao Trinh of Minocqua, Wisconsin.

f. On April 16, 2001, on a sales visit with Dr. William Bruno of Hollywood, Florida, a Glaxo representative "let him know about" Wellbutrin SR and ADHD.

g. On March 19, 2001, a Glaxo sales representative discussed the use of Wellbutrin SR for children with ADHD with Dr. Bruce McIntosh of Jacksonville, Florida, and advised him on suggested dosing.

h. On June 22, 1999, a Glaxo sales representative advised Dr. Shelley Griffin of Waynesboro, Georgia about Wellbutrin SR's "success" in treating ADHD.

i. On August 3, 1999, a Glaxo sales representative reviewed the use of Wellbutrin SR for treating ADHD and the "reasons why it is so successful" with Dr. Shelley Griffin of Waynesboro, Georgia.

j. On February 22, 2001, a Glaxo sales representative called on Dr. Gary Hayes of Jasper, Tennessee and told him about the use of Wellbutrin SR in ADHD patients, and showed him Dr. James Hudziak's study (funded by Glaxo) concerning treatment of ADHD with Wellbutrin SR. On a June 28, 2001 visit with Dr. Hayes, a Glaxo representative reviewed the use of Wellbutrin for ADHD and also for weight loss.

k. On August 14, 2000, a Glaxo sales representative told Dr. Josh Smith of Chattanooga, Tennessee about the use of Wellbutrin SR for ADHD.

l. On September 27, 2001, a Glaxo sales representative discussed the use of Wellbutrin SR in treating pediatric ADD with Dr. David Suholet of Atlanta, and advised him about dosing for a twelve year old patient.

m. On December 5, 2000, a Glaxo sales representative told Dr. Herbert Copeland of Greenfield, Massachusetts about using Wellbutrin SR for children with ADD and ADHD. Although Dr. Copeland prescribes Ritalin, he indicated that he was "willing to give Wellbutrin SR a try more often."

n. On May 14, 2002, a Glaxo representative called on Dr. Juan Bonetti of Abbeville, South Carolina and noted that "[e]ven though he is a pediatrician, I talked with him about my products, because all have data in children. (adhd-wbsr; imitrex nasal spray-adolescent migraine). Had a good talk about kids."

o. On a February 4, 2000 sales call to Dr. Jamison Roberts of Newnan, Georgia, a Glaxo representative reviewed the use of Wellbutrin SR for treating ADHD.

p. On October 19, 2001, a Glaxo sales representative "went over" the use of Wellbutrin SR for ADD and ADHD with Dr. Robert Benak of Dothan, Alabama.

q. On a May 26, 1999 sales visit to Dr. Rosemary Faust of Birmingham, Alabama, a Glaxo sales representative advised her that lots of psychiatrists use Wellbutrin SR for ADHD.

r. On June 10, 1999, a Glaxo representative advised Dr. Linda Spencer of Indianapolis, Indiana about the use of Wellbutrin SR for ADHD in pediatric

patients.

127. Glaxo sales representatives also proactively promoted the results of recent studies of nondepressed patients treated with Wellbutrin SR for weight loss and sexual dysfunction. Similarly, Glaxo directly promoted Wellbutrin SR as an "add on" combination therapy to address SSRI-induced side effects, such as weight gain, sexual dysfunction, and so-called "poop out" or loss of energy. The use of Wellbutrin as an "add on" was distinct from its use as an antidepressant for the combined therapy was to address indications other than depression, such as weight gain, loss of libido and loss of energy. None of these off-label treatments are FDA-approved indications.

128. The following examples are representative of Glaxo's off-label sales efforts with prescribing physicians promoting the use of Wellbutrin SR as an off-label treatment for sexual dysfunction, energy loss, weight loss, or as an "add on" for SRI side effects.

a. On January 6, 2003, a Glaxo sales representative visited with Dr. Richard. Gerhardstein of Port Washington, Wisconsin and "reminded" him that Wellbutrin SR can be added to SRI treatment "to get rid of sexual dysfunction." He also advised Dr. Gerhardstein on dosing.

b. On a September 12, 2002 call on Dr. Marjaneh Rouhani of Battle Creek, Michigan, a Glaxo sales representative "previewed" the major points on the Pradko tape, and also provided weight loss data involving nondepressed patients treated with Wellbutrin SR.

c. On a July 24, 2001 call to Dr. Donna Scott of Newnan, Georgia, a Glaxo sales representative reviewed Dr. Pradko's conclusions and suggested adding

Wellbutrin SR for patients taking SSRIs.

d. On February 15, 2001, a Glaxo sales representative informed Dr. Craig Tutton of Ardmore, Oklahoma about Wellbutrin SR's treatment of SRI "poop out," weight gain and sexual dysfunction, as well as ADHD. He reported that Dr. Tutton "definitely was attentive and interested. Cha-Ching!!!"

e. On a February 21, 2003 visit to Dr. Robert Bulten of Grand Rapids, Michigan, a Glaxo sales representative discussed the use of Wellbutrin SR for addictions and ADD, and "encouraged" him to treat ADD patients with Wellbutrin "to counter the addictions."

f. On June 13, 2002, a Glaxo sales representative called on Dr. Susan Seidler of Westerly, Rhode Island and reported that he gave her a tape of Dr. Pradko's presentation and now she is "augmenting" with Wellbutrin SR.

g. On January 23, 2001, a Glaxo sales representative "reminded" Dr. Stephen Besson of Cynthiana, Kentucky to write Wellbutrin SR to treat sexual dysfunction and weight gain.

h. On July 31, 2001, a Glaxo sales representative provided Dr. Douglas Keagle of Darby, Pennsylvania with Dr. Pradko's tape and slides and discussed recent weight loss trials involving nondepressed patients.

i. On July 12, 2001, a Glaxo sales representative called on Dr. Edward Opass of Doylestown, Pennsylvania and reported that after listening to Dr. Pradko he is using Wellbutrin SR as an "adjunct" treatment with some of his patients receiving SSRIs.

j. On November 13, 2002, a Glaxo sales representative proactively provided Dr. Pushpa Mukerjee of Canton, Michigan with recent weight loss data concerning use of Wellbutrin SR in nondepressed patients.

k. On July 10, 2002, a Glaxo sales representative previewed a study involving use of Wellbutrin SR to treat sexual dysfunction with Dr. Lalitha Gurijala of Wallingford, Pennsylvania.

l. On a December 17, 2002 a Glaxo sales representative promoted the Pradko tape to Dr. Leopoldo Covarrubia of Battle Creek, Michigan, and proactively reported on a recent Glaxo-funded study concerning use of Wellbutrin SR for the treatment of sexual dysfunction.

m. On June 28, 2001, a Glaxo sales representative told Dr. Gary Hayes of Jasper, Tennessee about the use of Wellbutrin SR for ADHD and weight loss.

n. On August 19, 2001, a Glaxo sales representative told Dr. Yolanda Spraggins of Chattanooga, Tennessee about the use of Wellbutrin for ADHD and "weight issues" in kids.

o. On November 13, 2000, a Glaxo sales representative told Dr. Kristina Wagner of Dillsburg, Pennsylvania about recent studies that involved use of Wellbutrin SR for weight loss and increased sexual satisfaction in nondepressed patients.

p. On March 25, 2001, a Glaxo sales representative told Dr. Ralph Green of Knoxville, Tennessee about the "weight benefits" of Wellbutrin SR and a recent Glaxo-funded study concerning weight loss in nondepressed patients.

q. On March 12, 2002, a Glaxo sales representative "reminded" Dr. Robert Jones

of Ranson, West Virginia about the use of Wellbutrin SR for weight loss.

r. On February 28, 2001, a Glaxo sales representative advised Dr. Michael Visick of Logan, Utah about the use of Wellbutrin SR for erection disorder and sexual desire disorder.

129. Glaxo's improper off-label promotional tactics continued with the introduction of Wellbutrin XL. See Exhibit 87 (2003 Wellbutrin XL Operating Plan Presentation stating, inter alia, that 50,000 physicians account for 80 percent of all Wellbutrin SR prescriptions and that of the $50 million advertising and promotion budget for 2003, 70 percent would be directed towards the 50,000 high-decile prescribing physicians through samples, PRIDE programs and targeted media. In addition, the presentation identifies PRIDE and CME programs as two of the "key tactics" for converting SR users to Wellbutrin XL. It also provides for a "launch" program that included promoting "add-on" treatment for SSRI patients. In addition, notes to the slides state: "Hold sales force promotion SOV equal to Wellbutrin SR market share SOV for details, samples, and education events. Position Wellbutrin SR with 1st line efficacy with focus on the benefits associated with N/E: impact on sexual functioning and weight. Optimize use of strong clinical data for prevalence of sexual dysfunction, weight loss and HSDD"). See also Exhibit 88 (noting, inter alia, that Glaxo expected 168 trained PRIDE speakers by July 2003).

B. Glaxo Improperly Promoted Valtrex For Numerous Unapproved And Off-Label Uses

130. In June 1995, Valtrex - valocyclovir - received FDA approval for the treatment of shingles (herpes zoster). Six months later, in December 1995, Valtrex's on-label indication expanded to include the treatment of recurrent genital herpes (herpes simplex) in

immunocompetent patients.

131. On or about May 15, 2003, Valtrex received FDA approval for use in reducing transmission of genital herpes in otherwise healthy, heterosexual monogamous couples.

132. On or about April 2, 3003, Valtrex was approved for use in suppressing recurrent genital herpes in HIV-infected individuals.

133. On or about September 10, 2002, Valtrex was FDA-approved for the treatment of cold sores in otherwise healthy individuals.

134. At no time has Valtrex been approved for the treatment of Bell's Palsy, multiple sclerosis, Epstein Barr (mononucleosis), or chronic fatigue.

135. Glaxo may properly market Valtrex for an indicated treatment once it has received FDA approval. It is illegal, however, for Glaxo to promote Valtrex for off-label treatments years in advance of federal review and approval. The hope that the FDA will approve an indication at a later date does not legitimize earlier off-label promotion by a pharmaceutical manufacturer, and the filing of an application for expanded indications will only provide a "safe harbor" for limited off-label marketing if certain pre-conditions are met, (as described in Part V above). Such preconditions were not satisfied by Glaxo in this instance.

136. It has at all times been illegal for Glaxo to market Valtrex as a treatment for any virus or condition other than herpes zoster, herpes labialis, or genital herpes.

137. In this instance, Glaxo had not even applied to the FDA for approval of the suppression in HIV-infected patients, cold sore, and reduction of transmission indications when it was actively promoting such off-label treatments.

138. With respect to the indication for reduction of genital herpes transmission, Glaxo

filed its application for approval on October 31, 2002. With respect to the indication for the treatment of cold sores, Glaxo filed its application for approval on November 13, 2001. And, with respect to the indication for suppression of genital herpes in HIV-infected individuals, Glaxo filed its application for FDA approval on September 30, 2002.

139. In spite of the limited scope of Valtrex's on-label indications, Glaxo aggressively promoted the drug off-label for treating cold sores, reducing genital herpes transmission and herpes suppression in HIV-infected individuals, years in advance of receiving approval for those expanded indications. In this way, Glaxo illegally disregarded the FDA's approval process, usurping for itself federal decisionmaking authority over Valtrex safety and efficacy. See Exhibits 89, 90, 91 and 92.

140. Among other things, Glaxo representatives promoted Valtrex to providers at HIV clinics years before the FDA's April 2003 approval of Valtrex's use to suppress genital herpes in HIV-infected individuals. Glaxo representatives targeted HIV clinics and doctors who treated HIV-infected patients for sales calls promoting Valtrex's use in immuno-compromised patients. See Exhibit 90.

141. Valtrex's closest competitor drug, Famvir, now manufactured by Novartis, was FDA-approved for suppression treatment of recurrent genital herpes in HIV-infected individuals in or about early 1999 - many years in advance of Valtrex.

142. Rather than yield the large and lucrative HIV-patient market to its competitor, Glaxo engaged in an extensive off-label marketing effort promoting Valtrex for the suppression of recurrent genital herpes in HIV-infected individuals. In addition, Glaxo often went a step further and made additional, unapproved claims about the efficacy of Valtrex in preventing the

transmission of genital herpes between sexual partners.

143. As is the case with Wellbutrin SR, Glaxo's off-label marketing combined aggressive nonindependent speaker programs and targeted sales efforts by Glaxo field sales force, both of which disseminated the off-label message. See Exhibits 93, 94 and 106.

144. Glaxo's decision was purely financial - by ignoring federal law, patient safety and federal approval processes, Glaxo rapidly expanded Valtrex's market share years in advance of receiving FDA approvals. See e.g., Exhibit 95. For example, in the year 2000 alone, sales of Valtrex in the United States grew by 70 percent over 1999 U.S. sales. Sales of Valtrex in 2002 exceeded $600 million.

145. Glaxo widely disseminated and advocated Valtrex's off-label uses through non-independent speaker programs. The speaker programs were primarily funded by Glaxo Marketing's "Speakers Bureau," although speaker events were also funded through local and regional sales budgets. See Exhibit 96.

146. Among the top national speakers for Valtrex are: Dr. Jeffrey Gilbert, Dr. David Baker, Dr. Gary Richwald, Ms. Terri Warren, Dr. Christopher Sartori, Dr. Anne Rompalo, Dr. Lucille Lanna, Dr. Zane Brown, Dr. Kenneth Fife and Dr. John Gnann. These individuals received between $1,000 and $2,000 for each speaking presentation they made. See Exhibit 94.

147. In 2002, alone, Dr. Jeffrey Gilbert spoke at 209 "Speakers Bureau" non-independent speaking events for Valtrex. Dr. David Baker spoke 89 times and Dr. Gary Richwald spoke 70 times. In just a single year - 2002 - Drs. Gilbert, Baker and Richwald were paid approximately $420,000, $135,000 and $105,000, respectively, for these headquarter-sponsored events. In addition, however, these physicians substantially supplemented their

Glaxo-income by making presentations at dozens of local speaker events and "special advisory boards" as well. See Exhibit 93, 94 and 106.

148. Drs. Gilbert, Baker and Richwald, and numerous others promoted the off-label use of Valtrex in suppressing genital herpes in HIV-infected patients and in preventing and/or reducing the transmission of genital herpes by sexual partners, far in advance of receiving FDA approval.

149. Non-independent speakers' off-label promotion was coupled with aggressive marketing to prescribers by Glaxo's sales force. The following examples are representative of Glaxo's off-label and unapproved promotion of Valtrex (i) to treat immuno-compromised HIV-infected patients, (ii) to prevent transmission to a partner, and (iii) to treat cold sores.

a. On March 20, 2001, a Glaxo representative discussed the advantageous pricing and use of Valtrex to treat HIV-infected patients with Susan Swain, NP, Dr. Christopher Wang, and Dr. Mauricio Murillo at the HIV Clinic they staff in New York City.

b. On February 26, 2001, a Glaxo representative "reminded" Dr. Anna Hayden, DO of Ft. Lauderdale, Florida about the use of Valtrex for HIV patients.

c. On February 9, 2001, a Glaxo representative discussed the use and dosing of Valtrex in HIV-infected patients with Dr. Patrick Cadigan of Miami Beach, Florida.

d. On a January 5, 2001 sales visit with Dr. Max Scheer of Woodmere, New York a Glaxo representative promoted the use of Valtrex in HIV patients.

e. On February 9, 2001, a Glaxo representative discussed the use of Valtrex for

the suppression of herpes in HIV patients with Dr. Raymond Elliott's office in Ft. Lauderdale, Florida.

f. On April 11, 2001, a Glaxo representative arranged for a reprint mastery training session in which Dr. Franklin Graziano of Madison, Wisconsin would be paid "to discuss the role of Valtrex and HIV."

g. On April 19, 2002, a Glaxo sales representative provided information to Drexel Jordan, NP of Little Rock, Arkansas about the use of Valtrex to suppress genital herpes in HIV patients.

h. On a February 14, 2001 sales call to Dr. Thomas Quarnstrom's office in Grand Rapids, Michigan a Glaxo sales representative discussed, among other things, Valtrex's "off label areas" and coming cold sore studies.

i. On April 27, 2001 sales calls to Dr. Michael Tanaka's office in Torrance, California and Dr. Gene Hawkins' office in Manhattan Beach, California, a Glaxo sales representative claimed that Valtrex would reduce the time of viral shedding which would reduce the risk of herpes transmission.

j. On March 19, 2001, following a "reprint mastery training" session, a Glaxo sales representative "reviewed" with Dr. Edward Linkner of Ann Arbor, Michigan ongoing trials evaluating the reduction of herpes transmission through the use of Valtrex.

k. On January 26, 2001, a Glaxo sales representative advised Dr. Christopher Gee of Bellmore, New York that Valtrex should be taken once a day "like a vitamin" to cut down on herpes transmission.

l. On January 31, 2001, a Glaxo sales representative marketing Valtrex discussed the prevention and transmission of herpes with Dr. Federico Ferris of Johnston, Rhode Island.

m. On May 1, 2001, a Glaxo sales representative discussed with Dr. Michael Feinstein, DO of San Diego, California how suppression with Valtrex would help reduce herpes transmission "especially" during asymptomatic viral shedding.

n. On March 30, 2001, a Glaxo sales representative advised Dr. Ray Mahoubi of Phoenix, Arizona to use suppressive therapy to reduce herpes transmission.

o. On September 18, 2002, a Glaxo representative promoted Valtrex transmission data to Susan Bonner, PA in Chesapeake, Virginia.

p. On June 21, 2002, a Glaxo representative advised Dean Schiller PA, of New Berlin, Wisconsin about using Valtrex for patients "worried about asymptomatic transmission."

q. On November 21, 2002, a Glaxo sales representative reviewed data about the use of Valtrex to reduce transmission of genital herpes with Dr. Jennifer Cameron of Tucson, Arizona.

r. On October 7, 2002, a Glaxo sales representative discussed the use of Valtrex in reducing herpes transmission with Dr. Peter Hansen of Denver, Colorado.

s. On October 11, 2002, a Glaxo sales representative presented the Valtrex "new transmission data" to Dr. David Kotun of Tampa, Florida.

t. On August 29, 2002, a Glaxo sales representative "touched" on the Valtrex transmission study and the results showing a reduction in herpes transmission

with Sandy Skidell, PA of Tallahassee, Florida.

u. October 16, 2002, a Glaxo sales representative presented the "couples transmission data" concerning Valtrex's reduction of herpes transmission in monogamous heterosexual couples to Dr. Raymond Elliott of Ft. Lauderdale, Florida.

v. On January 22, 2001 , a Glaxo sales representative discussed the use of Valtrex to prevent herpes transmission with Dr. Steven Winiarski of Chicago, Illinois.

w. On February 15, 2001, a Glaxo representative reviewed the use and dosing of Valtrex for the treatment of cold sores with David Birch, PA of Corbin, Kentucky.

x. On December 18, 2001, a Glaxo representative discussed the use of Valtrex "off-label" for treating oral labialis with Joan Galbraith NP, of Somerset, New Jersey.

y. On June 21, 2001, a Glaxo sales representative explained the "off label" use of Valtrex for treating cold sores with Dr. William Flannery of Grand Rapids, Michigan.

z In January 2001, a Glaxo sales representative discussed the "off label use" of Valtrex to treat cold sores with Robert Ruhlman, PA of Salisbury, North Carolina and loaded cold sore dosing information in his Palm Pilot.

aa. On October 10, 2001, a Glaxo sales representative gave Ed Mathes, PA of Dr. Stephen Stanton-Reid's office in Fairport, New York a "testimonial" about the use of Valtrex for cold sores.

bb. On May 16, 2001, a Glaxo sales representative "reminded" Dr. Michael Slattery of Carroll, Iowa about the use of Valtrex for labialis.

cc. On March 22, 2001 and March 8, 2001, respectively, a Glaxo sales representative talked about "the off label information on herpes labialis for Valtrex" with Dr. Stacy Mevs and Dr. Dinesh Patel of Newark, New Jersey.

dd. On October 25, 2002, a Glaxo sales representative discussed the reduction of herpes transmission with Valtrex with Staci Burrell, NP of Rock Hill, South Carolina.

ee. On October 26, 2001, a Glaxo sales representative discussed the use of Valtrex to reduce herpes transmission with Dr. Mervyn Smith of Grand Rapids, Michigan.

ff. On February 9, 2001, a Glaxo sales representative "hit" the use of Valtrex to reduce transmission during asymptomatic viral shedding with Dr. Maria Tayag of Warner Robins, Georgia.

gg. On April 27, 2001, a Glaxo sales representative told Dr. Gerardo Guba of Carson, California that the risk of herpes transmission could be reduced with Valtrex suppression.

150. Glaxo also actively promoted the unapproved and off-label use of Valtrex for the treatment of chicken pox, Bell's Palsy, Epstein Barr/mononucleosis, and multiple sclerosis. The following are representative examples of such improper off-label marketing.

a. On a November 8, 2001 sales call with Dr. Irene Flatau of Glen Falls, New York, a Glaxo representative discussed the use of Valtrex in treating children with

chickenpox.

b. On January 23, 2001, a Glaxo sales representative talked about the use of Valtrex "off label" for chicken pox and cold sores with Dr. George Kochik's office of Pittsburgh, Pennsylvania.

c. On January 29, 2001, a Glaxo sales representative reviewed studies of the use of Valtrex to treat multiple sclerosis, mononucleosis and chronic fatigue syndrome with Drs. Martzke, Duemler, Applegate's office in Wyoming, Michigan.

C. Glaxo Improperly Promotes Zofran For The Off-Label Treatment Of Morning Sickness In Pregnant Women

151. Zofran - ondansetron and ondansetron hydrochloride - is a prescription drug that has as its only on-label indications (i) the prevention of nausea and vomiting associated with certain cancer chemotherapies and radiotherapies, and (ii) the prevention of post-operative nausea and/or vomiting. Zofran is marketed for intravenous administration and in oral tablets. Zofran in tablet form was approved for its on-label indications in or about 1999.

152. Zofran, however, is not FDA-approved for use in treating morning sickness in pregnant women, nor Glaxo has sought approval for such an indication from the FDA. Indeed, Zofran is a "Pregnancy Category B" drug, which means that there are no adequate and well-controlled studies of the drug's effects in pregnant women.

153. Zofran is one of Glaxo's "blockbuster" drugs. In 2002, sales of Zofran in the United States grew 28 percent - outpacing growth elsewhere - to a total of $1.1 billion. Global sales of Zofran were approximately $1.4 billion for 2002.

154. Historically, Zofran's marketing and sales have been undertaken by Glaxo's Oncology Division sales force. In or about late 2001, Glaxo's Consumer Healthcare and Oncology Divisions entered into a co-marketing arrangement whereby Consumer Healthcare sales representatives would market Zofran to obstetricians and gynecologists.

155. Glaxo's Consumer Healthcare sales force routinely call on obstetrician and gynecologists to promote and sell Tums. Tums, which is also manufactured by Glaxo, is promoted as an over-the-counter calcium supplement for adult women.

156. The purpose of the co-marketing arrangement was to utilize the Consumer Healthcare sales force's visits to obstetricians and gynecologists to promote Zofran.

157. Although obstetricians and gynecologists perform some surgeries and could order Zofran for post-operative nausea, the primary focus of this co-marketing effort was to encourage prescriptions of Zofran for the treatment of morning sickness.

158. Since the improper off-label promotion of Zofran through the co-marketing arrangement began, prescriptions of Zofran written by obstetricians and gynecologists have risen dramatically. Internal Glaxo analyses conclude that the vast majority of the Zofran prescriptions written by obstetricians and gynecologists are for the off-label treatment of morning sickness.

D. Glaxo Illegally Promoted Lamictal For Off-Label Use In Treating Bipolar Disorder And Neuropathic Pain

159. In or about 1994, the FDA approved Lamictal - lamotrigine - as an adjunctive therapy for partial seizures in adults with epilepsy. This indication was expanded in 1998 to include adjunctive therapy for generalized seizures of Lennox-Gastaut syndrome, and in 2003 to include the treatment of children older than 2 years with partial seizures. Lamictal is also FDA-

approved as a conversion monotherapy in adults with partial seizures who receive treatment with a single enzyme inducing anti-epileptic drug. Lamictal was approved in June 2003 for the maintenance treatment of Bipolar I to delay the time to occurrence of mood episodes in patients treated for acute episodes with standard therapy.

160. However, Lamictal is not approved for use in the treatment of Bipolar II Disorder or chronic or neuropathic pain. In addition, it was marketed for the treatment of Bipolar disorder long before FDA approval.

161. Use of Lamictal has been associated with life-threatening rashes, the incidence of which is greater in pediatric patients than adults. There are no known predictors of the risk of the occurrence or severity of rash associated with the drug.

162. In spite of Lamictal's limited on-label indications and the serious health risks associated with the drug's use, Glaxo has at least since 1999 actively promoted Lamictal for off-label treatments such as bipolar disorder and chronic or neuropathic pain. The off-label promotion of Lamictal was conducted largely through speaker events and aggressive marketing to providers by sales representatives, as with the other Glaxo prescription drugs.

163. Although Glaxo filed with the FDA for an expanded indication for Lamictal in treating bipolar disorder on or about August 29, 2002, the company had for many years prior to that time aggressively promoted the drug for such off-label treatment. Glaxo has not filed for an indication for Lamictal in treating or managing pain.

164. As was the case with Wellbutrin SR and Valtrex, Glaxo organized Lamictal speaker training programs in luxury destinations. Lamictal speaker training was conducted, inter alia, in Newport Beach in 2001, with Glaxo paying all travel and other expenses for participants.

165. Among the many Glaxo-trained speakers who promoted Lamictal for the treatment of bipolar disorder and pain are Dr. Terence Ketter, Dr. Steve Wheeler, Dr. Reuben Joy, among many others. See Exhibits 94 and 97, attached. In addition to speaking events primarily devoted to Lamictal and bipolar disorder, PRIDE program events would also often promote Lamictal's use in treating bipolar disorder, in addition to advocating Wellbutrin SR for off-label treatments.

166. For example, Dr. Norman Sussman routinely told PRIDE program audiences that Lamictal was the "best way" to treat bipolar disorder. As alleged above, Dr. Sussman spoke at dozens of PRIDE events in 2002. Other PRIDE speakers who advocated the use of Lamictal for bipolar patients are Dr. Po Wang, Dr. Carol North, Dr. Luis Giuffra, along with many others.

167. As was true with the other Glaxo prescription drugs, speakers were selected based, at least in part, on the content of their presentation and whether they promoted Lamictal's off-label treatment of bipolar disorder. Glaxo rewarded favorable presenters with additional speaking engagements, grants and other remuneration. In addition, because speakers were very well-compensated relative to their effort, physicians actively sought speaking events, and expressed a willingness to bias their presentations toward Glaxo drugs as a quid pro quo for speaking engagements, grants or other funding.

168. For example, in October 2002, Dr. Terence Ketter of Palo Alto California sought Glaxo funding for a "grand rounds" at a local hospital (Santa Clara Good Samaritan Hospital), and suggested that he would give Lamictal some "fair play" if Glaxo provided financial support. Dr. Ketter routinely spoke on Lamictal's off-label use for bipolar disorder. Glaxo agreed to sponsor Dr. Ketter's "grand rounds."

169. Similarly, following his Lamictal "speaker training" in January 2001, Dr. Alan Jonas of Pikesville Maryland made presentations on Glaxo's behalf on the use of Lamictal to treat bipolar disorder. In July 2001, he noted to a Glaxo representative, that he wished to be used as a Glaxo speaker and that his Wellbutrin SR prescription would increase if he was.

170. Glaxo frequently reviewed speakers' "potential" and reminded them of the content Glaxo wanted them to get across. For example, Glaxo representatives met with Dr. Jacob Katzow of Washington DC in June 2002 to discuss his "potential" for Glaxo. Dr. Katzow reviewed his speaker presentation on so-called soft bipolar, which was proposed for presentation in July 2002, in which he favors treatment with Lamictal and Wellbutrin SR.

171. Glaxo sales representatives were also immersed in off-label treatment information about Lamictal's use in treating bipolar disorder and pain. Among the materials were Glaxo-funded studies by Dr. Joseph Calabrese. In 1999, Dr. Calabrese concluded, following a seven week trial, that Lamictal was an effective treatment for bipolar disorder. "A Double-Blind Placebo-Controlled Study of Lamotrigine Monotherapy In Outpatients With Bipolar I Depression," J. Calabrese et al. His subsequent study in 2000, also funded by Glaxo, reached the same conclusion. "A Double-Blind, Placebo-Controlled, Prophylaxis Study of Lamotrigine In Rapid-Cycling Bipolar Disorder," J. Calabrese et al. Glaxo sales representatives routinely discussed and distributed (without physician requests) reprints of Dr. Joseph Calabrese's studies.

172. During sales calls on physician-prescribers, Glaxo sales representatives actively promoted the use of Lamictal off-label, and often referred to favorable presentations by Glaxo-trained speakers or cited to advantageous reprints.

173. The following examples are representative of Glaxo's off-label promotion of

Lamictal for bipolar disorder and neuropathic pain.

a. On March 7, 2001, a Glaxo representative talked about Lamictal's "efficacy" in the treatment of trigeminal neuralgia, diabetic neuropathy, and the pain associated with AIDS, with Dr. Rollin Gallagher of Philadelphia, Pennsylvania.

b On May 14, 2002, a Glaxo representative explained the uses of Lamictal for headache prevention and for pain with Kathleen Nielsen, PA of Ontario, Oregon.

c On August 15, 2000, a Glaxo representative discussed Lamictal's "role" in treating bipolar disorder with Dr. William Lofthouse of Burlingame, California.

d. On August 19, 2002, a Glaxo sales representative presented information and some of Dr. Ketter's "pearls" on Lamictal and bipolar to Dr. Frank Adair of Redwood City, California.

e. On April 26, 2002, a Glaxo sales representative discussed the use of Lamictal for bipolar disorder with Dr. Kevin Brown of Rome, Georgia, and in the same call discussed a preceptorship with the doctor.

f. On March 21, 2001, a Glaxo representative discussed the use of Lamictal in treating bipolar disorder with Dr. Marian Chaires of Fort Myers, Florida.

g. As early as June 7, 1999, and possibly earlier, Glaxo representatives discussed the use of Lamictal for bipolar disorder with Dr. Schaerf and his office. Later in December 1999, a Glaxo representative presented Dr. Joseph Calabrese's data concerning treatment of bipolar disorder with Lamictal. In the same conversation the doctor reportedly committed to trying Lamictal for bipolar depression. The following year, in July 2000, a Glaxo representative discussed the use of Lamictal

in pain management, and showed data concerning treatment of peripheral neuralgia with Lamictal

h. On June 6, 2000, a Glaxo representative promoted the use of Lamictal in treating bipolar disorder to Dr. Kelly Palmer of Pocatello, Idaho, advising that Lamictal was preferable to Depakote (on-label for bipolar) because individuals taking Lamictal have no weight gain, hair loss, or gum problems.

i. On May 19, 2000, a Glaxo representative discussed the use of Lamictal in pain management with Dr. Raymond Higby of Las Vegas, Nevada.

j. On January 10, 2000, a Glaxo sales representative "went over" the use of Lamictal for bipolar disorder with Dr. Sol Kadish, DO of Philadelphia, Pennsylvania.

k. On July 2, 2001, a Glaxo representative discussed the "benefits" of Lamictal for seizures and bipolar disorder with Dr. Steve Kaplan of Phoenix, Arizona.

l. On September 10, 1999, a Glaxo sales representative gave Dr. Gilbert Chandler of Gainesville, Georgia information about using Lamictal for pain.

m. On May 2, 2001, a Glaxo sales representative discussed the use of Lamictal for bipolar disorder over lunch with Dr. Norman and Dr. John Bulrice of Big Bear Lake, California.

n. On August 2, 2001, a Glaxo sales representative explained the use of Lamictal for the treatment of bipolar disorder and pain with Dr. Morey Weingarten of San Leandro, California. The representative told Dr. Weingarten that the uses "weren't indicated" and also "went over" Dr. Joseph Calabrese's reprint.

o. On March 30, 2000, a Glaxo sales representative "brought up the idea" of Lamictal for bipolar with Dr. Jeanette Margolin of Kentfield, California, who expressed concerns about side effects and rash.

p. On March 30, 2001, a Glaxo sales representative "went over" the Calabrese study concerning Lamictal's use in treating bipolar disorder with Patrick Handlin of Grand Rapids, Michigan.

q. On June 10, 1999, a Glaxo sales representative "discussed the benefits" of using Lamictal to treat bipolar disorder with Dr. Rodney Brauher of Orleans, Michigan.

r. On February 5, 2001, a Glaxo representative discussed with Dr. Stephen Baskin of Berkeley, California the use of Lamictal in treating bipolar disorder and Wellbutrin SR for addictive, "chubby" patients.

s. On October 11, 2000, a Glaxo representative discussed the use and dosing of Lamictal for bipolar disorder over lunch with Dr. Debbie Ford's office in Prescott, Arizona.

t. On May 24, 1999, a Glaxo representative inquired of Dr. Elmer Harden of Riverdale, Georgia whether he had "heard of" using Lamictal for treating bipolar disorder.

u. On February 23, 2000, a Glaxo sales representative discussed a recent study involving the use of Lamictal for bipolar disorder with Dr. Melanie Thombre of Columbus, Ohio.

v. On June 8, 1999, a Glaxo sales representative discussed using Lamictal for

bipolar with Dr. Vincent Indovina of Orland Park, Illinois and left him with an article on the same topic.

w. On July 8, 1999, a Glaxo sales representative called on Dr. Daniel Beaudry of Greenville, South Carolina and mentioned the use of Lamictal for bipolar.

x. On August 11, 1999, a Glaxo sales representative "detailed" Dr. Susan Charlamb of West Bloomfield, Michigan on the use of Lamictal for pain and bipolar disorder.

y On July 20, 1999, a Glaxo sales representative "presented" Calabrese's results on Lamictal's treatment of bipolar to Dr. Raymond Moy of Milwaukee, Wisconsin.

z. On June 27, 2000, a Glaxo sales representative discussed a previous "bipolar program" with Dr. Linda Hungerford of Decatur, Illinois. Following the program, Dr. Hungerford was very interested in the use of Lamictal for bipolar, and agreed to consider trying it.

aa. On October 19, 2000, a Glaxo sales representative discussed the use of Lamictal in treating bipolar disorder with Dr. Daniel Williams of New Hyde Park, New York.

bb. On June 15, 1999, a Glaxo sale representative discussed Lamictal for bipolar disorder with Dr. Raymond Johnson of Ft Myers, Florida.

cc. On May 22, 2001, a Glaxo sales representative called on Dr. Donna Sigl of Albuquerque, New Mexico and discussed the use Lamictal for bipolar disorder.

dd. On July 12, 2000, a Glaxo sales representative reviewed the use of Lamictal

for bipolar with Dr. Jule McLaughlin of Muskegon, Michigan.

E. Glaxo Aggressively Promoted Advair With Illegal Financial Inducements

174. Advair is an inhaled combination of fluticasone propionate (an inhaled corticosteroid, or "ICS") and salmeterol xinafoate (a long-acting beta agonist, or "LABA"). The two components of Advair are also marketed by Glaxo as separate products under the trade names Flovent and Serevent, respectively. In August 2000, Advair was FDA-approved for a single on-label indication for the treatment of asthma in patients over 12 years of age. See Exhibit 98. In 2003, Advair 250/50 was approved for the treatment of chronic obstructive pulmonary disease ("COPD") associated with chronic bronchitis. And, in 2004 Advair 250/50 was approved for the treatment of COPD in certain limited circumstances. In April 2004, Advair 100/50 was approved for children ages 4 to 11 whose asthma is not controlled on inhaled corticosteroid therapy.

175. Advair is Glaxo's largest selling product. In 2009, Advair sales were approximately $8 billion.

176. Advair's introduction was highly anticipated because of its commercial significance. The launch was orchestrated by upper-level Glaxo marketing and sales officials. Among other things, Glaxo identified potential high-prescribing physicians for targeted marketing. For each such physician, Glaxo sales representatives were instructed to expose the targeted prescribers to a certain number of Advair "touches" for marketing purposes. These "touches" included, inter alia, paid participation in "special advisory boards," paid participation in "reprint mastery training," and paid participation in promotional speaking events, all of which were illegal financial inducements intended to influence physician prescribing practices. (See

infra, ¶¶ 286-330.)

177. Illegal inducements were critical to Glaxo upper management's plan for Advair. The PhRMA-code and internal "policies" were intentionally ignored so that payments to targeted physicians would continue to flow to potential Advair prescribers specifically. See generally, Exhibit 99. Such payments were intended to generate Advair sales and significantly contribute to the drug's launch and ultimate long-term success.

178. In addition to payments for participation in advisory boards, reprint mastery training, preceptorships and speaking events, Glaxo also offered payments to physicians through other means, including inter alia, honoraria, gift checks, luxury accommodations and travel to Advair's Las Vegas Launch; the "Project Spirometry" program; and, other financial inducements.

179. With respect to Project Spirometry, Glaxo offered targeted physicians the use of free spirometers in their practices. Physicians used the spirometers to assess whether patients were asthmatic, often billing for tests conducted on the free equipment. By providing valuable income-generating spirometers to prescribers at no-cost, Glaxo intended to, and often did, generate Advair prescriptions for Glaxo. Project Spirometry was among many Glaxo programs that offered illegal inducements for Advair prescriptions.

180. For example, on July 5, 2001, Drs. Michael Milstein and Bruce Barniville of Jupiter, Florida discussed Glaxo supplying a spirometer to their practice. They reportedly recognized the intended quid pro quo of the arrangement, acknowledging that they would make more money as would Glaxo since "more asthma patients means more Advair scripts."

F. Glaxo Actively Promoted Advair For Medically Unnecessary Treatments

Contrary To Federal Guidelines And Standard Of Care

181. Federal law requires that services and items reimbursed by Medicaid and Medicare be provided "only when, and to the extent, medically necessary" and that they be of "a quality which meets professionally recognized standards of health care." State Medicaid programs generally indicate that to be medically necessary, treatments must be consistent with the scientifically-based guidelines of national organizations and/or governmental agencies.

182. Under NIH's National Heart Lung & Blood Institute ("NHLBI") guidelines governing asthma treatment, the severity of asthma is divided into four categories: (1) intermittent, (2) mild persistent, (3) moderate persistent, and (4) severe persistent. The NHLBI guidelines have provided that only moderate and severe asthma should be treated with combination treatments that include long-acting beta agonists and low-dose inhaled corticosteroid. Advair is such a combination treatment. Advair' ICS component is fluticasone (Flovent), and its LABA is salmeterol (Serevent).

183. In this case, Glaxo consistently promoted Advair for mild asthma notwithstanding these federal guidelines. For mild persistent asthma, the NHLBI guidelines consistently recommended one daily "preferred" medication of low-dose inhaled corticosteroid. Alternative treatments for mild persistent asthma include cromolyn, leukotriene modifier, or nedocromil. Combination treatments with long-acting beta agonists have not been identified as a recommended, or an alternative, treatment for mild persistent asthma. One reason is that long-acting beta agonists have been found to cause serious patient risks – including elevated risk of asthma-related death and serious exacerbations. The LABA component of Advair, salmeterol, is a bronchodilator and may improve asthma symptoms, but it has no anti-inflammatory properties.

Studies have shown that salmetrol is associated with increased risk of life-threatening episodes and death.

184. NHLBI guidelines also recommend that individuals with intermittent asthma receive no daily medication. Short-acting beta agonists are advised for quick relief, but long-term beta agonists are not recognized treatment for management or control. Not only is Advair a combination therapy with long-acting beta agonists, but it is also administered daily.

185. NHBLI guidelines have always articulated a stepwise approach to controlling and treating asthma. Under this approach, medication types are "stepped up" as needed, and "stepped down" when it is possible. Thus, use of combination therapy of inhaled corticosteroids and long-acting beta agonists, which are generally viewed as one of the most aggressive treatments, has been reserved for moderate and severe asthma treatments, in most instances after other treatments fail.

186. In marketing Advair, however, Glaxo promoted treatments that were directly at odds with these federal guidelines and medically unnecessary. From the time the drug was launched, Glaxo marketed Advair for all severities of asthma - including mild asthma - and also as a first-line treatment (i.e., treatment prior to use of an inhaled corticosteroid). Glaxo's efforts not only pushed physicians to provide medically unnecessary treatments, but put patient safety in jeopardy in view of the risks of combination therapy.

187. Glaxo trained its sales representatives to market Advair for mild asthma. Among other things, Glaxo held Sales Workshops that specifically instructed representatives on how to respond to objections that Advair was not appropriate for patients with mild asthma. This company guidance promoted treatments that were contrary to federal NHBLI guidelines.

188. Glaxo held sales workshops that coached responses to such objections as "Advair is too strong for my patients with mild asthma;" "I don't believe that the majority of my patients are moderate/severe;" and "I don't believe that my mild patients are at that great of a risk." See Exhibit 100, Advair Leader Guide, Elion Workshops, Semester I 2003 at 5; and Exhibit 101, Central Nervous System Selling Resource, Semester I 2003 at PSR-3. The scripted responses and similar training promoted Advair off-label by (1) creating serious doubt as to the physician's judgment about a mild asthma case; (2) defining asthma in such a way that "mild asthma" does not exist; and, (3) promoting Advair's "convenience" even if not medically justified.

189. Glaxo also misled prescribers by suggesting that Advair is an appropriate substitute for inhaled corticosteroids across the board. The company tutored sales representatives to "handle resistance" by doctors that prescribe ICS alone by arguing that ICS-only patients "may benefit even more" with Advair. Glaxo instructed sales representatives to advise physicians that clinical studies "demonstrate the benefit" of treating with Advair instead of ICS alone. See Exhibit 101 at PSR-8,9. These recommendations are misleading and are contrary to the NHBLI guidelines that provide ICS alone as the standard treatment for mild persistent asthma.

190. Sales calls on doctors aggressively promoted medically unnecessary treatment of mild asthma with Advair. For example,

a. On March, 2001, a Glaxo sales representative "Emphasized use [of Advair] for mild asthma" to Dr. Adrienne Headley of Old Bridge, New Jersey.

b. On April 17, 2001, a Glaxo sales representative discussed the use of Advair "for mild asthmatics on one controller therapy" with Dr. Robert Lustig of

Bridgewater, New Jersey.

c. On April 20, 2001, a Glaxo sales representative told Dr. Robert Rhien of Farmington, New Mexico "that any patient that comes in could use Advair, [and] said that even mild persistent can benefit from the control it offers."

d. On April 24, 2001, a Glaxo sales representative made an "Advair push" with Dr. John Albanese of McHenry, Illinois, and discussed the use of "100/50 [Advair] for mild to moderate asthmatics."

e. On April 30, 2001, a Glaxo sales representative "detailed Advair dosing and targeting mild asthma patients" with dr. Ronald Codario of Philadelphia, Pennsylvania.

f. On May 11, 2001, a Glaxo sales representative "reviewed why to start mild asthmatics on Advair" with Dr. David Messinger of Newark Delaware.

g. On May 14, 2001, a Glaxo sales representative told Dr. Frederick Hill of Humble, Texas that "you can use Advair for those patients who have mild asthma."

h. On June 26, 2001, after calling on Dr. Mary Steadman Smith of North Augusta, South Carolina a Glaxo sales representative advised that "we need to stay focused and push tx of mild asthma w/ Advair."

i. On July 26, 2008 a Glaxo sales representative promoted "Advair for mild asthma not just severe" to Dr. James Proffitt of Maryville, Tennessee.

j. On August 29, 2001, a Glaxo sales representative advised Dr. Kimberly Kylstra of Chapel Hill, North Carolina that there is "no such things as mild"

asthma.

k. On August 30, 2001, a Glaxo sales representative told Dr. Jeffrey McMichael of Knoxville, Tennessee that "Advair [is] best for patients asthma, even mild."

l. On October 12, 2001, a Glaxo sales representative asked Dr. Ramlingeswara Yalamanchi of Southgate, Michigan to start patients on Advair instead of leukotriene.

m. On October 16, 2001, a Glaxo sales representative asked Dr. Michael Huey of Gainesville, Florida to "let some mild asthmatics try Advair 100/50."

n. On November 6, 2001, a Glaxo sales representative asked Dr. Luis Fanego-Gutierrez of Lincoln Park, Michigan "to use Advair for mild asthmatics."

o. On February 1, 2002, a Glaxo sales representative made "clear that Advair is for mild and moderate asthma" to Dr. Dennis Davis of Washington, Pennsylvania.

p. On May 9, 2002, a Glaxo sales representative promoted Advair as "offering even mild asthmatics a higher level of control" to Dr. Dr. Michael Hattan of South Sioux City, Nebraska.

q. On September 30, 2002, a Glaxo representative marketed the "importance" of prescribing Advair "even with mild asthma" with Dr. Debbera Speeter of Kalamazoo, Michigan.

r. On January 14, 2003, a Glaxo sales representative "pushed Advair for mild persistent asthma" to Dr. Barbara Brotine of Skokie, Illinois.

s. On March 24, 2003, a Glaxo sales representative asked Dr. John Klein of Cedar rapids, Iowa "to remember [Advair] 100/50 for patients with mild asthma."

191. Even in instances where physicians understood that Advair is not suitable for mild asthma, Glaxo sales representatives tried to override their judgment and convince them otherwise. For example, following a December 3, 2001 sales call on Dr. Aron Schlau of Palm Harbor, Florida, a Glaxo sales representative noted that the doctor "thinks Advair is too much beta agonist for mild asthma patients - need to follow up with long term studies of exposure to Serevent." Likewise, on January 3, 2002 a Glaxo sales representative noted that he "needed to work on" Dr. Shivinder Deol of Bakersfield, California after he indicated that he would never use Advair on mild patients.

192. By systematically promoting Advair for mild asthma contrary to NHLBI guidelines, Glaxo placed countless individuals at risk of harm and improperly caused beneficiaries of federal and state healthcare programs to receive medically unnecessary treatments. See generally Exhibit 102. In doing so, Glaxo caused the submission of nonreimbursable claims for payment or approval.

G. Glaxo Illegally Promotes Advair For Various Off-Label Uses

1. Glaxo Promotes Advair Off-Label As A First-Line Treatment For Mild Asthma

a. Advair's On Label Indication

193. Under the FFDCA, a drug may not be approved for any use or patient population for which its safety and efficacy have not been demonstrated by substantial evidence in clinical trials. 21 U.S.C. §355(d).

194. In 1999, Glaxo submitted to the FDA a New Drug Application ("NDA") for Advair for treatment of asthma based on clinical trials that studied its effectiveness on patients

with moderate or severe asthma. These clinical trials did not include patients with mild asthma. See Exhibit 98, stating: "Three double-blind, parallel-group clinical trials were conducted with ADVAIR DISKUS in 1208 adolescent and adult patients (≥12 years, baseline FEV1 63% to 72% of predicted normal) with asthma that was not optimally controlled on their current therapy." These FEV1 levels correspond to patients with moderate or severe asthma – not mild asthma.

195. Glaxo initially proposed a product label for Advair that raised FDA concerns because it did not identify the type of asthma patients for whom Advair was shown to be safe and effective in clinical trials. During a November 1999 meeting with the FDA's Pulmonary and Allergy Drugs Advisory Committee ("PADAC"), Glaxo's Director of Clinical Research, Dr. Tushar Shah, acknowledged that Advair had not been studied on mild asthmatics and assured the FDA that Glaxo was not seeking approval of Advair for treatment of patients with mild asthma. He acknowledged that such treatment would be inappropriate. At the same time that Dr. Shah made these representations to the FDA, Glaxo had brand plans and sales training materials in place to promote Advair for mild asthma. See Exhibit 103.

196. After reviewing Glaxo's NDA for Advair, the FDA instructed Glaxo to revise the proposed product label to clarify the patient population for whom the drug is appropriate. Dr. Susan Johnson, Medical Reviewer for the FDA, wrote in her January 4, 2000review of the Advair application, "As discussed with the PADAC on November 23, 1999, this indication does not provide prescribers with an adequate appreciation of the population studied or the patients in whom the product is expected to achieve efficacy. The sponsor will be asked to revise their proposal." See Exhibit 104. See also Exhibit 103 (including comments of PADAC Committee Charirman, Dr. Curtis Sessler, that he "would feel uncomfortable proposing the combination

drug for mild persistent patients").

197. In response to the FDA's concerns, Glaxo revised the proposed Advair product label. The resubmitted label, which was ultimately approved, stated that Advair is appropriate treatment "[f]or patients who are not currently on an inhaled corticosteroid, whose disease severity warrants treatment with two maintenance therapies, including patients on non-corticosteroid maintenance therapy." See Exhibit 98. This language made clear that patients not already using an inhaled corticosteroid should only be placed on Advair if "disease severity warrants treatment with two maintenance therapies" which, according to the testimony of Glaxo's Dr. Shah as well as NIH guidelines, excludes patients with mild asthma. See also comments of Dr. Homer Boushey, Glaxo Consultant stating "I understand [Advair's] proposed labeling to be for patients in whom combination therapy is appropriate, and that is, by implication, I think a reference to the guidelines;" and, comments of Dr. Tushar Shah, Glaxo Director of Respiratory Clinical Research stating "In these [mild] patients, combination therapy would be inappropriate" and "I think the label that we provided actually would exclude mild patients, because what we're saying is that this product is appropriate for patients in whom combination therapy is appropriate." Exhibit 103. From initial FDA approval through the present day, Advair has never been approved as a first-line treatment for mild asthma.

198. Even though Glaxo did not study Advair for mild asthma; assured the FDA that Advair was not intended for mild asthma; and agreed to a product label that did not include a mild asthma indication, it, from the outset, promoted the drug as a first-line medication for mild asthma. As explained below, Glaxo successfully carried out this plan after Advair's launch in April of 2001, quickly gaining a large share of the mild asthma market; it continues to illegally

market the drug for mild asthma through the present time. Glaxo's aggressive off-label marketing is directly contrary to its firm commitment to the FDA that "Glaxo Wellcome is committed to promote its appropriate use in the management of patients with asthma." See Exhibit 103 (statement of Dr. Tushar Shah, Glaxo Director of Respiratory Clinical Research).

b. Glaxo Has Used A Series of Strategies To Promote Advair Off Label for Mild Asthma

199. In addition to openly detailing physicians on the advantages of Advair for mild asthma, Glaxo has used a number of deceptive strategies to increase off-label use of Advair for treatment of mild asthma. From Advair's launch, Glaxo viewed its label and the national treatment guidelines as obstacles to increasing Advair's share of the mild asthma market.

200. One of Glaxo's anchor strategies was to undermine the guidelines-based categories of asthma severity – i.e., intermittent, mild persistent, moderate persistent and severe persistent – and to disseminate the incorrect and misleading view that there are actually only two categories of severity: intermittent and persistent.

201. In recharacterizing the NIH's four severity categories into only two categories – intermittent and persistent – Glaxo fraudulently promoted Advair as the treatment for "all persistent asthma," which includes persistent mild asthma. Glaxo's characterization misleads prescribers to believe, incorrectly, that Advair is intended for mild persistent asthmatics, as well as moderate and severe asthmatics. Glaxo's sales training guides, circulated even prior to Advair's launch, instructed sales representatives that market penetration would be achieved by establishing the rationale for Advair's use in "all severities of persistent asthma." Additionally, slides from a meeting of Glaxo managers in 2002 defined the company's strategy as, "Establish

ADVAIR Diskus as the Physician's First Choice for the Treatment of ALL Persistent Asthma." See e.g., Exhibits 105 and 106.

202. The following are examples of Glaxo's off-label promotion of Advair for "all persistent" asthma:

a. On April 19, 2001, a Glaxo sales representative decided to "bring proof of need for ADV in all persistent pats" after finding that Dr. Christine Carpenter of Kennewick, Washington "seemed to niche" Advair.

b. On April 19, 2001, a Glaxo sales representative told a nurse working for Dr. Larry Johnson of Albertville, Alabama about "the tons of reasons to RX [Advair] to all persistent asthma sufferers."

c. On May 10, 2001, a Glaxo sales representative "Covered indication for all persistent asthma and beneficial for all types" after learning that Dr. Roy Clemens of Siloam Springs, Arkansas generally used Advair in the more severe asthmatics.

d. On July 17, 2001, a Glaxo sales representative "Discussed Advair as first line for all persistent asthmatics" with Dr. Glenn Mac Donald of Oceanside, New York.

e. On December 2, 2002, a Glaxo sales representative asked Dr. Rex Rawls of Columbia, South Carolina to use Advair with "all persistent asthmatics."

f. On January 29, 2003, a Glaxo sales representative "Made the case for using ADV in all persistent asthmatic patients" to Dr. Robert Kobiela of Grandville, Michigan.

203. Another strategy that Glaxo uses to promote Advair for mild asthma involves

misrepresenting the NIH guidelines known as the "Rules of Two." When accurately described, the "Rules of Two" are a guideline-based tool that helps doctors identify patients currently treated with only a short-acting beta agonist ("SABA") who may need to add an ICS to their current asthma treatment.

204. Under the Rules of Two, a patient may need to be placed on an ICS if he or she falls into any one of the following categories: (1) using an inhaler more than twice a week; (2) waking up at night more than twice a month; (3) refilling his or her inhaler more than twice a year; or (4) dropping in peak flow by more than 20 percent with symptoms. In essence, the Rules of Two identify patients that were previously treated as intermittent asthmatics but who may actually be mild persistent asthmatics. Significantly, Advair is not approved for either type of patient – intermittent asthmatics or mild asthmatics – yet Glaxo misrepresents the Rules of Two to promote Advair off label for mild asthmatics in the following ways.

205. First, Glaxo informs doctors that patients treated with only a SABA who satisfy one of the Rules of Two (i.e., a mild persistent asthmatic) should be placed on Advair before attempting to treat them with an ICS. This is off-label promotion since Advair is not approved as a first-line treatment for mild asthmatics before they have tried and failed to achieve control with an ICS. See Exhibit 107; cf., Exhibit 103 (statement of Dr. Robert J. Fink, FDA PADAC, remarking, "I think for patients inadequately controlled on short-acting beta agonists alone, I would have to, I think, fairly strongly disagree with that as an indication, in that I think it is far too broad, and it brings in as many who were not studied as those who were").

206. Second, Glaxo informs physicians that patients who are currently treated with an ICS who satisfy the first Rule of Two – i.e., using an inhaler more than twice a week – may need

to be "stepped up" to a combination therapy like Advair. However, the 1999 and 2002 NIH Guidelines recommend that a patient already treated with an ICS be stepped up to a combination therapy only when inhaler use is daily.

207. The following examples are representative of Glaxo's misleading representations concerning the "Rules of Two" in order to promote Advair off-label:

a. On April 16, 2001, a Glaxo sales representative told Dr. Tamara McIntosh of Ohatchee, Alabama that "all asthma is severe enough for ADVAIR if they answer yes to one of rules for two!"

b. On June 29, 2001, a Glaxo sales representative claimed that Advair provided "optimal control for all asthmatics inc. those outside rules of 2 on albuterol [a short acting beta agonist] alone" in discussions with Dr. David Yoon of Chalfont, Pennsylvania.

c. On July 25, 2001, a Glaxo sales representative asked Dr. Clifton Howell of Jersey City, New Jersey to "consider step up patient" to Advair using the "rules of two."

d. On October 2, 2001, a Glaxo sales representative "asked for step up therapy based on rules of 2 and too much albuterol use" from Dr. William Griever of Halifax, Massachusetts.

e. On October 4, 2001, a Glaxo sales representative detailed "Advair 100/50 for those pts just on albuterol alone and not controlled using the rules of two" to Dr. Stephen Fischer of Chehalis, Washington.

208. Another strategy used by Glaxo to promote Advair off label for mild asthma

involves the manipulation and misleading use of Glaxo-sponsored scientific studies. In one such study, referred to in Glaxo documents as the "Calhoun study" (named after the lead author of the study), Glaxo compared Advair to Singulair (montelukast) in a head to head trial involving moderate and severe asthma patients. See Exhibit 108. Unlike Advair, Singulair is a monotherapy that is only recommended under the NIH Guidelines as a treatment for mild persistent asthma.

209. By designing the Calhoun study to compare Advair to Singulair, Glaxo sought to make inroads on the Singulair market share. And, since Singulair is only approved for treatment of mild asthma, Glaxo suggested Advair against Singulair as the preferred treatment for mild asthma. However, this is not what the Calhoun study examined, since all of the subjects in the study had moderate or severe asthma. Not surprisingly, Advair showed better results in this patient population since Singulair is a treatment for moderate or severe asthma. In promotional material, Glaxo deceptively referred to the moderate asthmatics in the Calhoun study as the "milder" asthmatics in the study, thus creating the false impression that Advair was the preferred treatment for mild asthma.

210. The following are examples of Glaxo's deceptive and misleading use of the Calhoun study to promote Advair for mild asthma:

a. On September 25, 2001, a Glaxo sales representative spoke to Dr. James Santella of Knoxville, Tennessee regarding "Calhoun for mild patients."

b. On October 24, 2001, a Glaxo sales representative told Dr. Roger Haas of Hillsborough, New Jersey that he "was leaving a study on Advair and mild asthmatics (Calhoun)."

c. On November 12, 2001, a Glaxo sales representative "discussed the calhoun study and [Advair] use for mild and severe patients" with Dr. Hubert Jones of Harrisburg, Pennsylvania.

d. On November 30, 2001, a Glaxo sales representative "Shared mild asthmatic pt type w/ Calhoun" with Dr. Edward Jeryan of West Palm Beach, Florida.

e. On January 3, 2002, a Glaxo sales representative discussed "Advair Calhoun data for mild asthmatics" with Dr. Michael Raffian of Washington, District of Columbia.

f. On February 5, 2002, a Glaxo sales representative "made sure to use [Calhoun] for mild persistent asthmatics" when showing it to Dr. Malcom Schoen of White Plains, New York.

211. Another Glaxo-controlled study that Glaxo misuses in promoting Advair off label for mild asthma was published in the Journal of Allergy and Clinical Immunology under the name of Mani Kavuru, a Glaxo-trained speaker, and ghost-written by a Glaxo employee (the "Kavuru study"). See Exhibit 109.

212. Even though the underlying data in the Kavuru study showed that Advair is no more effective than ICS for mild asthmatics who had not previously been treated with an ICS, the published article selectively ignored key data in the study and falsely represented that Advair was shown to be more effective than an ICS for these patients. Glaxo used this article to deliberately mislead doctors that Advair is more effective than an ICS for first-line treatment in mild asthma.

213. Glaxo also illegally promotes Advair off label for mild asthma by

mischaracterizing the variability of asthma. NIH Guidelines recognize that asthma is variable. However, variability itself does not determine the treatment or classification of asthma. Glaxo distorts the variability and unpredictability of asthma to promote Advair as a first-line treatment with mild patients. See e.g., Exhibit 110, 111, 105 and 112 (stating "The goal of this semester is to grow our start business by establishing that asthma severity is variable and unpredictable and that control is often overestimated"); ("Create Need: Variability: As we look at these patients, we see just how variable and unpredictable asthma can be over time"); ("Reasons why you might consider ADVAIR – Disease is variable – maybe mild today, but can become 'moderate' and subsequently serious. Don't want to leave patients 'unprotected'"); (Concern #1: Not all of my patients need ADVAIR DISKUS. Answer: Asthma is a variable and unpredictable disease."). Glaxo's "variability" promotions were designed to increase providers' doubt about their patients' true severity. But Glaxo's focus on variability is misleading because variability alone does not determine a patient's treatment.

214. For example, Glaxo created a survey, called the Fuhlbrigge survey, to increase doctors' doubts about their asthma patients' true severity. Glaxo designed the Fuhlbrigge survey to suggest that the unpredictable nature of asthma causes doctors to misdiagnose millions of moderate asthma patients as mild. See Exhibit 113. The Fuhlbrigge survey used vague questions and imprecise scoring to drive respondents to a moderate/severe classification. The survey was designed to and did overestimate the frequency of moderate and severe asthma.

215. Glaxo call notes reveal that the Fuhlbrigge survey was referred to in tens of thousands of sales calls on doctors in order to persuade the doctors that most asthmatics are moderate or severe and thus candidates for Advair. In 2003 alone, the variability campaign

increased Advair sales 48 percent to over $2.3 billion, nearly doubling Glaxo's penetration into the mild asthma market even with the news in late 2002 that a major clinical trial of salmeterol was halted because of patient deaths.

216. Glaxo took the "variability" message to its ultimate conclusion by claiming that, in fact, mild asthma does not exist. Glaxo's campaign was called the "myth of mild asthma." Glaxo even funded a CME program entitled "Myth of Mild Asthma." This campaign has been hugely successful in increasing Advair sales. See Exhibit 114.

217. Glaxo continues to promote Advair by suggesting that mild asthma is a "myth" and simply does not exist. For example, in late 2009 and/or early 2010, Dr. Ramalinga Polmareddy and Dr. Ronald Negrich of Toledo and Bowling Green, Ohio, respectively, were separately detailed by Glaxo sales representatives who represented that patients simply do not come to a doctor's office with mild asthma, and only go to their doctors when asthma is severe. Whenever a patient visits a doctor with asthma, Glaxo contends, it is severe enough to warrant a combination product like Advair.

218. Similarly, Glaxo representatives continue to misrepresent the NIH guidelines by advising prescribers that if a patient has ever gone to an emergency room for an exacerbation or asthma attack, he or she could never again be considered a mild asthmatic and must be treated with a combination product. See e.g.., Exhibit 110 (misleading sales training including script coaching sales representatives: "Although the proportion of patients reporting exacerbations decreased as reported FEV1 % increased, patients classified as mild persistent did exacerbate . This only reinforces the importance of not underestimating mild disease. Doctor, given the importance of effective asthma control, I would like to discuss how ADVAIR DISKUS can help

to reduce exacerbations." See also id. (instructing sales representatives to advise physicians: "Since studies have shown that patients with severe asthma are not the only ones who have exacerbations, will you prescribe ADVAIR DISKUS for your patients "); and Exhibit 115 (misleading sales training that states "76% of patients were classified as mild or moderate persistent one week prior to an exacerbation" when in fact the data showed that only 17% were mild persistent").

219. These false and misleading representations are directly contrary to the NIH Guidelines which contemplate that asthma patients of all severity levels may have exacerbations. See Exhibit 116 (NIH Guidelines stating that exacerbations alone do not indicate a higher level of asthma severity – exacerbations occur at all severity levels). See also Exhibit 117 (2007 NIH Guidelines stating "there are inadequate data to correspond frequencies of exacerbations with different levels of asthma severity").

2. Glaxo's Off Label Promotion of Advair For Mild Asthma Is Ongoing, Despite Known Health Risks And Repeated Warnings By The FDA

220. Since Advair's approval, further risks associated with use of the drug have been exposed. Studies have shown that salmeterol, the LABA component of Advair, can mask exacerbations that lead to hospitalization or possibly death.

221. In 1996, GSK began the Salmeterol MultiCenter Asthma Research Trial ("SMART") study due to reports of life-threatening episodes and death in patients taking salmeterol. SMART was halted prematurely in 2002 because preliminary findings showed an increased risk in African-American patients. Further statistical analysis found a significant increase in asthma-related deaths in all patients receiving salmeterol versus those receiving

placebo.

222. As a result, the FDA gave Advair a black box warning in 2003 and reiterated in 2006 that Advair should not be used in patients whose asthma can be controlled with an ICS. See Exhibits 118 and 119. The revised indication contains the following language:

> Long-acting beta$_2$-adrenergic agonists, such as salmeterol, one of the active ingredients in ADVAIR DISKUS, may increase the risk of asthma-related death. (see Warnings and Precautions). Therefore, when treating patients with asthma, physicians should only prescribe ADVAIR DISKUS for patients not adequately controlled on other asthma-controller medications (e.g., low-to-medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with 2 maintenance therapies. . . . ADVAIR DISKUS is not indicated in patients whose asthma can be successfully managed by inhaled corticosteroids along with occasional use of inhaled, short-acting beta$_2$-agonists.

Notwithstanding this renewed warning, Glaxo continued to market Advair for mild asthma and Advair 500 for COPD.

223. In February 2010, the FDA issued yet another warning about the risks associated with LABAs, either used alone or in combination drugs such as Advair. The latest safety warning, which applies to Advair, was based on the FDA's meta-analyses of studies "showing increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients using LABAs for the treatment of asthma." See Feb. 18, 2010 "FDA Drug Safety Communication: New Safety Requirements for Long-Acting Inhaled Asthma Medications Called Long-Acting Beta-Agonists (LABAs)."

224. Despite all of these warnings, Glaxo has continued to promote Advair off-label for mild asthma up to and including the present time. Although the particular messages have changed over the years, Glaxo's off-label marketing scheme has continued unabated.

225. Beginning about 2005, Glaxo's strategy evolved into an effort to capture

prescriptions for "less symptomatic" asthmatics, including those who had only been treated with albuterol, a short-acting beta agonist, often referred to as a "rescue inhaler."

226. Accordingly, Glaxo developed yet another in its string of promotional efforts to reach mild patients, this time focusing on raising patient and physician expectations of control, and further blurring the distinctions between severities. This effort, like others, mischaracterizing NIH Guidelines.

227. Glaxo's internal research suggested that patients often report that they feel fine, when in fact they still may experience occasional symptoms. To reach these mild patients, Glaxo launched a campaign that encouraged patients and physicians to consider stepping up to Advair even when asthma appears well-controlled. Glaxo pushed the idea that even patients with very mild symptoms "deserve" a higher level of symptom control and claimed that Advair could deliver that control.

228. As recently as 2009, Glaxo distributed a handout to doctors stating that Advair is "indicated for the long-term, twice-daily maintenance treatment of asthma in patients 4 years of age and older," disregarding the indication's additional limiting language that states that Advair is only appropriate for patients not adequately controlled on other asthma controller medications (e.g., low-to-medium-dose ICS). Furthermore, the same handout promotes Advair as an alternative to medium-dose ICS, despite the label's explicit restrictions against use in patients who can be controlled on ICS.

229. Taking the lead from these handouts, Glaxo sales representatives continue to improperly promote Advair off label for mild asthma. Examples of doctors to whom Glaxo sales representative promoted Advair off label for mild asthma in 2009 include Dr. Ramalinga

Polmareddy of Toledo, Ohio; Dr. Ronald Negrich of Bowling Green, Ohio; Dr. Craig Dolven of Flint Michigan; Dr.Joel Fiedler of Philadelphia, Pennsylvania; Dr. David Listello of Grand Rapids, Michigan; and Dr. Carmine Defusco of Manalpan, New Jersey.

230. Glaxo's off label promotion of Advair for mild asthma is ongoing at the present time, notwithstanding the longstanding concern over the risks associated with Advair use. As noted above, in February 2010, the FDA issued new warnings about the safety of LABAs that are used alone or in combination drugs such as Advair.

231. The latest warning states, inter alia, that LABAs "should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication." The FDA further advises that "LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications."

232. In keeping with the mandatory nature of the safety warning, the FDA requires a Risk Evaluation and Mitigation Strategy for drugs with LABAS that, inter alia, calls for provider and patient guidance and education on the appropriate use of LABAs.

233. Despite the very serious nature of this warning, added to all of the preceding warnings, Glaxo is directing its sales representatives to present misleading information to prescribers about the warning, and to continue marketing Advair off label in spite of the grave risks.

234. In particular, following publication of the February 2010 FDA warning, Glaxo initially considered reaching out to physicians to discuss the warning but quickly changed course and directed sales representatives affirmatively not to bring the FDA notice up with physicians.

Instead, Glaxo advised sales representatives to only discuss the safety warning responsively. Further, in an effort to dismiss the gravity of the FDA's action, Glaxo instructed its sales force to tell doctors that this is "old news" and that there is no new information or data in the latest warning.

235. Relators are informed that Deirdre Connolly, President of North American Pharmaceuticals, took the extraordinary step of issuing a voice message to all sales representatives advising them not to raise the warning with their physicians, and only to respond to physicians' questions in the fashion discussed above. Officials at Ms. Connolly's level rarely conduct blast communications to the sales force, which indicates the level of concern at the company.

236. Glaxo has also responded to the FDA safety warning by improperly recommending that doctors prescribe Advair 250 for six months and then "adjust" the patients to Advair 100 for the next six months, before moving them to an inhaled corticoid steroid. This message is directly contrary to the FDA's instructions to use a LABA for the "*shortest duration* of time required to achieve control" and then move to an asthma controller if continued medication is necessary. (Emphasis added.) Glaxo's marketing creates the false and misleading impression that patients must be "weaned" off LABA, and that a year is the shortest duration of treatment.

237. Glaxo's off-label marketing of Advair for mild asthma has been successful. A recent study of 87,459 patients from across the country found that almost 70 percent of new Advair users met the criteria for mild or intermittent asthma (i.e., most prescriptions were inconsistent with national guidelines and Advair's label); nearly 94 percent of new Advair users

had no prior ICS use; and nearly half had received no prior asthma-related medication. See Exhibit 102.

3. Glaxo Aggressively Markets Advair Through Other Unsubstantiated, Off-Label Claims

238. Glaxo aggressively marketed Advair as a means to reduce steroid use – particularly in children. As early as 1999, GSK planned to promote Advair as an effective way to reduce the dose of steroids needed to control asthma:

239. Glaxo's "steroid sparing" faxback was the anchor piece of its marketing effort, and was written to create an appearance of clinical support for using salmeterol (LABA) to reduce the steroids needed to control asthma. See Exhibit 120.

240. The steroid sparing marketing piece is misleading in numerous respects. First, Glaxo misrepresented the results of clinical trials that concluded that salmeterol has the potential to mask a worsening of inflammation due to steroid reduction, and could lead to life-threatening consequences. See Exhibit 121 (A. McIvor et al., "The Potential Masking Effects of Salmeterol on Airway Inflammation in Athsma"). Glaxo's steroid sparing faxback, however, falsely stated that the McIvor study shows that salmeterol allows patients to reduce ICS dose without adverse consequences. The McIvor study, however, concluded the opposite. Other studies cited in the Glaxo faxback support the fact that eliminating ICS worsens the disease. However, Glaxo not only fails to mention this critical fact but stresses the opposite conclusion.

241. Glaxo also trained sales representatives to promote Advair as steroid sparing. Advair training materials advocate the reduction of ICS, but fail to mention the potential masking effects of salmeterol as inflammation worsens with the reduction of a corticosteroid.

See e.g., Exhibit 120.

242. In addition, Glaxo trained paid physician speakers to promote the claimed steroid sparing qualities of Advair. Primary care physicians, pediatricians and specialists were all targeted for these speaker presentations. See Exhibit 106. In just the last half of 2003, Glaxo budgeted over $5 million to train speakers and hold thousands of "faculty led teleconferences" on topics including steroid sparing. Id.

243. Numerous sales representative notes of physician details used misleading steroid sparing claims to promote Advair, particularly to children: See e.g.,

> Columbus, Ohio March 11, 2003 prescriber detail note stating "F/U on Mahr talk – they were influenced by his review of steroid sparing data – will use Advair in any kids who can use it to reduce exposure to steroids."
>
> Gainesville, Florida, November 27, 2002 prescriber detail note stating "discussed advair and asthma, she said everyone doesn't need to be on advair, made the steroid sparing point."
>
> Taunton, Massachusetts, March 31, 2003: prescriber detail note stating "...talked about NIH and importance of LABA2 to lower steroid use, she still writes a lot of flov and pulmicort. I am sending her med info letter on steroid sparing with Advair."
>
> Bullhead City, Arizona, March 4, 2003 prescriber detail note stating "...Steroid sparing data ability to reduce dose of steroid by addition of laba."

244. While preparing the steroid sparing campaign, Glaxo was aware that the SMART trial showed salmeterol's serious risks. Indeed, in 2003 the FDA asked GSK to distribute a letter

to physicians explaining the SMART results and advising that corticosteroids should not be reduced when salmeterol is initiated. See Exhibit 123 (Glaxo "Dear Dr" Letter stating: "GSK and the FDA agree on the need to reiterate and reinforce advice for the management of patients... as established in the label for Serevent and national asthma management guidelines" and advising "Salmeterol is not a replacement for inhaled corticosteroids, which should be continued at the same dose, and not stopped or reduced, when treatment with salmeterol is initiated...").

245. Despite the SMART trial's results and the content of its own "Dear Doctor" letter, Glaxo promoted the supposed benefits of reducing a patient's inhaled corticosteroid dose with Advair. Glaxo targeted pediatricians as a group particularly susceptible to this message, as well as physicians who prescribed medium-dose ICS before adding a LABA. Steroid sparing claims were included in paid speaker presentations, and Glaxo sales representatives frequently initiated discussion of Advair's supposed steroid-sparing benefits without any mention of risks.

246. In addition, Glaxo aggressively marketed the unsubstantiated claim that "increased patient compliance" was a reason to prescribe Advair. In fact, the available data suggested lower – not higher – patient compliance with Advair. In two of the three clinical trial studies submitted to support Advair's FDA approval, there was no significant difference in compliance between the groups. In the third, the Advair group had the lowest compliance rates. As the FDA Medical Review observed: "Compliance was approximately 94 percent, with approximately 10 percent having less than an 80 percent compliance rate (range 8 to 14 percent). Of note, the Advair group had the lowest overall compliance rate (91 percent) and highest proportion of low-compliance patients (14 percent)." See Exhibit 104.

247. In spite of an acknowledged lack of evidence, Glaxo identified patient compliance as a strategic opportunity for Advair growth. Glaxo trained sales representatives to evade questions from doctors seeking proof that Advair increases compliance. They were trained to advise doctors that: "Improved compliance may result from a simpler dosing regimen, rapid onset of action, and improved asthma control;" and that "During clinical trials, compliance with ADVAIR DISKUS was approximately 95 percent." See Exhibit 124. Glaxo, however, omitted the fact that Advair had the lowest compliance rate in those clinical trial studies.

248. Notes of sales representative details of prescribers indicate that Glaxo used misleading compliance claims to promote Advair. See e.g.,

> Bossier City, Louisiana, April 4, 2001 prescriber detail note stating: "Had not used Advair yet, reminded him that it would improve control and compliance..."
>
> Ann Arbor, Michigan, April 30, 2001 prescriber detail note stating: "Advair most comprehensive mangement for mild to severe asthma pts...all these benefits and excellent features will increase the pts compliance..."
>
> Avilla, Indiana, April 19, 2001 prescriber detail note stating: "discussed ADVAIR Diskus 2 in one 1 co pay increased compliance and reduced exacerbations..."
>
> Milwaukee, Wisconsin, April 18, 2001 prescriber detail note stating: "patients better controlled on 100/50 vs double dose of steroids and compliance better..."
>
> Mount Holly New Jersey, April 24, 2001 prescriber detail note stating: "Advair convenience and compliance over ICS's..."
>
> Cherokee, Iowa, May 9, 2001 prescriber detail note stating: "Advair Diskus treats

both components of asthma in 1 easy to use device, only choice to increase compliance, technique, and lung function..."

H. Glaxo Unlawfully Promotes Advair For The Off-Label Treatment Of Chronic Obstructive Pulmonary Disease

1. Glaxo Marketed Advair for COPD Prior to Receiving FDA Approval for that Indication

249. Soon after Advair was approved, Glaxo also initiated off-label promotion of the drug for use in treating chronic obstructive pulmonary disease ("COPD"), a then-unapproved use. COPD treatment represents a huge potential market for Glaxo. Wall Street analysts estimated that the market for COPD drugs as of 2003 exceeded $3 billion, and will grow to $9 billion by 2010.

250. In September 2001, Glaxo applied to the FDA to expand Advair's on-label indication to include COPD. In 2002, the FDA's Pulmonary & Allergy Drugs Advisory Committee raised doubts about the sufficiency of evidence of Advair's safety for the treatment of COPD, especially over the long term. Among the issues raised were concerns about ocular manifestations, bone mass decrease and the vulnerability of COPD patients to adverse effects. Questions over the long-term effects of Advair for the treatment of COPD remain.

251. Indeed, in January 2003 clinical studies involving Serevent - one of the active components of Advair - were halted in part because an interim analysis suggested that some patients using the drug were at increased risk of asthma-related death or life-threatening asthma episodes. Notwithstanding these events, the FDA approved Advair 250/50 (fluticasone propionate 250 mcg and salmeterol 50 mcg inhalation powder) for use in treating COPD in 2003.

252. In spite of the safety concerns and the limited on-label indication, Glaxo actively

promoted Advair off-label for COPD well in advance of its approval. Once again, Glaxo combined speaker programs discussing COPD and Advair with saturated marketing efforts by Glaxo's field representatives.

253. The following are representative examples of Glaxo's off-label promotion of Advair for COPD in advance of receiving FDA approval for that indication:

a. On October 20, 2001, a Glaxo sales representative discussed the benefits of Advair for COPD in geriatric patients with Rebecca Allen, NP of Mishawaka, Indiana.

b. On October 5, 2001, a Glaxo sales representative discussed the use of Advair in geriatric patients with COPD with Nancy McDonald, PA of Duanesburg, New York.

c. On July 13, 2001, a Glaxo sales representative discussed the use of Advair to treat COPD with Catherine Hellman, NP of Harriman, Tennessee.

d. On November 13, 2001, a Glaxo sales representative discussed the use of Advair with COPD with Dr. Elizabeth O'Brien of Madison, Wisconsin.

e. On February 18, 2002, a Glaxo sales representative discussed Advair for COPD with Dr. Francis Daly of New Oxford, Pennsylvania.

f. On March 26, 2002, a Glaxo sales representative talked to Dr. Aziz Maksoud of Longview, Washington about using Advair for COPD.

g. On February 14, 2002, a Glaxo sales representatives "mentioned" the advantages of Advair for COPD to Dr. Tresha Ward of Hartsville, South Carolina.

h. On February 28, 2002, a Glaxo sales representative talked about Advair and

its use for COPD over lunch with Heather Wilkes, PA of Mesa, Arizona.

i. On February 13, 2002, Glaxo sales representatives "mentioned" to Lindsey Poulsen, NP of Downers Grove, Illinois that Advair's COPD indication was "forthcoming."

j. On February 7, 2002, a Glaxo sales representative "bombarded" Janet Wills, NP of Cuthbert, Georgia and reminded her of Advair's use for COPD.

k. On December 17, 2002, a Glaxo sales representative talked to Mary Louise Jackson, NP of Wilmington, North Carolina about the use of Advair for COPD.

l. On January 14, 2002, a Glaxo representative spoke to Laura Brooks, PA of Evanston, Illinois about the use of Advair for COPD.

m. On December 14, 2001, a Glaxo representative discussed the use of Advair for COPD with Mark Compton, PA of Madison, Tennessee.

n. On January 11, 2002, a Glaxo sales representative spoke to Dr. Ravi Santhanam of Palm Springs, California about using Advair to treat COPD.

2. <u>Glaxo Continues To Promote Advair 500/50 Off-Label For COPD</u>

254. Glaxo has focused much of its COPD marketing on promoting the higher dose Advair 500/50 that has never been approved for the treatment of COPD. Advair 500/50 (hereafter "Advair 500") has only been approved for use in the treatment of moderate or severe asthma. Only Advair 250/20 (hereafter "Advair 250") was approved for the COPD indication.

255. In 2003, when Advair 250 was approved as a treatment for COPD, the FDA specifically refused to approve Advair 500 for COPD, finding that it was not an acceptable dosage for both safety and efficacy reasons. Studies showed that the COPD patients treated with

Advair had a higher incidence of respiratory tract infections and pneumonia than those in control groups, and COPD patients treated with Advair 500 showed no documented advantage over those treated with the lower dose.

256. When the FDA approved Advair 250 to treat COPD, it added warnings in five different places in the Advair label, cautioning against use of the 500 dosage for COPD patients. See Exhibit 118. Every Advair label since then has contained explicit warnings against the use of Advair 500 as a treatment for COPD. Additionally, because of elevated safety concerns regarding Advair 500, the FDA imposed a "Risk Management Plan" on Glaxo requiring the company to review, investigate, and report adverse events as well as produce patient and health care provider educational material describing the possible risks of Advair use in COPD patients. See Exhibit 125. These risks include pneumonia, decreased bone mineral density, osteoporosis, and fractures; cataract and glaucoma, adrenal suppression; and lower and upper respiratory tract infections. See Exhibits 126 and 127.

257. Internally, Glaxo recognized the patient health risks as well asan absence of added efficacy. Nevertheless, and despite the label's warnings, Glaxo promoted Advair 500 as a treatment for COPD. In many instances, Glaxo's promotion put forward false or deceptive information about its safety. For example, Glaxo-sponsored articles publishing the results of clinical trials did not report adverse events and even claimed that treatment with Advair 500 did not increase the risk of side-effects. See e.g., Exhibits 128 and 129 (misrepresenting side effects and stating "Because inhaled long-acting β2 agonists and corticosteroid combination treatment produces better control of symptoms and lung function, with no greater risk of side-effects than that with use of either component alone, this combination treatment should be considered for

patients with COPD"). These misleading "results" were then incorporated into Advair faxbacks that Glaxo sales representatives distributed to physicians, as well as speaker and CME presentations. See e.g., Exhibits 130 and 131. See also Exhibit 132 (Glaxo's CME "Building A COPD Care Plan" representing that ICS has a positive impact on "quality of life" – even though the clinical data did not show a meaningful change in the quality of life – and making misleading claims about ICS increasing survivability and lowering hospitalizations in COPD).

258. Sales representatives were also trained to promote Advair 500 for COPD and to provide doctors with misleading information regarding its efficacy. Glaxo selling resources falsely claimed that adverse events in two clinical trials were "similar" among treatment groups in number of incidents, type and severity, when in fact, as the FDA Medical Reviewer looking at the same data reported, there was a higher incidence of respiratory infections in the group of patients on Advair See Exhibit 133 cf., Exhibit 127. The selling resources also falsely claimed that there was no difference in the incidence of adverse events in a one year trial, where an FDA Medical Reviewer reported more subjects with respiratory infections and pneumonia in the treatment group. See Exhibit 134. Glaxo's sales training materials misrepresented the safety data and the improvement in patient health status – the very concerns that led the FDA to deny approval of Advair 500 for COPD.

259. In 2004, Glaxo began a three year study of Advair 500 and mortality in COPD patients, generally referred to as "TORCH." See Exhibit 135. At least as early as 2006, Glaxo began using TORCH in its promotions. Presentations to investors claimed that Advair 500 demonstrated a "clinically meaningful" "survival benefit" for COPD, even though the FDA specifically denied the "mortality" claim. See Exhibits 136 and 137. Similarly, Glaxo promoted

TORCH as an "Expanding COPD Opportunity" and a "near term growth opportunity" even though the TORCH results did not support an expanded FDA approval. See Exhibits 138 and 139. Glaxo's misleading TORCH marketing paid off – by the third quarter of 2007, Advair 500 was the fastest growing strength. See Exhibit 140.

260. Glaxo submitted the results of the study to the FDA in 2007 in support of an Advair 500 indication for COPD, but the FDA again denied the indication because TORCH failed to show improvement in the survival rate of COPD patients and because Advair 500 continued to increase patients' risk of pneumonia. Indeed, Glaxo misrepresented to the FDA that TORCH was the first study that they had seen the pneumonia signal when in fact the pneumonia signal had been seen from the late 1990s in ISOLDE and then again with TRISTAN.

261. The following examples are representative of Glaxo's off-label promotion of Advair 500 as a treatment for COPD:

a. On May 25, 2001, a Glaxo sales representative discussed using Advair 500/50 for a COPD patient with Mary Bovier of Youngstown, Ohio.

b. On June 22, 2001, a Glaxo sales representative told Dr. Amy Kirby of Trenton, Florida how to "add on a Flovent 100 sample" to a prescription of Advair 500/50 for COPD.

c. On January 14, 2002, after Dr. Anita Remerowski of Moberly, Missouri said that she was switching all her COPD patients to Advair 250/50, a Glaxo sales representative "reminded her about 500/50."

d. On March 22, 2002, a Glaxo sales representative told Dr. Mervin Wolff of Detroit, Michigan to "start [COPD patients] on advair 500/50."

262. Glaxo's off-label marketing of Advair 500 for COPD continues to this day. Since at least mid-2003, one powerful message that sales representatives have been encouraged to convey is that Advair 500 (marketed as Serevent 500/50) is approved in Europe for the treatment of COPD. This is intended as a strong endorsement of Advair 500's safety and effectiveness for COPD, and to downplay or dismiss the lack of FDA approval. Such misleading representations are intended to encourage Advair 500's off-label use in the U.S.

263. Glaxo also distributes study data to its sales representatives concerning the use of Advair 500 for COPD. Although labeled "FYI only," these communications from Glaxo's home office are intended to be used by sales representatives to encourage the use of Advair 500 for COPD in the U.S., despite the FDA's express rejection of that treatment indication.

I. Glaxo Provides Significant Financial Inducements To Managed Care Insurers To Encourage Off-Label Uses And Punishes Those Comply With Label That Discourage It

264. Many beneficiaries of federal and state health insurance receive prescription drug coverage through so-called "managed care" insurance plans. Typically, managed care drug formularies have three tiers. Tier 1 generally has the lowest beneficiary co-payment and usually includes generic medications. Tier 2 has a higher co-payment than Tier 1 and usually includes preferred brand name medications. Tier 3 has the highest co-payment and usually includes non-preferred brand name medications. Each Tier is associated with different levels of rebate payments, price concessions or discounts provided by the pharmaceutical manufacturer to the managed care company.

265. Managed care insurance plans often subject prescription drugs to "prior authorization," "first fail" or "step edit" requirements. "Prior authorization" refers to an

insurer's requirement that a medication or treatment be approved by insurance company reviewers medication before the plan will pay for it. "Step edits" – sometime called a "first fail" requirement - refer to a requirement that the patient first try – but fail on - an alternative medication before being prescribed the prescription drug in question. Step edits are often imposed by managed care companies to control both the costs and risks of prescription drugs.

266. In the case of the use of Advair to treat asthma, the FDA-approved label requires (in nearly all cases) that patients first try – but fail to be controlled on - inhaled corticosteroids or other approved first-line treatments before "stepping up" to Advair's combination therapy. Very importantly, a step edit requiring that ICS or other first-line treatments be used before Advair is entirely consistent with Advair's labeling. In other words, Advair's very labeling imposes "step edit"-type requirements. Except for the most severe asthma patients, promoting Advair before a patient has tried and failed on ICS, or other approved first-line medications, is clearly off-label.

267. Glaxo was highly attuned to Advair's placement on managed care formularies. See Exhibit 141. The attached presentation by Glaxo regional vice presidents of managed care, was made at headquarters, and was attended by Stan Hull, David Stout (then-President, Glaxo) among other high level officials. The presentation suggests: "Send top MCO [managed care organizations] Influencers to asthma Advisory Boards this summer." An "influencer" is an individual who is involved in formulary and drug benefit decisions. With respect to Advair, Glaxo views the imposition of "disadvantages" such as step edits, first fail and prior authorization requirements, as one of the most critical managed care formulary decisions it must influence.

268. It is Glaxo's practice to improperly tie the payment of rebates and discounts to

agreements by the managed care companies not to "disadvantage" Advair with prior authorizations, step edits or first fail requirements. As a general matter, Glaxo will pay rebates and discounts only if the managed care company agrees not to disadvantage Advair.

269. By making the payment of rebates contingent on managed care companies not disadvantaging Advair with step edits, prior authorizations, or first fail requirements illegally, Glaxo has and continues to promote the drug for off-label uses. Eliminating step edits, prior authorizations and first fail requirements is intended by Glaxo to encourage physicians to prescribe Advair even when the label restricts use of the drug. Such label restrictions clearly include the use of Advair as a first-line treatment for asthma, or when asthma may be controlled by ICS or other non-combination medications. Label restrictions likewise exist for Advair's use in treating COPD.

270. Glaxo's conduct is directly at odds with Advair's label which itself calls for patients to first fail on ICS or other non-combination medications before stepping up to Advair. Making payment of managed care rebates or other pricing advantages contingent on the managed care companies' agreement not to impose step edits and similar "disadvantages" is intended to and does directly impact prescription of Advair off-label. Glaxo's tying arrangements both illegally promote Advair off-label and serve as impermissible financial inducements to further off-label uses.

J. Glaxo Promotes Imitrex for Off-Label Uses

271. Imitrex (sumatriptan) is approved by the FDA for treatment of one type of headache: migraine headache. The "WARNINGS" section of the Imitrex label cautions that Imitrex "should only be used where a clear diagnosis of migraine headache has been established"

because of the risk of adverse cardiac events. See Exhibits 142, 143 and 144. The US Headache Consortium guidelines ("the guidelines") provide that sumatriptan is for use in patients with moderate-to-severe migraine headaches as well as patients whose headaches have responded poorly to the recommended first-line treatments (including NSAIDs and combination analgesics such as aspirin plus acetaminophen plus caffeine). Imitrex, therefore is not an appropriate first-line treatment or a treatment for patients with less severe migraine attacks.

272. Glaxo circumvents the label's restrictions, however, and devised a strategy to persuade doctors to "diagnose" nearly all headaches as migraine headaches. Glaxo Strategic Brand Plans reveal that this strategy was motivated by Glaxo's view that the non-migraine headache market holds greater growth opportunity for Imitrex than the migraine market. See Exhibit 145. Glaxo's analysts determined that the largest potential for Imitrex growth existed not in the "Migraine" market, where triptans were prescribed 53 percent of the time, but in the "Headache" market, where triptans were only prescribed 10 percent of the time. Glaxo identified this market as a "megablockbuster growth opportunity" and described the company as "poised to pursue" it. In particular, Glaxo identified patients with sinus and tension headaches as well as those with other migrainous or mixed headaches as large sources of potential volume. They developed a strategy - called "expanding the diagnosis" - to target these patients. See Exhibit 146. Glaxo pushed the message that migraines are underdiagnosed and a high percentage of patients diagnosed with sinus or tension headache may actually have migraine, and should be taking Imitrex..

273. The same internal documents state that Glaxo planned to "[e]xpand diagnostic criteria" of migraine to include symptoms outside the definition of migraine. Id. Migraines are

diagnostically distinct from other headaches and have been defined by the International Headache Society ("IHS") as meeting the following criteria:

1.1 Migraine without aura:
- A. At least 5 attacks fulfilling B-D
- B. Headache attacks lasting 4-72 hours in adults or 2-48 hours in children under age 15 (untreated or unsuccessfully treated)
- C. Headache has at least two of the following characteristics:
  1. Unilateral location
  2. Pulsating quality
  3. Moderate or severe intensity (inhibits or prohibits daily activities
  4. Aggravation by walking stairs or similar routine physical activity
- D. During headache at least one of the following
  1. Nausea and/or vomiting
  2. Photophobia and phonophobia
- E. At least one of the following:
  1. History, physical- and neurological examinations do not suggest one of the disorders listed in groups 5-11
  2. History, physical- and/or neurological examination do suggest such a disorder, but it is ruled out by appropriate investigations
  3. Such disorder is present, but migraine attacks do not occur for the first time in close temporal relation to the disorder

1.2 Migraine with aura:
- A. At least 2 attacks fulfilling B
- B. At least 3 of the following 4 characteristics:
  1. One or more fully reversible aura symptoms indicating focal cerebral cortical- and/or brain stem dysfunction
  2. At least one aura symptom develops gradually over more than 4 minutes or, 2 or more symptoms occur in succession
  3. No aura symptom lasts more than 60 minutes. If more than one aura symptom is present, accepted duration is proportionally increased
  4. Headache follows aura with free interval of less than 60 minutes. (It may also begin before or simultaneously with the aura)
- C. At least one of the following
  1. History, physical- and neurological examination do not suggest one of the disorders listed in groups 5-11
  2. History, physical- and/or neurological examination do suggest such a disorder, but it is ruled out by appropriate investigations
  3. Such disorder is present, but migraine attacks do not occur for the first time in close temporal relation to the disorder.

274. Glaxo's sales materials, however, were contrary to the IHS definition of migraine. Glaxo improperly instructed physicians that "it is a migraine until proven otherwise," and "think migraine first." See Exhibits 147 and 148. In this manner, Glaxo sought to persuade doctors to use Imitrex for all types of non-migraine headaches, including tension headaches and sinus headaches, which are huge – and off-label – markets.

275. Glaxo encouraged doctors to diagnose patients who do not meet IHS criteria for migraine. Internal Brand Plans identified "action" priorities of "[e]xpand[ing] diagnostic criteria to include symptoms outside narrow definition" and "[e]ducat[ing] on atypical migraine (e.g., bilateral pain, watery eyes, etc.)." See Exhibit 145. Indeed, Glaxo handouts to physicians were dismissive of the IHS definitions as well as the label's warning that Imitrex be prescribed only when there is a "clear diagnosis" of migraine. Glaxo contradicted the FDA-approved label by advising physicians that: "Rigid adherence to IHS criteria in diagnosing migraine may result in underdiagnosis of migraine. IHS criteria do not include all symptoms that migraineurs frequently experience." See Exhibit 149.

276. Glaxo's promotion was also contrary to both IHS guidelines and the Imitrex label with respect to its aggressive efforts to recharactierize tension headaches as migraines. In this regard, Glaxo claimed that tension headached symptoms are actually indicators of migraines. For example, Glaxo promoted that "neck pain has been demonstrated to be quite common in migraine" and "stress and tension are common triggers for migraines." See Exhibits 149 and 150. These are actually the symptoms of tension-type headaches, and are not among migraine symptoms identified in the IHS guidelines.

277. Glaxo's marketing also attempted to expand the definition of migraine by

promoting that patients with migraines often do not meet IHS criteria. For example, sales materials provided the prescribers represented that "as many as 41% of patients have reported bilateral pain during a migraine attack," and that "more than 50% of migrainers reported their pain to be nonthrobbing during some attacks." See Exhibit 151.

278. Glaxo also trained its sales representatives to promote the idea that if patients' headache medications are not working, they likely have a migraine headache, even though there is no scientific basis for this conclusion. See Exhibit 145 (stating as "Key strategies for patient target group" that "non-response to current med. as sign of misdiagnosis").

279. Glaxo selling resources also promoted the idea that if an individual ever experiences a migraine, all of his or her headaches are migraines or could be treated with Imigrex. See Exhibit 152. Glaxo's promotion misled prescribers by eliminating any distinctions between types of headaches. As Glaxo sales materials stated, "It doesn't matter whether the pain is mild or severe, or what label we use. Whether they describe a tension headache, a mixed headache with features of migraine, or a classic migraine: new research shows that migraineurs experience just one type of headache with a common biological mechanism." See also id. (stating ". . . Imitrex gives comparable pain-free relief to migraineurs whether they treat a tension-type headache, a migrainous headache or a migraine. . . All headaches on the spectrum respond to Imitrex").

280. Glaxo also misrepresented the results of various studies in order to promote Imitrex for non-migraine headaches. For example, Glaxo misrepresented the results of the "Landmark Study" to suggest that migraine headaches are routinely misdiagnosed as tension headaches when in fact the study's findings did not support that conclusion. See Exhibit 146.

Indeed, the Landmark Study excluded patients with sinus or other secondary headaches and included patients who only met the IHS criteria but were never actually diagnosed with migraines.

281. Glaxo also encouraged doctors to diagnose patients presenting with sinus-like symptoms as patients with migraines. In support of this misleading effort, Glaxo ignored IHS guidelines which, by definition, excluded sinus heaaches from the criteria for migraines. The IHS states: "As part of diagnosing migraine, the physician excludes any secondary causes of the patients headache," which includes "headache attributed to rhinosinusitis" – commonly known as sinus headache. Thus, despite the fact that the IHS criteria for migraine includes ruling out sinus headaches, Glaxo pushed the idea that a high percentage of sinus headaches are actually migraines. See e.g., Exhibit 146, attached, stating that ("Data revealed that 90% of these self-described "sinus headache" patients were actually suffering with migraine (82%) or migrainous headache (8%), in accordance with IHS diagnostic criteria").

282. As with tension headaches, Glaxo claimed that migraines frequently presented non-IHS criteria resembling sinus headaches. For example, Glaxo promoted that "[a]lthough not used as part of the IHS definition of migraine, "sinus" symptoms such as sinus pain/pressure, nasal congestion and runny nose are common clinical features of migraine." See Exhibit 153. See also Exhibit 112 (stating "Many headache patients present with lacrimation, sinus pain and pressure, congestion, and rhinorrehea in addition to the traditional migraine symptoms"). Glaxo also encouraged doctors to diagnose migraine and prescribe migraine medications (Imitrex) to patients presenting with sinus-like symptoms. Prescribers were told: "By acknowledging that migraine may be accompanied by nasal symptoms, more patients may be diagnosed with

migraine and have access to migraine-specific therapies." See Exhibit 154. See also Exhibit 155.

283. Glaxo also distorted published study results to promote the idea that patients with migraines often present sinus-like symptoms even though the study data did not support that conclusion. See Exhibit 156 (making claim that "Sinus symptoms occur frequently during migraine attacks" based on study of patient population limited to patients with self-described or physician diagnosed sinus headaches- when, of course, patients with sinus headaches will have sinus-like symptoms). Glaxo also exaggerated the claims of experts in order to create the impression that sinus headaches are rare. See Exhibits 149 and 154.

284. To further increase the use of Imitrex among non-migraine patients, Glaxo advocated "Early Intervention." See Exhibits 157 and 158. Glaxo promoted the idea that Imitrex is most effective when taken at the first sign of pain, before the patient knows whether it is a migraine. See Exhibit 158. Glaxo even encouraged prescribers to that Imitrex should be taken before the "start of the migraine," id.. Notwithstandng the label's requirement that Imitrex be used "only to treat an actual migraine1 attack sales representatives were trained to "handle resistance" of doctors reluctant to tell patients to take Imitrex early. See Exhibit 159.

285. In all of the above ways, among others, Glaxo unlawfully promoted Imitrex for off label treatment of non-migraine headaches.

1 Imitrex injection formulation may also be used to treat an actual cluster headache.

J. Glaxo Used Paid "Special Advisory Boards," "Reprint Mastery Programs," "Preceptorships" And Other Consideration As Financial Inducements To Influence Physicians' Prescribing Practices And To Disseminate Off-Label Promotional Claims About Glaxo Prescription Drugs

1. Glaxo Promoted Off-Label Uses Through "Special Issue Boards" Which Paid High-Prescribing Physicians To Listen To Improper Promotional Claims

286. During 2000 and 2001 at least, Glaxo utilized "Special Advisory Boards" or "Special Issue Boards" to disseminate its promotional messages for Wellbutrin SR, Lamictal, Valtrex, Imitrex and Advair. Although the Special Advisory Boards were purportedly comprised of local "thought leaders" for the purpose of providing independent advice on the Glaxo prescription drugs, in fact, the "advisory" boards were little more than promotional events coupled with financial inducements for prescribing physicians. See e.g., Exhibits 160, 161 and 162 (sales representative business plans indicating that migraine special advisory board intended to "increase Imitrex use"; Lotronex special advisory board intended to "switch" prescribers from competitor drug; and Imitrex special advisory board because prescribers "increased Zomig" a competitor drug).

287. Physicians invited to the "advisory" meetings were not asked for advice or expert consultation. Instead, Glaxo invited and paid high-prescribing physicians to listen to off-label promotion and/or to influence their prescribing practices. Glaxo held many hundreds, if not thousands, of these "special advisory" boards across the country. Indeed, in the first six months of 2001, for example, Glaxo held twenty "advisory" board meetings on Wellbutrin SR in and around just the Philadelphia area alone.

288. Glaxo typically paid the thousands of physician participants between $250 and

$750 each simply to attend a single "advisory" meeting. The payments did not reflect the value of services provided. The physician was not required to do anything but show up to receive his or her payment. In addition, Glaxo had no legitimate business reason to hire thousands of "advisors" - who also were high prescribing physicians - to "consult" with the company about a single drug. Each of these payments constituted a reward or kickback for the purpose of influencing the recipients' prescribing practices.

289. With respect to Glaxo's promotion of Wellbutrin SR, the "advisory" board speakers - Drs. Pradko, Hudziak, Green and others - typically received $2,000 to $3,000 to make their standard "pre-packaged" presentation. Each of these payments constituted a reward or kickback for the recipients' promotion of the Glaxo drugs.

290. In most cases physician participants were selected to attend the "advisory" board meeting based on the strength and history of their Glaxo prescriptions and their ranking in the regional market, rather than on their leadership or distinction in professional practice. Glaxo targeted physicians with "high decile" prescribing activity, particularly those who had written fewer prescriptions in the most recent quarter. Glaxo invited such "high decile" physicians with a recent "negative" prescribing trend to participate in the advisory board in order to influence and increase their future prescribing activity. See Exhibit 163 (among other things, instructing on targeting physicians generally).

291. The "advisory" meetings were typically conducted over dinner at fine local restaurants or top-notch hotels. At the "advisory board" meeting, physicians would listen to extended presentations concerning the Glaxo prescription drugs, including about their off-label uses. Frequently, if not most of the time, the "advisory board" presentations were made by

PRIDE or other Glaxo-trained speakers who gave the same standard presentations as they did at PRIDE and other speaking events. The majority of the material presented to the Wellbutrin SR "advisory boards," for example, concerned the off-label uses for Wellbutrin SR, rather than its on-label indication.

292. The following are among the Wellbutrin SR "advisory" board meetings Glaxo conducted in just the Philadelphia area. In 2000 and 2001, hundreds of other, similar "advisory" board meetings were conducted by Glaxo at luxury locations around the country.

Date	Location	Presenter	Payment To Attend
December 12, 2000	Ritz Carlton, Philadelphia	Dr. Jeffrey Green	$300.
See Exhibit 164.			
January 5, 2001	Ritz Carlton, Philadelphia	Dr. Troy Thompson	$500-$250
See Exhibit 165.			
January 6, 2001	Ritz Carlton, Philadelphia	Dr. Troy Thompson	$250
See Exhibit 166.			
January 11, 2001	Four Seasons, Philadelphia	Dr. James Pradko	$250
See Exhibit 167.			
January 30, 2001	Four Seasons, Philadelphia	Dr. James Pradko	$250-$350
See Exhibit 168.			
January 31, 2001	Manhattan Steak House	Dr.Matthew Pitera	$250
See Exhibit 169.			
February 23, 2001	Savona, Philadelphia	Dr. Timothy Smith	$500
See Exhibit 170.			

March 1, 2001	Green Hills Inn	Dr. James Pradko	$250
See Exhibit 171.			
March 14, 2001	Catalano Restaurant, Enola	—	$250
See Exhibit 172.			
March 18, 2001	Four Seasons, Philadelphia	Dr. James Pradko	$250-$350
See Exhibit 173.			
March 28, 2001	Knife & Fork, Atlantic City	Dr. Matthew Pitera	$250
See Exhibit 174.			
April 4, 2001	Jean Pierre, Philadelphia	Dr. James Hudziak	$500
See Exhibit 175.			
April 20, 2001	Four Seasons, Philadelphia	Dr. James Hudziak	$250-$350
See Exhibit 176.			
April 21, 2001	Four Seasons, Philadelphia	Dr. James Hudziak	$500
See Exhibit 177.			
May 5, 2001	Ritz Carlton, Philadelphia	Dr. James Pradko	$250
See Exhibit 178.			
May 12, 2001	Ritz Carlton, Philadelphia	Dr. James Pradko	$250
See Exhibit 179.			
May 12, 2001	Conshohocken Marriott	Dr. James Pradko	$250
See Exhibit 180.			
May 18, 2001	Four Seasons, Philadelphia	Dr. James Hudziak	$250-$350
See Exhibit 181.			

May 19, 2001	Westin Philadelphia	Dr. James Hudziak	$500
See Exhibit 182.			
May 20, 2001	Westin Philadelphia	Dr. James Hudziak	$500
See Exhibit 183.			
May 25, 2001	Glasbern Inn	Dr. Norman Sussman	$250
See Exhibit 184.			
June 2, 2001	Ritz Carlton, Philadelphia	Dr. Jeffrey Green	$750
See Exhibit 185.			
June 14, 2001	Accomac Inn	Dr. B. Kenneth Nelson	na
See Exhibit 186.			
June 16, 2001	Hershey Hotel	Dr. James Pradko	$250
See Exhibit 187.			
June 19, 2001	Susanna Foo, Philadelphia	Dr. Jeffrey Green	$350
See Exhibit 188.			
June 21, 2001	High Point	Dr. James Pradko	$250
See Exhibit 189.			
July 14, 2001	Philadelphia Marriott	Dr. James Hudziak	$750
See Exhibit 190.			
August 25, 2001	Ritz Carlton, Philadelphia	Dr. James Hudziak	$250
See Exhibit 191			
September 24, 2001	Savona, Philadelphia	Dr. James Hudziak	$350
See Exhibit 192.			

September 28, 2001	Ryland Inn	Dr. James Pradko	$250

See Exhibit 193.

November 10, 2001	Princeton Hyatt	Dr. James Hudziak	$500

See Exhibit 194.

293. In addition, Glaxo held dozens of "special advisory boards" about Wellbutrin SR in New York City including on January 30, 2001; January 31, 2001; February 5, 2001; February 6, 2001; February 7, 2001; February 13, 2001; February 21, 2001; February 25, 2001; February 26, 2001; February 27, 2001 (multiple board events the same day); February 28, 2001; March 7, 2001 (multiple board events the same day); March 8, 2001; March 22, 2001 (multiple board events the same day); March 26, 2001; March 27, 2001; March 29, 2001; April 4, 2001; April 5, 2001 (multiple events the same day); May 3, 2001; May 9, 2001; May 15, 2001; and May 16, 2001.

294. Glaxo also paid physicians to attend promotional "special issue boards" about Imitrex, Valtrex, Lamictal, and Advair. See e.g., Exhibit 195, attached. The "advisory boards" were held at hundreds of locations across the country to promote these drugs. With respect to its migraine drug Imitrex, Glaxo conducted 14 "special advisory boards" in New York City in just the seven weeks from late September through mid-November 2000.

295. In particular, Glaxo paid physicians to attend special advisory boards on Imitrex in New York City on September 27, 2000; September 28, 2000 (two separate boards held); October 2, 2000; October 9, 2000; October 12, 2000; October 19, 2000 (two separate boards held); October 20, 2000; October 24, 2000; October 25, 2000; October 26, 2000; and, November 17, 2000 (two separate boards held).

296. As was the case with respect to Wellbutrin SR, physicians were targeted to attend the Imitrex, Valtrex, Lamictal, and Advair "special advisory boards" based chiefly on their high-decile prescribing power and the desire to increase their prescriptions of Glaxo drugs. See also Exhibit 196 (indicating that in 2002 Glaxo's CNS and Respiratory Divisions, alone, held about $5.4 million in luxury boxes, and another approximately $1 million in season ticket holdings).

2. Glaxo Used "Reprint Mastery Training" And "Preceptorships" To Further Disseminate Off-Label Uses And To Induce Physicians To Prescribe Glaxo Prescription Drugs

a. Reprint Mastery Training

297. In or about 2000, Glaxo developed yet another program to promote its products. The "Reprint Mastery Training Program" was structured so that Glaxo sales representatives could set up "training sessions" with providers to review and discuss reprints of clinical studies. The training sessions were sometimes referred to as "tutorials." Although the training was putatively for the Glaxo sales representatives, in fact, the sales force was already very familiar with the materials being reviewed. See "Tutorial Schedule" Exhibit 202.

298. Glaxo typically paid providers $250 to $500 to review the reprint material with a sales representative - a meeting that usually took less than an hour to complete.

299. Material that was eligible for "training" included "Level 1" and "Level 2" materials. Level 1 materials are "on label," and sales representatives were extremely versed in their content. Review of Level 1 material was not intended to train Glaxo sales representatives. Rather, it was an opportunity for Glaxo to pay physicians for listening to product promotion. See e.g., Exhibits 197, 198, 199 and 200 (sales representatives "Business Plans" showing reasons for reprint training was to "increase Lotronex business"). See also Exhibit 45; "increas[ing] usage"

and competition) Exhibit 213; "expand[ing] usage," "shrinking migraine market," "improve business relations," "low WSR share," and "large SSRI user", Exhibit 56; and "increase Lotronex business" Exhibit 201.

300. Level 2 materials are generally "off-label" reprints and Medical Information letters, or reprints about competitor drugs. Such off-label reprints are permitted to be discussed only in response to providers' unsolicited questions. "Training" on such materials subverted this restriction by providing off-label information directly to the physician for discussion with the Glaxo representative.

301. For example, in the case of Wellbutrin SR, reprint training covered such materials as, inter alia, "Bupropion for Weight Loss: An Investigation of Efficacy and Tolerability in Overweight and Obese Women," K. Gadde, et al; "Buproprion SR Significantly Enhances Weight Loss When Used With A Moderate-Intensity Lifestyle Intervention," J. Anderson et al.; "Effects of Bupropion SR on Body Weight," K. Fujioka, as well as Anita Clayton's study of the treatment of SSRI-induced sexual dysfunction with bupropion.

302. Likewise, in the case of Lamictal, Dr. Joseph Calabrese's Glaxo-funded studies – "A Double-Blind Placebo-Controlled Study of Lamotrigine Monotherapy In Outpatients With Bipolar I Depression," J. Calabrese et al., and "A Double-Blind, Placebo-Controlled, Prophylaxis Study of Lamotrigine In Rapid-Cycling Bipolar Disorder," J. Calabrese et al. - were often the subject of Glaxo's paid reprint "training."

303. Glaxo representatives typically had already received training on the reprints. Thus, the educational value of such training to the representatives was low to nonexistent. However, it was extremely beneficial commercially for Glaxo because it purchased guaranteed

physician exposure to new, off-label uses of the company's drugs. See e.g., "Tutorial Schedule" Exhibit 202 (indicating that reprints that were supposed to be the basis for sales representative training, were frequently materials that the sales force was already well-acquainted with. In many cases, the articles were used in the sales representatives initial training courses and/or were included in product sales aids. See also Exhibits 203, 197, 161, 200 and 162. ("Business Plans" showing sales representative was "trained" on the same reprint multiple times: Exhibit 50 ("trained" on same Lotronex faxback twice); Exhibit 45 ("trained" on Croft reprint on Wellbutrin six times); Exhibit 67 ("trained" on Imitrex "spectrum" reprint twice and Croft reprint four times); Exhibit 201 ("trained" on Croft reprint three times and Coleman reprint four times); Exhibit 204 ("trained" on O'Quinn reprint twice).)

304. Many of the physicians who participated in reprint mastery "tutorials" did so repeatedly, and often also participated in numerous other paid events, including special issue boards, speaker's training, preceptorships, grants, and "CME Express" as alleged below. See Exhibit 205, attached (sales representative "Business Plan" showing multiple Lotronex preceptorships by same sales representative, as well as single physician - Dr. Roeshman - receiving multiple Imitrex preceptorship payments). Such repeated participation was offered as financial inducements to influence the physicians' prescribing practices. See also Exhibit 206, attached.

305. Among the hundreds if not thousands of prescribing physicians who received compensation from Glaxo for multiple reprint mastery tutorials, and other paid events are:

Dr. Anthony Pietropinto of New York City

Dr. Daniel Crane of New York City

Dr. Ashok Shah of Titusville, Florida

Dr. Edward Rose of Ft. Lauderdale, Florida

Dr. Bradley Diner of Little Rock, Arkansas

Dr. David Haga of Madison Heights, Virginia

Dr. James Hubbs of Glassboro, New Jersey

Dr. Seth Ivins of Wilmington, Delaware

Dr. Edward Rosa of Ft Lauderdale, Florida

Dr. Robert Drake of Somerset, Kentucky

b. Glaxo's "Preceptorships" Compensated Physician Generously For Sales Representatives "Shadowing" Them

306. At least as early as 2000, Glaxo also initiated a "preceptorship" program in which physicians were paid as much as $1,000, if not more, to be "shadowed" by a Glaxo sales representative for part of the work day. By "pairing up" with the physician, the sales representative was able to promote over a period of many hours, without the usual problems of gaining access to prescribing physicians.

307. Preceptorships were an important means by which off-label promotion of the Glaxo prescription drugs was conducted. In essence, the "preceptorships" amounted to Glaxo buying access to prescribing physicians. See e.g., Exhibit 205 (sales representative Business Plan indicating that Imitrex preceptorships intended to "grow migraine business," and "increase Imitrex market share"). As a Glaxo representative stated with respect to a local physician practice - Dr. Gregory Hill's office in Fultondale, Alabama – "They will also do RMTs and preceptorships allowing us another way to gain access."

308. Preceptorship payments were offered to high prescribing physicians, and physicians whose prescribing patterns could be shifted or strengthened. They were extended both to convey promotional and off-label information, and to influence prescribing behavior with cash payments.

309. The following are among the thousands of physicians who received paid "preceptorships":

Dr. Stanley Cohen of New York City

Dr. Paul La Russa of Pelham, Alabama

Dr. Kenneth Peters of Mountain View, California

Dr. Phillip Dines of Willoughby, Ohio

Dr. Mark Agresti of West Palm Beach, Florida

Dr. Edward Goldenburg of Norfolk, Virginia

Dr. Jonathan Rothman of Westborough, Massachusetts

Dr. Alvin Burstein of Phoenix, Arizona

Dr. William Solomon of Southfield, Michigan

Dr. Ina Sue Itzkovitz of New York City

Dr. Brian Izzo of Saratoga Springs, New York

Dr. Stephen Wieder of Newburyport, Massachusetts

Dr. Rex Birkmire of Casselberry, Florida

Dr. Terence Ketter of Palo Alto, California

Dr. Yong-Hsiu Tsai of Ormond Beach, Florida

Dr. Shaukat Matin of Ludlow, Massachusetts

Dr. Joseph Thrombi of Garden City, New York

Dr. Gavidae Casta of Baldwin, New York

Dr. Julio Munoz of Carlsbad, New Mexico

Dr. Joseph Grizzante of Hawthorne, New Jersey

Dr. Eshwar Punjabi of Cambridge, Ohio

Dr. William Rakauskas of Bloomsberg, Pennsylvania

Dr. Ralph Ankenman of London, Ohio

Dr. Ramesh Khurana of Pittsburgh, Pennsylvania

Dr. Ahmed Mekkawy of Clifton, New Jersey

Dr. David Burgoyne of Mesa, Arizona

Dr. Edward Rosa of Ft Lauderdale, Florida

Dr. Luis Allen of Orlando, Florida

Dr. Mukesh Rangwani of Zanesville, Ohio

Dr. Ernest Galbreath of Cherokee, Iowa

Dr. Ralph Mayberry of Sierra Vista, Arizona

Dr. Matthew Graziano of Buffalo, New York

Dr. Gary Grove of Paradise Valley, Arizona

Dr. Anthony Ellis of Lansing, Michigan

Dr. Michael Dee of Louisville, Kentucky

K. Glaxo Paid Kickbacks To Physicians Through CME And "CME Express" Honoraria For Presentations That Were Not Objective Or Free Of Glaxo Influence

310. In addition to non-independent speaker programs such as PRIDE and local

speaker events, Glaxo also used so-called CME and CME Express programs for marketing purposes, and to promote off-label uses for the Glaxo prescription drugs. See e.g., Exhibits 207 and 208 (Glaxo emails attaching CME program that advocated, among other things, adding-on Wellbutrin to treat SSRI-induced sexual side effects). See also Exhibit 209 (indicating use of Imitrex CME programs for promotion and to reach high decile physicians; also indicates that Glaxo marketing funded CME programs for top-decile physicians). Glaxo also used the "speaker" payments for CME and CME Express programs to reward and induce physician loyalty and increased prescriptions.

311. As alleged above, to be legitimate under federal law, CME programs must be truly independent of drug company influence and bias. Among the various factors considered in determining independence and influence are, inter alia, the drug company's control of or influence over content and selection of presenters, whether multiple presentations of the same program are held; and whether the audience is selected by the company's sales and marketing staff.

312. In Glaxo's case, its company-sponsored CME programs violated federal requirements of independence and absence of company influence and bias. Glaxo maintained control and influence over speaker selection, presentation content and audience. Although third party vendors were usually also involved, they served only as artificial "firewalls" that did not insulate the CME program content from Glaxo's influence. See e.g., Exhibit 210.

313. In fact, Glaxo had great influence - if not complete control - over the selection of speakers who were picked based on the content of their presentations. Indeed, in advance of the program vendors routinely sent the speaker presentations to Glaxo representatives for their

advance review and approval.

314. Glaxo representatives also targeted providers for invitations to the programs because of the favorable promotional content. Glaxo sales representatives routinely requested the attendance of and distributed invitations to prescribing physicians.

315. Physicians trained at Glaxo "speaker training" programs often doubled as CME presenters, giving substantially the same presentation as they did for the non-independent speaking event. At least the following Glaxo-trained and compensated speakers presented CME programs that were influenced by and biased toward the Glaxo prescription drugs - Dr. James Pradko, Dr. James Hudziak, Dr. Sarah Atkinson, Dr. Richwald, Dr. Sussman, Dr. Mark Green, Dr. Jeffrey Green, Dr. Gilbert, among many others. See Exhibits 41, 42, 21, 43 and 211. See also Exhibit 212 (indicating Glaxo's active influence and contributions to Dr. Sussman PRIDE speaker presentation by for example, suggesting that he integrate weight data into the presentation; that the label's express seizure risk warning is a "non-issue;" and that he compare seizure risks among anti-depressants even though no head-to-head trials have established relative risks).

316. For example, Dr. Pradko's standard PRIDE lecture at non-independent speaking events, "The Neuroreceptor Basis of Initial Antidepressant Choice," is the same presentation that he made hundreds of times as a CME program. See Exhibit 38. In both formats Dr Pradko was paid by Glaxo in amounts between $1,500 and $2,000. As alleged above, the Pradko PRIDE lecture included numerous and repeated representations advocating Wellbutrin SR's off-label uses.

317. Glaxo representatives frequently reviewed speakers' CME program presentations

in advance and discussed, inter alia, the positioning of Glaxo prescription drugs, the message Glaxo wished to get across, and particular off-label treatments.

318. Because of the high promotional value of the so-called CME presentations, Glaxo frequently distributed copies of the presentation to prescribing physicians that did not attend the event. The unsolicited distribution of such "enduring materials" with off-label content is prohibited by federal law.

319. Indeed, in or about 2001, Glaxo purchased hundreds of copies of Dr. Pradko's CME presentation in CD-ROM format for distribution to prescribers in the southeastern United States sales region. Glaxo representatives actively distributed this "enduring material" to physicians because of its favorable off-label promotion of Wellbutrin SR.

320. The regional Pradko CD distribution effort was so successful that Lisa Gonzalez - Director of CNS Marketing - commissioned and agreed that Glaxo's Marketing Department would pay for the production of Dr. Pradko's CD-ROM for distribution nationally in all sales regions. Upon information and belief, Glaxo agreed to pay Dr. Pradko at least as much as $400,000 for the CDs. The project was suspended before the national distribution occurred. See Exhibit 226.

321. Glaxo viewed CME programs interchangeably with non-independent speaker programs - i.e., as promotional and marketing events. Glaxo representatives selected speakers, influenced content, and invited participants. Indeed, the CME programs were so integrated into Glaxo's promotional efforts that they were frequently referred to internally as "Wellbutrin CME," "Valtrex CME," "Lamictal CME," "Valtrex CME," "Advair CME" or "Imitrex CME."

322. In or about 2001, Glaxo initiated a "CME Express" program, funded by Glaxo's

Marketing Department, and which offered CME credits for attendance at certain Glaxo-sponsored events. See Exhibits 2 and 3. CME Express was not independent of Glaxo's influence. Both the presenters and audience were typically selected by Glaxo representatives, and the content was often reviewed and approved by Glaxo representatives. See Exhibit 212.

323. Third party vendor involvement in CME Express programs was particularly thin. Glaxo sales representatives selected the speaker, chose the date and venue, and targeted potential attendees for invitation.

324. CME Express "speakers" received a generous honorarium, typically a $500 payment, but often as much as $1,000. Glaxo routinely paid CME Express honoraria as a way to reward physicians and/or to induce prescriptions, knowing that the "presentation" would be minimal. In this way, programs such as CME Express were also used as a vehicle for channeling payments and inducements to high-prescribing physicians or physicians whom Glaxo wished to reward.

325. CME Express programs were often conducted over lunch (also paid for by Glaxo) in the presenting doctor's office, with only his or her office staff in attendance. Glaxo knew that these often were not meaningful presentations, but rather were a way of funneling money to the physician.

326. For example, a Glaxo representative noted that he would "work on setting [Dr. Pradumna Jain of Knoxville] up to speak for us possibly as CME express speaker on roundtable presentation to his own group over lunch. $'s may be the way to his business." Similarly, when Dr. Kachigere Krishnappa of Albany New York expressed displeasure with the $500 CME Express honorarium, Glaxo's representative told him that it could be just a "quick in-office talk."

327. In another instance, in June 2002, Dr. Peter Diamond of Amsterdam New York approached Glaxo for a donation for an annual fundraiser. The Glaxo representative suggested in response that Dr. Amsterdam have an in-office CME Express, with the staff as his "audience," and noted that he could "use the $500 honorarium any way he wants."

328. In the case of Dr. Edmond Ross Glaxo used CME Express as both a "carrot" and a "stick." In January 2003, when Dr. Ross inquired about doing a CME express lunch in his office, and asked what else would he get besides CME credit and food, he was told by Glaxo's representative that there would be no "dollars" for him, because they needed more "support," i.e., prescriptions, of Imitrex and Wellbutrin SR from him.

329. The following are among the prescribing physicians who were paid through CME Express, many of whom received multiple payments from Glaxo for various programs and inducements, and many of whom also reviewed the promotional content of their program with Glaxo in advance.

Dr. John Schremly of Corbin, Kentucky

Dr. Alan Jonas of Pikesville, Maryland

Dr. Jeffrey Barke of Newport Beach, California

Dr. Karin Hastik of San Francisco, California

Dr. Thomas Fogarty of Fairfax, Virginia

Dr. Aloyisus Tang of Burbank, California

Dr. Gary Wardstadt of Randolph, Massachusetts

Dr. Paul Reilly of Williamsburg, Virginia

Dr. Antonio Cusi of Fayetteville, North Carolina

Dr. Ann Rathe of Billings, Montana

Dr. Richard Marciniak of Colorado Springs, Colorado

Dr. Laura Rames of Charleston, South Carolina

Dr. Romeo Isidro of Northridge, California

Dr. Fawzy Basta of Northridge, California

Dr. Damaso Oliva of San Antonio, Texas

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

330. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

332. 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.

333. By virtue of the acts described above, Glaxo 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.

334. Each prescription that was written as a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary or illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent

claim for payment.

335. Plaintiffs cannot at this time identify all of the false claims for payment that were caused by Glaxo's conduct. The false claims were presented by thousands of separate entities, across the United States, and over many years. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

336. 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 Glaxo's illegal marketing practices and inducements.

337. 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. Federal health insurance programs have paid many thousands of claims, amounting to many hundreds of millions of dollars, for off-label prescriptions for indications that were not approved by the FDA, for prescriptions that were medically unnecessary, and/or for prescriptions that were illegally induced by Glaxo.

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

338. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

340. 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.

341. By virtue of the acts described above, Glaxo 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.

342. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

343. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

344. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

345. 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.

346. 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 Glaxo.

Count III
Colorado False Claims Act
Colo. Rev. Stat. § 25.5-4-303.5, et seq.

347. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

348. This is a claim for treble damages and penalties under the Colorado False Claims Act.

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

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

351. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

352. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

353. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and

continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

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

355. The State of Colorado 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 Glaxo.

Count IV
Connecticut False Claims Act
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356. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

357. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

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

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

360. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions

submitted to a state-funded program represents a false or fraudulent claim for payment.

361. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

362. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

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

364. The State of Connecticut 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 Glaxo.

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

365. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

367. 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.

368. By virtue of the acts described above, Glaxo 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.

369. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

370. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

371. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and illegal inducements.

372. 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.

373. 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 Glaxo.

Count VI

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

374. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

376. 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.

377. By virtue of the acts described above, Glaxo 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.

378. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

379. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

380. 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 defendant, paid and

continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

381. 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.

382. 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 Glaxo.

Count VII
Georgia False Medicaid Claims Act
Ga. Code. Ann. §49-4-168 et seq.

383. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

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

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

387. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions

submitted to a state-funded program represents a false or fraudulent claim for payment.

388. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

389. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

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

391. The State of Georgia 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 Glaxo.

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

392. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

394. 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.

395. By virtue of the acts described above, Glaxo 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.

396. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

397. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

398. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

399. 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.

400. 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 Glaxo.

Count IX

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

401. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

403. 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.

404. By virtue of the acts described above, Glaxo 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.

405. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

406. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

407. 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 defendant, paid and

continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

408. 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.

409. 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 Glaxo.

Count X
Indiana False Claims and Whistleblower Protection Act
Ind. Code Ann. §5-11-5.5-1 et seq.

410. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

412. 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.

413. By virtue of the acts described above, Glaxo 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.

414. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions

submitted to a state-funded program represents a false or fraudulent claim for payment.

415. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

416. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

417. 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.

418. The State of Indiana is entitled to the maximum penalty of $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 Glaxo.

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

419. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

421. 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.

422. By virtue of the acts described above, Glaxo 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.

423. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

424. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

425. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

426. 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.

427. The State of Louisiana 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 Glaxo.

Count XII

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

428. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

430. 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.

431. By virtue of the acts described above, Glaxo 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.

432. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

433. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

434. 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

defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

435. 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.

436. 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 Glaxo.

Count XIII
Michigan Medicaid False Claims Act
Mich. Comp. Laws. §§400.601 et seq.

437. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 299 above as though fully set forth herein.

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

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

440. By virtue of the acts described above, Glaxo 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.

441. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

442. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

443. 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 Glaxo, paid and continues to pay the claims that would not be paid but for Glaxo's unlawful conduct.

444. By reason of Glaxo's 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. Code Ann. § 17-8-401 et seq.

445. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

447. 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.

448. By virtue of the acts described above, Glaxo 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.

449. Each prescription written as a result of Glaxo's illegal marketing practices or

inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

450. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

451. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

452. 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.

453. 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 Glaxo.

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

454. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

Act.

456. 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.

457. By virtue of the acts described above, Glaxo 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.

458. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

459. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

460. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

461. 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.

462. 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 Glaxo.

Count XVI
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167.61 et seq.

463. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

465. 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.

466. By virtue of the acts described above, Glaxo 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.

467. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

468. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

469. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

470. 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.

By reason of the

471. The State of New Hampshire 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 Glaxo.

Count XVII
New Jersey False Claims Act
N.J. Stat. §§2A:32C-3(a), (b) and (g)

472. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 299 above as though fully set forth herein.

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

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

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

476. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

477. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

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

479. By reason of Glaxo's acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

480. Additionally, the New Jersey State Government is entitled the maximum civil penalty of $11,000 for each and every violation alleged herein.

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

481. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

483. 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.

484. By virtue of the acts described above, Glaxo 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.

485. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

486. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

487. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

488. 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.

489. The State of New Mexico 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 Glaxo.

Count XIX
New York False Claims Act
N.Y. State Fin. §187 et seq.

490. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

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

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

494. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

495. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds

of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

496. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

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

498. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Glaxo.

Count XX
North Carolina False Claims Act
N.C. Gen. Stat. §1-605 et seq.

499. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

500. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

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

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

503. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

504. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

505. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

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

507. The State of North Carolina 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 Glaxo.

Count XXI
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 §5053 et seq.

508. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

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

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

512. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

513. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

514. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

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

516. The State of Oklahoma 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 Glaxo.

Count XXII
Rhode Island False Claims Act
R.I. Gen. Laws §9-1.1-3(a)(1), (2), and (7)

517. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 299 above as though fully set forth herein.

518. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

519. By virtue of the acts described above, Glaxo knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

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

521. By virtue of the acts described above, Glaxo 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 Rhode Island State Government.

522. Each prescription that was written as a result of Glaxo's illegal marketing practices 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.

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

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

525. By reason of Glaxo's acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

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

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

527. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

529. 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.

530. By virtue of the acts described above, Glaxo 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.

531. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

532. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

533. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

534. 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.

535. 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 Glaxo.

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

536. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

538. 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.

539. By virtue of the acts described above, Glaxo 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.

540. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

541. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds

of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

542. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

543. 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.

544. 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 Glaxo.

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

545. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

547. 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.

548. By virtue of the acts described above, Glaxo 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.

549. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

550. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

551. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

552. 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.

553. 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 Glaxo.

Count XXVI
Wisconsin False Claims for Medical Assistance Act
Wis. Stat §§20.931(2)(a), (b), and (g)

554. Plaintiffs reallege and incorporate each and every allegation contained in paragraphs 1 through 299 above as though fully set forth herein.

555. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.

556. By virtue of the acts described above, Glaxo knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

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

558. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

559. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

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

561. By reason of Glaxo's acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

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

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

563. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

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

565. 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.

566. By virtue of the acts described above, Glaxo 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.

567. Each prescription written as a result of Glaxo's illegal marketing practices or inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label, medically unnecessary and illegally induced prescriptions submitted to a state-funded program represents a false or fraudulent claim for payment.

568. Plaintiffs cannot at this time identify all the false or fraudulent claims for payment that were caused by Glaxo's conduct. The false or fraudulent claims were presented by hundreds of separate entities across the State. Plaintiffs have no control over or dealings with such entities and have no access to the records in their possession.

569. 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 defendant, paid and continues to pay claims that would not be paid but for Glaxo's illegal marketing practices and inducements.

570. 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.

571. 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 Glaxo.

Prayer

WHEREFORE, plaintiffs pray for judgment against the defendants as follows:

1. that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the States and the District of Columbia's 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 damages the State of Colorado has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*;

5. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 2009 Ct. P.A. 5;

6. 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);

7. 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);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. §49-4-168.1(a);

9. 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);

10. 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);

11. 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 $5,000 for each violation of Ind. Code Ann. §5-11-5.5-2(b);

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §483.3;

13. 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;

14. 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 Mich. Comp. Laws §400.601;

15. 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. Code Ann. §17-8-403(1);

16. 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)(a), (b);

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of N.J. Stat. § 2A:32C-3;

18. 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 a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. §167.61-b(I);

19. 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 a civil penalty of $10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §189(1);

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §1-607(a);

22. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63 §5053.1(B);

23. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws §9-1.1-3(a);

24. 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. §71-5-182(a)(1);

25. 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;

26. 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)(1), (2);

27. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat §20.931(2);

28. 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. §1-1188.14(a)(1), (2);

29. that plaintiffs be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the States and the District of Columbia statutes set forth above;

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

31. that the plaintiffs 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, plaintiffs hereby demand a trial by jury.

Dated: January 14, 2011

By: Erika A. Kelton

PHILLIPS & COHEN LLP
Erika A. Kelton
Larry Zoglin
Phillips & Cohen LLP
2000 Massachusetts Ave, N.W.
Washington, D.C. 20036
(202) 833-4567

BARTLETT HACKETT FEINBERG PC

By: Howard M. Brown
Howard Brown (B.B.O. # 547948)
Bartlett Hackett Feinberg PC
155 Federal St., 9th Floor
Boston, MA 02110
(617) 422-0200

Attorneys for Qui Tam Plaintiffs