IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 03-10641-NG-RWZ
Civil Action No. 11-10398-NG-RWZ

UNITED STATES OF AMERICA, *et al., ex rel.*

GREGORY W. THORPE and

BLAIR HAMRICK,

Plaintiffs,

v.

SMITH KLINE BEECHAM, INC., and

GLAXOSMITHKLINE PLC d/b/a GLAXOSMITHKLINE,

Defendants.

SEVENTH AMENDED COMPLAINT

FILED UNDER SEAL
PURSUANT TO 31 U.S.C. §§ 3729 *et seq.*

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UNITED STATES OF AMERICA, the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA AND THE CITIES OF NEW YORK AND CHICAGO, *Ex rel*. GREGORY W. THORPE and BLAIR HAMRICK, and

GREGORY W. THORPE and BLAIR HAMRICK, *individually,*

Plaintiffs,

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SMITH KLINE BEECHAM, INC., and

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Defendants.

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Plaintiffs Greg Thorpe and Blair Hamrick, by their undersigned attorneys, on behalf of the United States of America, the District of Columbia, New York City, the City of Chicago and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin, state the following as their Seventh Amended Complaint based upon their non-public, indirect and independent knowledge:

19. 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 those sections authorize nationwide service of process and because each Defendant has minimum contacts with the United States. Moreover, Defendants can be found in, reside, and transact business in this District.

20. This Court has supplemental jurisdiction over the State law claims pursuant to 28 U.S.C. §1367(a).

21. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because each Defendant transacts business in this judicial district, and acts proscribed by 31 U.S.C. §3729 have been committed by Defendants in this District. Therefore, venue is proper within the meaning of 28 U.S.C. §1391(b) & (c) and 31 U.S.C. §3732(a).

IV. GENERAL ALLEGATIONS

22. The False Claims Act, 31 U.S.C. § 3729 *et seq.* imposes liability on any person or corporation that knowingly presents or causes to be presented a false or fraudulent claim to the United States government for payment or approval (31 U.S.C. § 3729(a)(1))[1]; any person or corporation that makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the United States government (31 U.S.C. § 3729(a)(2)); and/or, conspires to defraud the Government by getting a false or fraudulent claim allowed or paid (31 U.S.C. § 3729(a)(3)). Proof of specific intent is not required.

23. The FCA provides that any person who violates any of the aforementioned provisions is liable not just for return of all payments falsely made, but also for civil penalties of

[1] 31 U.S.C. §3729(a)(1), (a)(2) and a(3) were amended in 2009 and renumbered. These statutory sections are now styled as 31 U.S.C. 3729(a)(1)(A), (a)(1)(B) and (a)(1)(C), respectively. To the extent that the new language of the amended statute is not retroactive, Plaintiffs assert that any and all false claims submitted after the enactment of the Fraud Enforcement and Recovery Act are deemed to be violations of the FCA, as amended by the Fraud Enforcement and Recovery Act.

up to $11,000 per false claim, and for three times the amount of the damages sustained by the government. The FCA further provides that any person with direct and original knowledge of false claims submitted to the United States by a person or corporation may bring an action on behalf of the United States and may obtain a share of the damages and civil penalties recovered by the United States.

24. The Plaintiff States have enacted *qui tam* laws analogous to the Federal FCA that precisely mirror its language. The same unlawful conduct of Defendants in marketing the drugs alleged herein that gives rise to their liability under the FCA likewise gives rise to their liability under the analogous laws of the Plaintiff States. As such, Defendants are subject to civil monetary fines and penalties under both the FCA and the parallel statutes of the Plaintiff States.

25. From 1997 to the present and continuing, GSK's marketing plan, devised at a senior executive level, has been to "Exploit the Bolus" of government-funded healthcare programs such as Medicaid and Tricare, with the direct and intended effect of causing the submission of false claims to such programs as identified herein.

26. GSK effected this plan in at least the following ways:

- GSK has illegally and fraudulently promoted and marketed the sale of its drugs for off label, non-medically accepted uses, *i.e.* uses not approved by the United States Food and Drug Administration ("FDA") and not supported by the medical compendia identified in the Medicaid Act. As part of this scheme, GSK overtly and aggressively targeted physicians identified by GSK's prescription tracking methods to have the largest volumes of patients enrolled in government-funded healthcare programs such as Medicaid and Tricare.

- GSK has paid illegal remuneration (*i.e.* kickbacks) to physicians and other health care providers with the purpose and intent of inducing those physicians and healthcare providers to prescribe GSK drugs in return in violation of the federal Anti-Kickback law and the analogous anti-kickback laws of the Plaintiff States. GSK's kickback payments include gifting of unrestricted grants to individuals and institutions, paying premium fees to physicians to participate in speaker's bureaus and provide speakers' services, providing remuneration for sham participation on advisory boards and providing substantial sums of money for lavish dinners and entertainment. GSK's kickback scheme, as evidenced by GSK internal records, has proved enormously successful in expanding the off-label market of GSK's drugs, especially the off-label, non-medically accepted use of GSK drugs by beneficiaries of healthcare plans funded by the government-plaintiffs.

27. Top level GSK managers and executives, including but not limited to GSK's Chief Executive Officer J.P. Garnier, current President of Pharmaceutical Operations David Stout, Vice Chairman of Pharmaceuticals (and former President of Pharmaceutical Operations) Robert A. Ingram, Senior Vice President Stan Hull, Regional Director Mike Bennett, and Vice President and Head of Corporate Compliance Arjun Rajaratnam, have been aware of GSK's illegal marketing schemes and have played an active role in supporting and promoting these schemes.

28. GSK executives availed itself of its unparalleled sales force and speaker's bureau, in terms of size, to implement its scheme with maximum financial impact. GSK's Chief Executive Officer J.P. Garnier specifically acknowledged the pervasive power of the company's marketing force by boasting that, because of its unrivaled size of its sales force, GSK had the

ability within a week to reach physicians responsible for 80% of all of the prescriptions written in the United States. President of Pharmaceutical Operations David Stout, in a confidential speech made to members of GSK's sales force in year 2000 (labeled the "Big Orange" tape and reserved expressly for "Glaxo Smith Kline employees only" and "not for external distribution") admitted when discussing the issue of "integrity" that he would not "be proud" to be "a sales representative again" in the "three years, four years" previous to the speech.

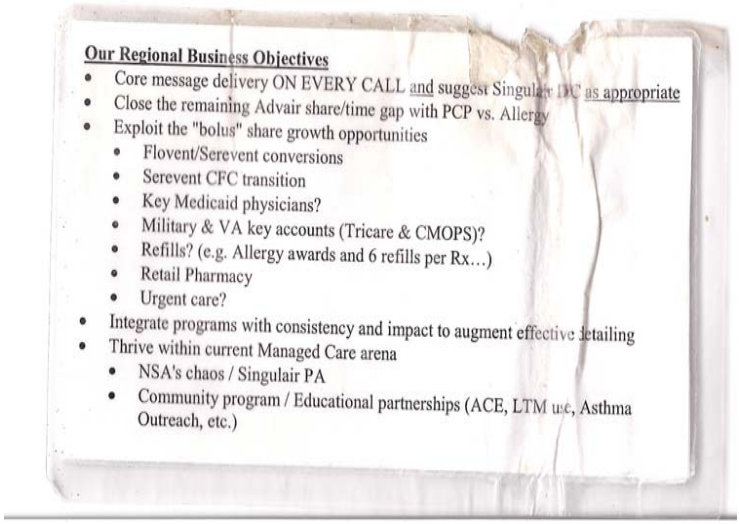
29. To complement its dominant sales force, GSK had equally unrivaled resource of speakers to promote its drugs. GSK's speaker's bureau is comprised of approximately 49,000 physicians, all of whom made their peer-to-peer marketing services available in return for premium compensation. These kickbacks were also a method used by GSK to reward the biggest prescribers of its drug or as a way to incentivize physicians to increase their writing of GSK drug prescriptions.

30. GSK attempted to conceal its scheme by maintaining a 'dual policy' of printing prominent disclaimers on the written materials distributed to its sales force, such as "for internal use only," "not to be used in marketing," and "not to be left in health care offices," while simultaneously encouraging its sales force to ignore such disclaimers and market its prescription products for off-label indications.

31. GSK refers to third party payors for its prescription drugs "targets." Sources such as Medicaid and Tricare/Champus, and "high decile" (high prescribing) physicians, who predominantly treat patients enrolled in Medicaid and Tricare/Champus reimbursement, are labeled "targets" in numerous confidential data sheets, emails and other documents distributed to its marketing force. GSK has consistently pushed its sales representatives to focus their efforts

on gaining the business (i.e. increasing prescriptions) of high prescribing Medicaid and Tricare/Champus physicians.

32. As evidence of GSK's hyper-vigilance paid to success in gaining Medicaid market share, in 2003, GSK Regional Vice President Gregg Far went so far as to distribute to each member of his sales force a laminated wallet-size card to carry at all times to provide a reminder of 3 keys to successfully marketing GSK's drugs. This card directed GSK sales representatives to "**Exploit the Bolus**" to be successful:



33. Relator Hamrick received additional directives specifically to "Exploit the Bolus of Medicaid" in his performance evaluations prepared by his manager.

34. The reimbursement claims GSK caused to be submitted to Medicaid and other government-funded programs for these uses were not eligible for reimbursement, and as such, constituted false claims. Moreover, as alleged herein, GSK caused the submission of these false claims because its marketing efforts specifically targeted physicians who treat large volumes of

beneficiaries of Medicaid, Tricare/CHAMPUS and other government-funded healthcare programs.

A. Drugs Marketed By GSK For Off-Label Use

35. GSK is well aware that physician visits by drug representatives, or 'detailing' as it is known in the industry, has a direct causal impact on the choices physicians make in writing prescriptions. GSK documents establish that the national average for physician visits by GSK sales reps is at least eight per day per representative and the average for retail pharmacies at least three per day per representative. As part of these detailing efforts, GSK requires its sales representatives to be thoroughly conversant with Current Procedural Technology ("CPT") codes relevant to their products and the services of the physicians they visit. Many times the coding and billing advice related to providing services that resulted in off-label use of the GSK drugs: for example, COPD diagnosis codes resulting in an off-label prescription of Advair for COPD.

36. In fact, GSK provides *a toll free number* for physicians and clinics to call for assistance in billing programs such as Medicaid and Tricare/Champus, and particularly for advice concerning appropriate CPT coding.

37. Off-label marketing can be extremely dangerous, given the fact that the FDA has not approved dosage information and there is no "label" which a health care practitioner can turn to for advice. This is especially the case in off-label marketing of GSK's drugs approved for adult use for pediatric patients.

38. Thousands of GSK sales representatives nationwide have detailed physicians for off-label pediatric uses of GSK prescription drugs without the information necessary to establish appropriate dosage. Inadequate dosing information may expose pediatric patients to dangerously high doses or to ineffective treatment.

39. Confidential “return on investment” data maintained by GSK for the time period relevant hereto affirmatively indicates that GSK's aggressive marketing approach, and particularly its programs which compensate health care practitioners and/or provide medical education credits, such as attendance of "peer-to-peer" programs, participation in speaker programs, CME (Continuing Medical Education) programs, participation in preceptorships, serving on therapeutic specialty boards and receiving honorariums, in addition to the numerous social and athletic events, skiing trips, 'spa' meetings and concerts sponsored by GSK during the period in question, have been enormously successful in producing increased sales of its prescription medications.

40. Relators have personal, direct and independent knowledge that GSK implemented nationwide off-label promotional schemes in the following manner for the following drugs:

1. Advair

41. Advair (fluticasone propionate and salmeterol) was first approved by the FDA on August 24, 2000 in dosages of 100/50, 250/50 and 500/50 (these dosages reflect the proportion of fluticasone propionate to salmeterol) for patients 12 and older with moderate to severe asthma whose asthma symptoms were inadequately controlled on a previous course of corticosteroids or whose disease severity warranted daily maintenance therapy with two medications.

42. However, GSK has effusively marketed this prescription drug from the date of its launch as follows for off-label, non-medically accepted uses:

- Since 1999, GSK has promoted all doses of Advair for the treatment of mild intermittent and mild persistent asthma, knowing the drug was not indicated for mild asthma patients;

- Since 1999, GSK has marketed Advair 250/50 for the treatment of Chronic Obstructive Pulmonary Disease ("COPD") even before it received FDA approval in November 2003 for the treatment of COPD *associated with Bronchitis*. Even after the November 2003 approval, GSK marketed Advair 250/50 beyond the limited COPD/bronchitis indication despite the FDA's expanded approval of Advair 250/50 for COPD on April 30, 2008. This off-label marketing for of Advair for COPD continues as of the date of the filing of this Seventh Amended Complaint;
- GSK has marketed Advair 500/50 for the treatment of COPD from 1999 and continuing to the present. Advair 500/50 never received FDA approval for any form of COPD. To the contrary, in August 2007 the FDA *rejected* GSK's supplemental new drug application for Advair 500/50 for COPD;
- Since 1999, GSK has marketed Advair 150/50 and 250/50 for the treatment of pediatric asthma in children under the age of 12 even prior to receiving FDA approval for Advair 100/50 for patients aged 4 through 11 on April 24, 2004; and
- GSK has also marketed Advair in all three doses for uses that were off-label, that were not medically accepted uses, that were not medically necessary, and that were contrary to Black Box warnings subsequently put on the Advair label by the FDA, including active marketing of Advair to African Americans despite knowing and acknowledging that the drug contained a component, salmeterol, that was dangerous to that population sub-group.

2. Amerge

43. Amerge (naratriptan hydrochloride) was initially approved by the FDA on February 10, 1998 for the acute treatment of migraine headache with or without aura in adults

only. Despite the limited FDA approved indications, GSK has aggressively marketed the drug for the following off-label uses:

- For the treatment of tension and sinus headache;
- For the treatment of menstrual migraine, menstrually-related migraine, for prophylaxis for headache and for prophylaxis for menstrual migraine;
- For use in pediatric and adolescent patients for migraine, including the promotion of Amerge as a "long acting" migraine medication;
- For prophylaxis in pediatric and adolescents; and,
- For use during pregnancy as a safer choice comparatively to GSK's second migraine drug Imitrex, on the basis that Amerge is milder and has a favorable side effect profile. However, Amerge has never been specifically approved for use during pregnancy.

3. Flonase

44. Flonase (fluticasone propionate), an aqueous based nasal spray approved by the FDA on October 19, 1994 for the treatment of seasonal and perennial allergic rhinitis. However, GSK has been heavily marketed the drug off label as follows:

- For the treatment of nasal polyps; and,
- As an efficacious "as needed" medication, when in fact, clinical trials show that the drug requires several days of use to build up in the body to achieve maximum effectiveness.

4. Flovent HFA and Flovent Diskus

45. Flovent Diskus (flucticasone propionate/aerosol) was initially approved on September 29, 2000 and Flovent HFA was initially approved on May 14, 2004. Both are currently FDA-approved for the maintenance of asthma as prophylactic therapy in adults and

pediatric patients 4 years of age or older as well as for patients requiring oral corticosteroid therapy for asthma.

46. Despite the FDA's limited indication relating to asthma exclusively, GSK has aggressively marketed Flovent HFA and Flovent Diskus since their launch for the treatment of COPD.

5. Imitrex

47. The FDA gas approved three formulations of Imitrex: Imitrex Injection received its initial approval by the FDA in 1993, followed by approval in tablet form in 1995 and in nasal spray form in 1997. Imitrex Tablets, Nasal Spray and Injection are FDA approved for the acute treatment of migraine attacks with or without aura in adults. Imitrex Injection has a second FDA-approved use, for the acute treatment of cluster headache episodes.

48. Contrary to Imitrex's narrow FDA approvals, GSK has marketed the drug in all of its formulations for the following uses:

- For the treatment of mild headache;
- For the treatment of sinus or tension headache;
- For the treatment of pediatric migraine, with particular focus on the promotion of Imitrex Nasal Spray for this use. GSK promoted the drug for this use by making false assertions to physicians that Imitrex Nasal Spray was on the verge of receiving FDA-approval; and,
- For the treatment of Menstrual Migraine, Prophylaxis and Use During Pregnancy

6. Lamictal

49. In December 1994, Lamictal (active ingredient *lamotrigine*) was FDA approved for use as adjunctive therapy in adults with partial seizures, and as adjunctive therapy in the

generalized seizures of Lennox-Gastaut syndrome in adults and pediatric patients ages two and older.

50. However, despite the narrow indications for which it was approved, GSK heavily marketed Lamictal for the treatment of bipolar disorders both before and during the period it was pending a supplemental new drug application for treatment of bipolar I disorder, which was finally granted by the FDA on June 20, 2003.

51. This new bipolar I indication was far more narrow than the aggressive marketing campaign for the treatment of bipolar disorder which GSK had in place both before and after the June 2003 approval.

52. GSK also marketed Lamictal for a variety of off-label uses for which it never gained subsequent approval, including neuropathic pain, multiple sclerosis, trigeminal neuralgia, peripheral neuropathy, cluster headache and PTSD.

53. Lamictal was subsequently approved in an extended release form known as Lamictal XR. Lamictal XR's approval is limited to adjunctive therapy for primary generalized tonic-clonic seizures and partial onset seizures with or without secondary generalization in patients 13 years of age and older. GSK promoted Lamictal XR for the same off-label uses as Lamictal. In addition, as Lamictal's patent expiration date came closer, GSK sales representatives were trained to promote switches to Lamitcal XR, including those prescriptions known to be written off-label.

54. GSK's off-label promotion of Lamictal and Lamictal XR recklessly disregarded the drug's serious side effect of rash, which can result in hospitalization or even death.

7. Paxil

55. Paxil (paroxetine hydrochloride) was initially approved by the FDA on December 29, 1992 for the treatment of Major Depressive Disorder in adults. Thereafter, the FDA approved the drug for other uses, however neither Paxil, nor its extended release formulation known as Paxil CR, has been approved for any use whatsoever in patients under the age of 18.

56. Nevertheless, GSK has aggressively promoted Paxil and Paxil CR as a safe and effective treatment for a litany of mental issues for children, including, depression, anxiety, ADHD, shyness, and bi polar disorder, among others.

57. GSK's off-label marketing for pediatric use was particularly egregious because GSK knew no later than November 1998 that Paxil was *ineffective* in this age group and, even worse, that depressed pediatric users of Paxil were up to three times more likely to commit suicide or engage in other self-harming conduct. GSK not only knew these seminal facts, but withheld its own clinical study data that proved them to be true from the medical community and the public to protect pediatric Paxil sales.

58. However, the bulk of Paxil and Paxil CR sales stemmed from GSK's unlawful promotion for off-label uses in adult patients for such diverse disorders as premature ejaculation and general social phobias, anxiety, ADHD, shyness, and bipolar disorder. As part of this scheme, GSK concealed that Paxil is highly addictive.

59. Finally, GSK aggressively promoted Paxil as safe and effective for use during pregnancy. This marketing scheme rivals the contemptibility of its pediatric scheme. GSK characterized Paxil as having treatment benefits that outweighed the risks, when in fact GSK knew the opposite to be true. GSK knew that the drug substantially increased the risk of severe congenital birth defects, particularly holes in the heart of the fetus. The drug is now also known

to cause Persistent Pulmonary Hypertension of the Newborn. When information about Paxil's link to birth defects finally became public in December 2005, the FDA reclassified the drug as Category D. Category D classification is reserved for drugs with a proven link to birth defects when used during pregnancy.

60. Paxil is the only SSRI with a Category D designation. GSK's concealment of evidence of birth defects deprived physicians and expecting mothers of the ability to make informed choices about the risks of its use during pregnancy. Had GSK disclosed the truth, undoubtedly the use of Paxil during pregnancy would have been severely curbed, which is exactly what GSK endeavored to avoid. This is particularly true of off-label use of Paxil, where safer alternatives would have been available.

8. Valtrex

61. On June 23, 1995, the FDA approved Valtrex caplets (valacyclovir hydrochloride) for the treatment of Herpes Zoster, commonly known as “shingles” in adults.

62. Shortly thereafter, on December 15, 1995, the FDA approved Valtrex caplets for the treatment of Recurrent Genital Herpes in adults.

63. On September 9, 2002, Valtrex received FDA approval, and its first pediatric indication, for the treatment of Herpes Labialis (cold sores) in adults and adolescent patients 12 years and older.

64. On April 1, 2003, the FDA approved Valtrex for use in the suppression of Recurrent Genital Herpes.

65. Following the suppression indication, on August 29, 2003, Valtrex was approved for these uses in combination with safe sex practices to reduce risk of transmission of herpes in heterosexual couples.

66. Finally, on September 2, 2008, the FDA approved Valtrex for the treatment of chicken pox in children between 2 years and 18 years old.

67. Although it eventually received the aforementioned FDA indications, GSK marketed Valtrex for uses well in advance of approvals and, in some instances, pushed the drug for prophylactic use in the 2nd and 3rd trimesters of pregnancy to prevent transmission to the fetus, and the treatment of multiple sclerosis.

9. Wellbutrin

68. Initially approved by the FDA on December 30, 1985, Wellbutrin (bupropion hydrochloride), was indicated for the treatment of Major Depressive Disorder ("MDD").

69. On October 4, 1996, the FDA approved Wellbutrin SR (sustained release) tablets for the treatment of MDD in adults.

70. In 2003, the FDA approved the use of Wellbutrin XL (extended release) for the treatment of MDD in adults.

71. Wellbutrin, Wellbutrin SR and Wellbutrin XL have never received FDA approval for pediatric use.

72. Despite their narrow MDD indications , GSK has aggressively promoted this drug, in all of its formulations, in pediatric psychological disorders, weight loss, ADHD (Attention Deficit Hyperactivity Disorder) in adults and children, for anxiety co-morbid to depression, for co-administration with SSRI's (selective serotonin re-uptake inhibitors), sexual dysfunction, bipolar disease and addictions, including smoking cessation and for treatment of depression in pregnant women, and a litany of other off-label uses detailed herein.

10. Zofran

73. On January 4, 1991, Zofran (ondansetron hydrochloride) was approved by the FDA for the prevention of nausea and vomiting induced by chemotherapy and radiation therapy as well as the prevention of post-operative nausea and vomiting.

74. Since its initial approval as an injectable, Zofran has received subsequent approvals on January 24, 1997 for an oral solution and on January 27, 1999 for an orally disintegrating tablet.

75. On March 25, 2005, Zofran received FDA approval for use in children as young as one (1) month of age to prevent nausea and vomiting associated with general anesthesia, and for use in children as young as six (6) months to prevent nausea and vomiting associated with chemotherapy.

76. Despite the limited indication, GSK attempted to expand dramatically the off-label use of Zofran and has marketed the medication for the treatment of morning sickness in pregnant women, as well as nausea and vomiting associated with influenza and gastrointestinal distress.

11. Zyban

77. Zyban (bupropion), was originally approved by the FDA on May 14, 1997 as a smoking cessation drug.

78. Although it contains the same ingredient as Wellbutrin, because federal law prohibits Medicaid from being compensating drugs identified and approved specifically for smoking cessation, GSK elected to promote Zyban off-label for use in pregnancy and in the treatment of non-nicotine addictions.