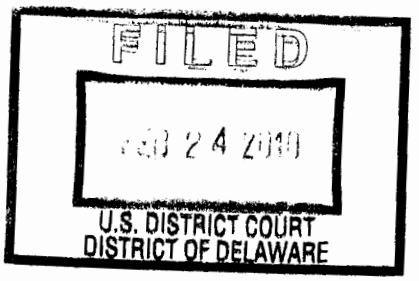

~~FILED UNDER SEAL~~

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

PLAINTIFF UNDER SEAL v. DEFENDANTS UNDER SEAL

Civil Action No. 10-154

~~FILED UNDER SEAL~~ unsealed per order of 1/29/2015

JURY TRIAL DEMANDED

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

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Counsel for Plaintiff-Relator

Dated: February 24, 2010

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

UNITED STATES OF AMERICA *ex rel.* TRACY MIKSELL-BRANCH, and on behalf of THE DISTRICT OF COLUMBIA, CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, **Plaintiff,** **v.** **ASTRAZENECA PHARMACEUTICALS, L.P., ASTRAZENECA, L.P., and ASTRAZENECA PLC,** **Defendants.**	**Case No.** **COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS** **JURY TRIAL DEMANDED** **FILED UNDER SEAL**

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This is an action brought on behalf of the United States of America and certain States (the "*Qui Tam*" States) by Tracy Miksell-Branch, by and through her attorneys, Blank Rome LLP, against the Defendants pursuant to the qui tam provisions of the federal False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"); the California False Claims Act, CAL. GOV'T CODE § 12650 (Deering 2000), *et seq.*; the Connecticut False Claims Act, 2009 Conn. Pub. Acts No. 09-5 (Sept. Spec. Sess.), *et seq.*; the Delaware False Claims and Reporting Act, DEL. CODE ANN. Tit. 6, § 1201 (2000), *et seq.*; the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.13 (2000), *et seq.*; the Florida False Claims Act, FLA STAT. 68-081 (2000), *et seq.*; the Georgia False Medicaid Claims Act, GA. CODE ANN.§ 49-4-168 (2007), *et seq.*; the Hawaii False Claims Act. HAW. REV. STAT. § 661-22, (2006) *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. § 175/1 (2000), *et seq.*; the Indiana False Claims and Whistleblower Protection Act, INDIANA CODE § 5-11-5.5, (2007) *et seq.*; the Louisiana Medical Assistance Programs Integrity, LA. REV. STAT. ANN. § 46.439.1 (2006), *et seq.*; the Massachusetts False Claims Act, MASS. ANN. LAWS ch. 12, § 5(A) (2007) *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.601, (2007) *et seq.* (2007); the Montana False Claims Act, MONT. CODE ANN. § 7-8-401 (2005), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. § 265 (2007); the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1 (2007), *et seq.*; the New York False Claims Act, N.Y. CLS ST. FIN. § 190.6. (2007), *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. § 357.010 (1999), *et seq.*; the North Carolina False Claims Act,

N.C. GEN. STAT. § 1-605 (2010), *et seq.*; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*; the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*; the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181(c) (2006), *et seq.*; the TEX. HUM. RES. CODE § 36.001 (2006), *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 (2006), *et seq.*; and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 (2007), *et seq.* ("State Qui Tam Statutes").

I. BACKGROUND

1. Plaintiff-Relator brings this action to recover hundreds of millions of dollars under the FCA and the State *Qui Tam* Statutes resulting from a fraudulent scheme relating to the off-label marketing of Seroquel XR®. Plaintiff-Relator also brings an action for employment-related retaliation that she has suffered as a result of alerting AstraZeneca's management to the fraudulent and unlawful conduct.

2. As alleged herein, Defendants have engaged in a scheme since 2007, and continuing until today, to submit and cause to be submitted hundreds of thousands of false claims to federal and state health care programs by systematically and illegally promoting Seroquel XR® for unapproved, off-label uses throughout the United States. These false claims cheated the federal and state governments out of hundreds of millions of dollars that should not have been paid, thereby enriching the Defendants, and subjected patients to non-approved, ineffective, and unsafe uses of the Seroquel XR®.

3. The illegal schemes and harm to the federal and state governments described in this Complaint are continuing.

4. The off-label indications Defendants promoted for Seroquel XR® include generalized anxiety disorder ("GAD"), major depressive disorder ("MDD"), the treatment of children, and the treatment of dementia and other neurological conditions in elderly patients.

5. Defendants, *inter alia*, (a) knowingly disregarded Food and Drug Administration ("FDA") laws and regulations on off-label promotion; (b) knowingly misrepresented the evidence concerning the efficacy and safety of the off-label use of the Seroquel XR®; (c) knowingly promoted Seroquel XR® for uses that were neither effective nor safe; (d) improperly disseminated written materials to physicians and other health care providers as a result of improperly solicited requests by sales representatives; and (e) paid financial inducements to "key opinion leaders" or "KOLs" who gave presentations concerning the off-label use of the Seroquel XR®, either at promotional speaker programs or at continuing medical education ("CME") events.

6. At the time Defendants' illegal activities alleged herein were under way, Defendants were already subject to a Corporate Integrity Agreement ("CIA") related to the settlement and criminal plea with regard to the promotion of the drug Zoladex®. Moreover, Defendants were also under investigation related to the off-label promotion of the drug Seroquel® (also known as Seroquel IR®), the predecessor to Seroquel XR®, recently announcing a settlement with the United States government for $520 million. As such, Defendants' conduct herein is particularly egregious since AstraZeneca has knowingly flouted FDA regulations and CMS limits on off-label reimbursement even while negotiating a settlement of the Seroquel® case.

7. Accordingly, the Plaintiff-Relator, on behalf of the United States and the *Qui Tam* States, seeks to recover pursuant to the FCA and the State *Qui Tam* Statutes.

II. JURISDICTION AND VENUE

8. This Court has subject-matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1345. This Court has personal jurisdiction over the Defendant because, among other things, the Defendants' U.S. headquarters are in this district and engaged in wrongdoing in this district.

9. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants' principal place of business in the U.S. is within this judicial district, and acts proscribed by 31 U.S.C. § 3729 occurred in this district.

10. The claims for relief alleged herein are timely brought because, among other things, of efforts by the Defendants to conceal from the United States and the *Qui Tam* States their wrongdoing in connection with the allegations made herein.

III. PARTIES

A. Plaintiff-Relator Tracy Miksell-Branch

11. Plaintiff-Relator Tracy Miksell-Branch ("Plaintiff-Relator") is a resident of Grimes, Iowa. After receiving a Bachelor of Arts degree in Psychology in 1988, Plaintiff-Relator has worked in the health-care field continuously since 1988. She received the degree of Master of Social Work from Adelphia University in 1990, and has completed her coursework for a Doctor of Social Work from the International University for Graduate Studies in 2005 from New York University. She is, among other things, a licensed independent social worker in the state of Iowa.

12. Plaintiff-Relator has worked as an Executive Specialty Pharmaceutical Sales Representative in the Central Nervous System Division of the Defendant AstraZeneca from November 2000 until the present. In this capacity, Plaintiff-Relator's primary duties and responsibilities involved the marketing of Seroquel® and, later, Seroquel XR®. Plaintiff-

Relator was responsible for a sales territory in and around Atlanta, Georgia from November 2000 until December 2002. Since December 2002, Plaintiff-Relator has worked in this capacity in the region covering the central portion of the state of Iowa.

13. Plaintiff-Relator has received numerous honors and awards in recognition of her outstanding performance. She was chosen as a Field Training Associate by a national selection committee, a position for which only a small percentage of the company's workforce were selected. She received nominations for 13 "Sales Value Awards" from both peers and managers since joining the company in 2000. She was also chosen five times for the "Being the Best Award" by her District Sales Manager, Regional Sales Director, and Area Sales Director. She has received awards for largest market share growth and largest growth in average daily dose. She has been in the top 10 percent of the CNS Sales team for two consecutive years in previous years. She was also chosen as a "Customer Solutions Champion" by her district manager. As a result of her outstanding performance, Plaintiff-Relator earned a promotion to "Executive Level Sales Representative."

14. In addition to these awards, Plaintiff-Relator's Regional Sales Director selected her to sit on a "Directors Council." The Directors Council was a committee of the most highly regarded sales representatives in the company who recommended changes to improve efficiencies in the way representatives were trained and managed. A different Regional Sales Director also selected her to sit on a panel at a National Sales meeting to answer questions regarding the roll-out of a new sales promotional aide with a new computer system. AstraZeneca selected Plaintiff-Relator as a member of a national training committee to write training modules for competitive information regarding Abilify®. And, she was chosen to mentor new hires and

primary care representatives for clinical training materials over the years by several different district sales managers.

15. Through her employment at AstraZeneca, in her role as an Executive Specialty Pharmaceutical Sales Representative, Plaintiff-Relator gained a wealth of direct and independent knowledge of the fraudulent schemes perpetrated by the Defendants.

16. Plaintiff-Relator was involved in meetings and discussions regarding maximizing sales of Seroquel XR®. AstraZeneca's attempts to maximize sales included efforts to induce, encourage, and convince psychiatrists, pharmacists, and/or other health care professionals at psychiatric hospitals to prescribe and use Seroquel XR® in patients and/or for indications for which this medication had not been approved by FDA.

17. Plaintiff-Relator is the original source of the allegations in this Complaint, and the allegations regarding AstraZeneca's conduct are not based upon publicly disclosed information. She has voluntarily provided the government with information and documents prior to the filing of this Complaint in accordance with 31 U.S.C. § 3730(b)(2). Prior to filing this Complaint, Plaintiff-Relator brought the wrongdoing described in this Complaint to the attention of AstraZeneca.

B. Defendants

18. Defendant AstraZeneca Pharmaceuticals LP ("AZ Pharm") is a Delaware Limited Partnership with its headquarters located at 1800 Concord Pike, Wilmington Delaware 19850. AZ Pharm's general and limited partners include: (1) AstraZeneca AB, a Swedish corporation with its corporate headquarters in Sweden; (2) Zeneca Inc., a Delaware corporation with its corporate headquarters in Delaware; (3) Astra USA, a New York corporation with its principal place of business in Delaware; and (4) Astra US Holdings Corporation, a Delaware corporation with its corporate headquarters in Delaware. AZ Pharm designs, produces, markets

and promotes mental health prescription medications, including Seroquel XR®, nationwide. AZ Pharm is a subsidiary of Defendant AstraZeneca PLC. At all relevant times, AZ Pharm acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting through the course and scope of their actual and apparent authority, agency, duties or employment.

19. Defendant AstraZeneca PLC ("AZ") is one of the world's leading pharmaceutical companies. AZ is a foreign entity and headquartered in London, England. AZ, through its operating companies and subsidiaries, manufactures, produces, formulates, markets and promotes mental health prescription medications, including Seroquel®, nationwide. At all times, AZ acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting through the course and scope of their actual and apparent authority, agency, duties or employment. Defendant AZ Pharm is a subsidiary of AZ. AZ maintains a substantial presence in the United States.

20. Throughout the relevant period, AZ and its subsidiaries marketed and sold substantial quantities of its drug products in Delaware and throughout the rest of the United States, including within this judicial district. Defendant AZ benefited from and is liable for the actions of its predecessors, affiliates and subsidiaries in carrying out the fraudulent scheme described below. AZ has had notice of these fraudulent acts due to the substantial continuity in ownership and management with its subsidiary corporations and partnerships.

21. Defendant AstraZeneca LP ("AstraZeneca LP") is a limited partnership organized under the laws of Delaware, and conducts business nationwide. AstraZeneca LP's general and limited partners include: (1) Defendant AZ Pharm; and (2) KBI Sub Inc., a Delaware

corporation with its principal place of business in New Jersey. AstraZeneca LP is a United States subsidiary of AstraZeneca PLC.

22. AZ Pharm and AstraZeneca LP (collectively "AstraZeneca") are engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products throughout the United States. Throughout the relevant period, AstraZeneca employed as many as 15,000 sales representatives/sales managers located across the United States to promote, market or otherwise sell AstraZeneca drugs, including Seroquel XR®.

23. AstraZeneca markets and sells brand-name prescription drug products, including Seroquel XR®, paid or reimbursed by various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Shield Association ("BCBSA"); the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq.* via Medicare Part C, also known as Medicare+Choice; patients covered by Medicare Part D; the Indian Health Service; Medicaid; the Mail Handler's Health Benefit Plan ("MHHBP"); the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan; the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"); and the Veteran's Health Administration ("VHA") (collectively, the "Federal Programs").

24. As a result of AstraZeneca's actions, the *Qui Tam* States and Federal Programs have suffered financial harm.

IV. SUMMARY OF THE FRAUDULENT SCHEME

25. Seroquel XR® (quetiapine fumarate) is the successor to Seroquel®, also known as Seroquel IR®. Seroquel XR® is in a class of drugs known as "atypical anti-psychotics" or "Second Generation Anti-Psychotic" Drugs ("SGAs"). At all times material hereto,

Seroquel XR® and its predecessor, Seroquel®, have been among the best-selling drugs in the world in the SGA therapeutic class.

26. Almost immediately following the launch in July 2007 AstraZeneca marketed and promoted Seroquel XR® for uses and indications for which it had not received FDA approval.

27. In particular, AstraZeneca required its sales force to induce, encourage, and convince psychiatrists, other mental health practitioners, and hospitals and other institutions providing psychiatric care to prescribe Seroquel XR® for use in persons under the age of 18 or over the age of 65, uses for which the FDA had not approved Seroquel XR®. In addition, AstraZeneca required its sales force to induce, encourage, and convince psychiatrists, other mental health practitioners, and health care professionals at hospitals and other institutions providing psychiatric care to prescribe Seroquel XR® for specific diagnostic conditions and indications for which the drug had not received FDA approval, including GAD and MDD, use in children and adolescents, and use in the elderly for treatment of dementia and other neurological disorders. This resulted in the writing of numerous prescriptions that should never have been written and the pricing of the drugs at prices exceeding the appropriate price had the truth been known. Collectively, these schemes will be referred to herein as the "Fraudulent Marketing Schemes." AstraZeneca is liable under the FCA, and the State *Qui Tam* Statutes, due to the payment or reimbursement for these off-label prescriptions.

28. It was the plan and purpose of the Defendants' scheme to market Seroquel XR® illegally beginning at least as early as July 2007, and continuing to the present, in order fraudulently to obtain governmental reimbursement by causing false and fraudulent claims to be submitted for payment in order to maximize AstraZeneca's profits.

29. It was part of the scheme that AstraZeneca illegally promoted the off-label sales and use of Seroquel XR® in order to obtain reimbursement for non-medically accepted indications and other off-label treatments in order to maximize profits by making false and fraudulent statements to the public, healthcare providers, and the FDA.

30. In violation of federal law, AstraZeneca knowingly and falsely promoted Seroquel XR® by the use of unsubstantiated comparative claims, comparing Seroquel XR® with competing products such as Abilify® and AstraZeneca's own earlier version of quetiapine fumarate, Seroquel®. These unsubstantiated, comparative claims are prohibited by the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 352, and 21 C.F.R. § 202.1(e)(6). The use of unsubstantiated comparative claims renders a drug "misbranded" by the FDA. AstraZeneca promoted these falsehoods to physicians to induce physicians to prescribe Seroquel XR®. Once Seroquel XR® became "misbranded," it was no longer eligible for reimbursement by Federal Programs, including Medicaid and Medicare Part D.

31. AstraZeneca's unlawful promotion of Seroquel XR® involved the unlawful making of false records or statements to cause the Government's payment of false or fraudulent claims.

32. AstraZeneca's conduct had a material effect on the governments' decision to pay for Seroquel XR®. Had the governments known that reimbursements were being made for Seroquel XR® caused by the Defendant's unlawful promotion, the governments would not have made such reimbursements.

33. It was further part of the scheme that AstraZeneca attempted to conceal and cover up the off-label marketing of Seroquel XR® by making false statements to the FDA and directing employees to conceal evidence.

V. BACKGROUND ON PROMOTING SEROQUEL XR® OFF-LABEL

A. The FDA Regulatory System

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

34. Under the 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 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 step in a multi-year process of study and testing. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents.

35. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

36. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5).

37. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with: (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias;

and (5) well defined and reliable methods of assessing subjects' responses to treatment. *See* 21 C.F.R. § 314.26.

38. After a drug is approved, the FDA continues to exercise control over the product labeling. To ensure or promote safety, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off-Label Marketing and False and Misleading Statements About a Drug's Use.

39. The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

40. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels – including all marketing and promotional materials relating to the drug – may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

41. The same general requirements governing the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved

product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

42. A manufacturer wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA ("sNDA") must be filed in order to seek approval of the new indication. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

43. "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 on the label, or treating a different patient population -- *e.g.,* treating a child when the drug is approved to treat adults.

44. 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 physicians from prescribing the drug for uses that are different than those approved by the FDA.

45. When considering off-label prescribing, physicians depend on the patient-specific evidence available to them. This includes the particular patient's symptoms and medical history, the severity of his or her problems, the success of prior treatment, and the risks of not treating.

Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers.

46. 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, or for a patient group that is unapproved. Specifically, 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. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. § 202.1(e)(4)(i)(a), prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,076 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product." *Id.*

47. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing contained in 21 C.F.R. § 202.1, as well as the FDA's "fair balance" requirement, described below.

48. FDA regulations provide that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." 21 C.F.R. § 202.1(e)(6)(xi);

see also 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

49. These regulations ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6).

50. The regulations also prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. § 202.1(e)(6)(iv).

51. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. §202.1(e)(5) *et seq*. A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

52. FDA Regulations broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug. 21 C.F.R. § 202.1(1)(2). The FDA has interpreted oral communications as falling under the umbrella of "labeling."

53. FDA regulations require labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibit "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." 21 C.F.R. § 201.56

54. These regulations also lay out the stringent requirements that must be met by a manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. § 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." *Id.* § 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. *Id.* § 99.101(b)(2).

55. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. § 99.101(a)(4).

56. Off-label information may be disseminated only in response to an "unsolicited request from a healthcare practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use 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 are submitted in unabridged form and are neither false nor misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

57. Companies such as AstraZeneca may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Federal Programs, including Medicaid.

58. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. Moreover, the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

B. The Limited Role of the FDA in Regulating Off-Label Promotion of Drugs

1. The FDA Relies on Information Provided by Drug Manufacturers for New Drug Approvals

59. FDA approval of prescription drugs is wholly dependent on the accuracy of information provided by drug manufacturers. *See generally* Wayne A. Ray & Michael Stein, "Reform of Drug Regulation—Beyond an Independent Drug-Safety Board," *New England Journal of Medicine*, 354(2):194 (Jan. 12, 2006).

60. FDA approval does not require that a new drug be more effective or safer than other drugs approved to treat the same condition, or that it be cost-effective. A drug need only be shown to be more effective than a placebo in treating a particular condition, without any statistically significant safety findings. Comparative data showing performance as compared to existing drugs is not required; the FDA has no basis for determining that one drug is better than another drug.

61. Because short-term studies are accepted, drug applications often do not contain long-term data on the safety or efficacy of the drug. Approval of a new drug generally contains a requirement that the manufacturers pursue further long-term studies, but two thirds of the promised studies never materialize and the FDA lacks any enforcement authority to require the manufacturer to complete these studies.

62. Many of the effects of newly approved drugs could not possibly be known at the time of FDA approval, particularly the long-term effects of taking a medication, given the short length of and relatively few participants in the clinical trials conducted for approval. *See* "AP Analysis: How a Drug's Risks Emerge," *New York Times*, May 23, 2007. There is no systematic provision requiring drug companies to conduct—or provide results from—post-marketing studies.

63. The FDA often finds itself in a quandary: "Safety and speed are the yin and yang of drug regulation. Patients want immediate access to breakthrough medicines but also want to believe the drugs are safe. These goals can be incompatible." Gardiner Harris, "Potentially Incompatible Goals at F.D.A.: Critics Say a Push to Approve Drugs Is Compromising Safety," *New York Times*, June 11, 2007, at A14.

2. DDMAC's Limited Ability to Regulate Drug Maker Marketing and Promotion.

64. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off-label uses. *See* Statement by Janet Woodcock, M.D., Director Center for Drug Evaluation and Research, FDA, Before the Senate Special Committee on Aging (July 22, 2003).

65. DDMAC's ability to regulate off-label promotion is limited. In 2003, its entire staff consisted of 40 members, with 25 reviewers responsible for reviewing all drug advertisements and promotional materials.

66. Moreover, drug materials do not have to be pre-approved. FDA review of promotional materials occurs, if it does at all, after the materials have already appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* DDMAC occasionally requires sponsors to correct publicly product misimpressions created by false, misleading, or unbalanced materials. *Id.*

67. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

68. FDA's inability to police off-label promotion effectively was confirmed in a July 28, 2008 U.S. Government Accountability Office Report, which found that the FDA took an average of seven months to issue letters in response to off-label promotions. *See* Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses (GAO 08-835), http://www.gao.gov/new.items/d08835.pdf.

69. Among the Report's findings: (1) FDA does not have separate oversight activities sufficient to capture off-label promotion; (2) FDA is unable to review all promotional submissions because of the volume of materials it receives; instead, the FDA must prioritize its reviews in order to examine those with the greatest potential impact on human health;

(3) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (4) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives; (5) during calendar years 2003 through 2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

70. AstraZeneca is among the companies cited in the GAO Report, cited for Merrum I.V., which had been approved only for treatment of intra-abdominal infections and bacterial meningitis when caused by specific pathogens that are not drug resistant. Despite the limited indication, AstraZeneca was warned that it was improperly marketing Merrum I.V. for treatment of infections caused by particular bacteria and drug-resistant pathogens

3. On December 1, 2008, AstraZeneca Receives DDMAC Warning Letter

71. On or about December 1, 2008, AstraZeneca received a DDMAC Warning Letter, concerning misleading promotional materials and misleading oral statements for Seroquel XR®. According to the Warning Letter, an AstraZeneca sales representative had made oral statements to a health care professional on January 3, 2008, and had sent a mailing to the same healthcare provider on January 4, 2008, regarding Seroquel® and Seroquel XR®. According to the letter, the sales representative and the mailing had "recommended or suggested a use for Seroquel and Seroquel XR® that has not been approved by FDA, and thus created a new 'intended use' for Seroquel and Seroquel XR® for which the products lack adequate directions." Letter to James L. Gaskill, Pharm.D, Director, Promotional Regulatory Affairs, AstraZeneca LP, from AmyToscano, Pharm.D., CPA, Regulatory Review Office, DDMAC, Dec. 1, 2008. As a result,

"these promotional activities and materials misbrand the drugs in violation of the [FFDCA] and FDA implementing regulations ...." *Id.*

72. The DDMAC Warning Letter requested that AstraZeneca "immediately cease the dissemination of violative promotional materials for Seroquel and Seroquel XR® such as those described above" and respond to the FDA stating that AstraZeneca has complied with the FDA's request.

73. On information and belief, AstraZeneca falsely informed the FDA that all violative promotion had ceased when, in fact, it had no intention of complying with the FDA's request, and it continued the unlawful promotion of Seroquel XR®.

VI. PRESCRIPTION DRUG PAYMENT UNDER FEDERAL HEALTH CARE PROGRAMS

A. The Medicaid Program

74. Whether an FDA-approved drug is approved for a particular indication (*i.e.*, use) determines whether a prescription for that use may be reimbursed under Medicaid and other federal health care programs.

75. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million 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.

76. 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." 42 U.S.C. § 1396r-8(k)(3).

77. A medically accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that 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, AstraZeneca promoted off-label uses of Seroquel XR® that were not eligible for reimbursement from Medicaid because the off-label uses were neither listed in the FDA-approved labeling nor included in any of the drug compendia specified by the Medicaid statute.

78. Between the third quarter of 2003 and the second quarter of 2008, Medicaid reimbursements for Seroquel XR® totaled more than $950 million, covering more than 13 million prescriptions.

B. The Medicare Program

79. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

80. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k), as described above.

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

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

83. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all beneficiaries, with low-income individuals receiving the greatest subsidies. AstraZeneca has targeted Medicare Part D beneficiaries for sales of Seroquel XR®, including for off-label uses, by, among other things, distributing marketing materials that highlight formulary coverage of Seroquel XR® by Medicare Part D plans.

84. During the time period relevant to this Complaint, AstraZeneca promoted off-label uses of Seroquel XR® that were not eligible for reimbursement from Medicare because the off-label uses were neither listed in the FDA-approved labeling, nor included in any of the drug compendia specified by the statute.

C. Reimbursement Under Other Federal Health Care Programs

85. In addition to Medicaid and Medicare, 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.

86. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependants affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for families of veterans with 100 percent service-connected disabilities. The Federal Employees 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).

87. During the time period relevant to this Complaint, AstraZeneca promoted off-label uses of Seroquel XR® that were not eligible for reimbursement under any of the various federal health care programs.

VII. THE DEVELOPMENT OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS TO TREAT SCHIZOPHRENIA AND BIPOLAR DISORDER

88. Schizophrenia is a severe, debilitating mental illness that afflicts over one percent of the general population—2.5 million Americans—often beginning in late adolescence or early adulthood. One of the most complex and challenging of psychiatric disorders, schizophrenia is a heterogeneous syndrome of disorganized and bizarre thoughts, delusions, hallucinations, inappropriate affect, impaired psycho-social functioning, cognitive dysfunction, and profound mood disorders. *See* DSM-IV-TR 298-302. The illness occurs when a patient suffers two or more of the following characteristic symptoms: (1) delusions, (2) hallucinations, (3) disorganized speech, (4) grossly disorganized or catatonic behavior, and (5) negative symptoms, *see id.*, or has bizarre delusions or hallucinations of voices commenting on the person's behavior or thoughts. Research has shown a variety of abnormalities in schizophrenic brain structure and function.

89. Bipolar disorder is a serious, lifelong mental illness marked by dramatic shifts in mood, from abnormally elevated, expansive, or irritable moods to states of extreme sadness and hopelessness, often with periods of normal mood in between. Bipolar I, characterized by the occurrence of one of more manic episodes or mixed episodes, often with major depressive episodes, and Bipolar II, characterized by one or more major depressive episodes accompanied by at least one hypomanic episode, are separate disease states. *See* DSM-IV-TR 382-92. Because of its complexity, bipolar disease can be difficult to diagnose; between seven and ten years of misdiagnoses and incorrect treatment is typical for bipolar patients.

90. An extensive amount of research into diagnosing and recommending treatments for bipolar disorder has occurred in the last five years, funded in part by pharmaceutical manufacturers. This has occurred in conjunction with a corresponding growth of bipolar diagnoses—correct and incorrect—leading to an increase in patients and greater awareness of the disease.

91. Many patients labeled "bipolar" are mentally ill but, upon detailed psychiatric exam, are not bipolar. An estimated 5.7 million American adults are affected by the disorder, and at least 800,000 children in the United States have been diagnosed as bipolar, no doubt some of them wrongly.

92. Seroquel XR® is generally known as an "atypical anti-psychotic" or a "second generation antipsychotic" or "SGA," to differentiate it from older, first-generation antipsychotics ("FGAs"), which were the common drug therapy for schizophrenia until the 1990s. FGAs include chlorpromazine (Thorazine®), fluphenzine (Proxilin®), haloperidol (Haldol®), molindone (Moban®), thioridazine (Mellaril®), loxapine (Loxitane®), mesoridazine (Serentil®), perphenazine (Trilafon®), thiothixene (Navane®), and trifluoperazine (Stelazine®), some of which have been in use since the 1950s.

93. FGAs are sometimes referred to as "typical" antipsychotics and SGAs "atypical." Although many different FGAs exist, they share similar levels of efficacy. They are, generally speaking, post-synaptic dopamine-receptor antagonists -- *i.e.,* they target dopamine receptors in the brain. A troubling side effect of typical antipsychotics is that the blockage of dopaminergic neurotransmission causes extrapyramidal syndromes ("EPS") such as Parkinsonian effects or tremors. Tardive Dyskinesia ("TD"), a long-lasting movement disorder, also frequently occurs with prolonged treatment.

94. During the 1990s, pharmaceutical companies, building on the "atypical" hypothesis, developed newer, SGAs, attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and, they hoped, without the side effects, such as EPS and TD, caused by traditional antipsychotics. The introduction of atypical antipsychotic medications was trumpeted by the manufacturers of these pharmaceutical agents as a major advance in the treatment of schizophrenia with improved symptomatic control of the psychosis and a reduction in both tardive dyskinesia and extra pyramidal side effects.

95. SGAs now account for about 90 percent of all antipsychotic drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications or not. Although the two primary uses of SGAs remain the treatment of schizophrenia and bipolar disorder, SGAs are prescribed "off label" to treat symptoms related to agitation, anxiety, psychotic episodes, obsessive behavior, behaviors related to dementia, depression (including MDD and GAD), obsessive compulsive disorder ("OCD"), Post Traumatic Stress Disorder ("PTSD"), personality disorders, and Tourette's Syndrome. Although there is only mixed evidence about their efficacy for these purposes (as well as for their indications), SGAs have become a booming business.

96. The use of SGAs in the patient population under the age of 18 is large and ever growing. In a presentation entitled "Outpatient use of Atypical Antipsychotic Agents in the Pediatric Population Years 2004 – 2008," the FDA's Division of Epidemiology, the Office of Surveillance and Epidemiology (Dec. 8, 2009), the FDA determined that the total number of SGA prescriptions from U.S. outpatient retail pharmacies had grown from 3.94 million in 2004 to 4. 8 million, in 2008, a 22 percent increase. *Id.* at 5. The FDA estimated that the number of prescriptions for Seroquel® or Seroquel XR® had been written during this time

period, rising from just under 1 million prescriptions written in 2004 to just over 1 million prescriptions written in 2008. *Id.* at 6.

VIII. MARKETING EFFORTS BY THE PHARMACEUTICAL INDUSTRY

A. The Importance of Marketing

97. Marketing and advertising have been critical to the success of the pharmaceutical industry in the last two decades, and particularly at AstraZeneca. Whether via increasingly common direct-to-consumer ("DTC") advertising or one-on-one physician detailing, drug companies spend billions on drug promotion. Gardiner Harris, Group Urges Ban on Medical Giveaways, *New York Times*, April 28, 2008. In 2000, for example, total national prescription drug promotion expenditures totaled more than $15.7 billion. Of that amount, $4.8 billion is spent on drug detailing alone.

98. A study recently published in the Archives of Internal Medicine concerning the effect of DTC on the sale of clopidogrel concluded that, although DTC advertising did not necessarily result in an increase in the number of units of the drug prescribed, Medicaid pharmacy expenditures on this drug increased substantially after the initiation of DTC advertising because of a concomitant increase in the cost per unit. Michael R. Law, *et al.*, "Costs and Consequences of Direct-to-Consumer Advertising for Clopidogrel in Medicaid," 169 Arch. Intern. Med. 1969 (2009).

99. It is undisputable that expenditures for drug marketing increase sales and revenues. Intense pharmaceutical marketing saturates the pharmaceutical industry and appears in many forms—some of which some people would call disguised. To accomplish these goals and raise sales, AstraZeneca utilized all the various channels of information through which pharmaceutical companies can market their products to propel Seroquel XR®'s brand message. Those channels—today highly susceptible to industry influence—are described below.

100. The most obvious source of information about a medication is its own prescription label. Although a pharmaceutical company must obtain the FDA's approval for its drug's label, the label is the property of the manufacturer, not the FDA. Initially drafted by the manufacturer, labels are then subject to negotiations between the federal agency and the manufacturer. Because the FDA depends solely on drug safety and efficacy information provided by pharmaceutical companies, however, it cannot object to a label's shortcomings if it never received the data from the manufacturer showing the drug's drawbacks.

B. Drug Maker Detailing: Visits to Doctors and Other Health Care Professionals

101. "Detailing" is the one-on-one promotion of drugs to physicians by pharmaceutical sales representatives, usually through regular office visits, free gifts, and friendly advice. Detailing involves visits during which "drug reps go to doctors' offices to describe the benefits of a specific drug." Daniel Carlat, "Dr. Drug Rep.," *New York Times Mag.,* Nov. 25, 2007, at 67.

102. Medical detailing is a large field, employing over 90,000 sales representatives, which represents an average of approximately one detailer for every 4.5 doctors. The vast majority of doctors—85 to 90 percent—do speak with drug detailers, and most consider them and the information they provide helpful and accurate. Drug representatives ostensibly provide useful information for physicians as they address "difficult problems in treating patients." Jonna Perala, *et al.*, "Lifetime Prevalence of Psychotic and Bipolar I Disorders in a General Population," 64 *Arch. of Gen. Psychiatry* 19, 1892 (2007).

103. Drug company-controlled and -produced information has great potential to mislead, however. One study found that nearly half (42 percent) of the material given to doctors by drug reps made claims in violation of FDA regulations. *See* Chimonas, et al., "Physicians and Drug Representatives: Exploring the Dynamics of the Relationship," *Journal of*

General Internal Medicine, February 2007, (www.pubmedcentral.nih.gov/article render.fcgi?pubmedid=17356984) Only 39 percent of the material provided by drug representatives provided scientific evidence to back up the claims being made. *Id.*

104. Drug makers, including AstraZeneca, use a core marketing strategy of identifying "Key Opinion Leaders" ("KOLs") – i.e., physicians who would influence their peers' medical practice, including but not limited to prescribing behavior. As described herein, AstraZeneca engaged numerous KOLs beginning at least as early as the launch of the Seroquel XR® in July 2007 to provide advocacy, as well as key marketing feedback and activities, including speaker programs and CME programs throughout the United States. Many of these KOLs had been advocates for AstraZeneca's off-label use of Seroquel® and engaged as advocates for the off-label use of Seroquel XR®.

C. Drug Maker Influence and the Exploding Off-Label Use of SGAs in Children and Adolescents

105. Off-label use of SGAs among children and adolescents has exploded despite little research into the long-term effects on children's brains. Doctors influenced by pharmaceutical company propaganda and financial "incentives" to prescribe these drugs are putting children's lives at risk by prescribing these highly toxic drugs. Dr. Ronald Brown, who headed an American Psychological Association committee that evaluated the issue, put it succinctly: "The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness." *See* DeAngelis, "Should our children be taking psychotropics?" American Psychological Association: Monitor on Psychology, December 2004, Vol 35, No. 11.

106. There was a 40-fold increase over nine years in the number of children diagnosed with bipolar disorder, fueling an explosion in the use of antipsychotic medications made by AstraZeneca and other drug makers. *See* C. Moreno, et al., "National Trends in the

Outpatient Diagnosis and Treatment of Bipolar Disorder in Youth," *Archives of General Psychiatry*, 64(9): 1032-1039 (Sept. 2007). The number of prescriptions written for children doubled to 4.4 million between 2003 and 2006. The expanded use of bipolar disorder as a pediatric diagnosis has made children the fastest-growing part of the $11.5 billion United States market for antipsychotic drugs. The study noted that the number of children diagnosed with bipolar disorder during outpatient visits to doctors skyrocketed to 800,000 in 2003 from 20,000 in 1994. The numbers have continued to climb even amid reports that more physicians are influenced to prescribe off-label by drug company inducements.

107. Recent federally-financed drug research reveals a stark disparity: children covered by Medicaid are given powerful antipsychotic medicines at a rate four times higher than children whose parents have private insurance. And the Medicaid children are more likely to receive the drugs for less severe conditions than their middle-class counterparts, the data shows. Duff Wilson, "Poor Children Likelier to Get Antipsychotics," *New York Times*, Dec. 9, 2009, available at http://www.nytimes.com/2009/12/12/health/12medicaid.html?_r=3&scp=1&sq=antipsychotics&st=cse

D. Burgeoning Off-Label Use of SGAs to Treat Dementia

108. Nearly 1.7 million elderly and disabled Americans live in 17,000 nursing home facilities across the country. Combined Medicare and Medicaid payments for nursing home services total an estimated $70 billion annually. In 2005, the most recent year for which total expenditure figures are available, Medicaid spent $5.4 billion on atypical antipsychotic drugs, or 13.7 percent of all Medicaid expenditures on prescription drugs.

109. The off-label use of SGAs to control or reduce the agitation, combative behavior and outbursts of dementia patients has soared, especially in the elderly. Part of this increase can be traced to prescriptions in nursing homes. Laurie Tarkan, "Doctors Say Medication Is

Overused in Dementia," *New York Times*, June 24, 2008. Researchers estimate that as much as 30 percent of all nursing home patients have been given antipsychotic drugs, particularly SGAs. *Id.*

110. According to CMS, nearly 21 percent of nursing-home patients who do not have a psychosis diagnosis are on antipsychotic drugs. *See* Lucette Lagnado, "Prescription Abuse Seen In U.S. Nursing Homes: Powerful Antipsychotics Used to Subdue Elderly; Huge Medicaid Expense," *Wall Street Journal*, Dec. 4, 2007; Page A1.

E. The Promotion of "Disorders" to Sell Drugs

111. Word of the hidden GAD epidemic began spreading in the spring of 2001. Local newscasts around the country reported that as many as 10 million Americans suffered from an unrecognized disease. Viewers were urged to watch for the symptoms: restlessness, fatigue, irritability, muscle tension, nausea, diarrhea, and sweating, among others. Their testimonials were interspersed with peaceful images of a woman playing with a bird, and another woman taking pills. The disease was generalized anxiety disorder ("GAD"), a condition that, according to the reports, left sufferers paralyzed with irrational fears. Mental-health advocates called it "he forgotten illness." Print periodicals were awash in stories of young women plagued by worries over money and men.

112. For pharmaceutical companies, marketing existing drugs for new uses makes perfect sense: A new indication can be obtained in less than 18 months, compared to the eight years it takes to bring a drug from the lab to the pharmacy. Managed-care companies also have been encouraging the use of medication, rather than more costly psychotherapy, to treat problems like anxiety and depression.

113. According to a February 2002 study published in the *Archives of General Psychiatry*, "When people look at numbers that say close to 30% of the American public has a

mental disorder and therefore needs treatment, most would say that it is implausibly high." "You often hear: 'There are 10 million Americans with this, three million Americans with that,'" says Barbara Mintzes, an epidemiologist at the University of British Colombia's Center for Health Services and Policy Research. "If you start adding up all those millions, eventually you'll be hard put to find some Americans who don't have such diagnoses." *See* Brendan I. Koerner, "Disorders Made to Order," Mother Jones, July/August 2002.

114. In 1989, as few as 1.2 percent of the population suffered the obscure DSM disorder GAD. After the FDA approved the antidepressant Paxil® for treatment of it in 2001, followed by a massive marketing campaign, the media reported that 10 million Americans suffered the "disorder."

115. A drug company's modus operandi-marketing a disease rather than selling a drug-is typical of the post-Prozac era. Typically, a corporate-sponsored "disease awareness" campaign focuses on a mild psychiatric condition with a large pool of potential sufferers. Companies fund studies that prove the drug's efficacy in treating the affliction, a necessary step in obtaining FDA approval for a new use, or "indication." Prominent doctors are enlisted to publicly affirm the malady's ubiquity. Public-relations firms launch campaigns to promote the new disease, using dramatic statistics from corporate-sponsored studies. Finally, patient groups are recruited to serve as the "public face" for the condition, supplying quotes and compelling human stories for the media; many of the groups are heavily subsidized by drug makers, and some operate directly out of the offices of drug companies' public relations firms.

F. AstraZeneca Promotion of Seroquel® and Seroquel XR®

116. AstraZeneca has been among the most aggressive drug makers in the marketing of its SGAs, Seroquel® and Seroquel XR®. For example, AstraZeneca set a strategy of marketing Seroquel for unapproved, off-label uses as early as 2000. A December 2000

"Seroquel Strategy Summary" stated that "Key Success Factors: Broaden Seroquel use on and off label." Under required actions by the company, the plan called for sales managers to "utilise whole selling team. Educational programmes to share off label data." *See* Fisk, et al., "AstraZeneca Planned Off-Label Drug Sales in 2000," Bloomberg News, May 20, 2009, http://www.bloom berg.com/apps/news?pid=20601085&sid=akGbE1_8hvu0&refer=europe (last checked on February 19, 2010).

117. A 2001 public relations plan for Seroquel® states that AstraZeneca should focus on achieving "aggressive market penetration" among adolescents, the elderly and patients with bipolar disorder to protect the drug's market share against rival antipsychotics. *Id.*

118. AstraZeneca later prepared a paper to highlight the drug's performance in clinical tests on bipolar patients. One of the paper's objectives was to "continue to encourage off-label use of Seroquel for the treatment of bipolar disorders through publications presented at major congresses." *Id.*

119. AstraZeneca executives were aware that issues involving off-label marketing and information were sensitive. AstraZeneca officials noted in a May 2004 e-mail that slides prepared in connection with a study involving off-label use of Seroquel® were "financed outside of commercial for obvious legal reasons." *Id.*

IX. ASTRAZENECA'S FRAUDULENT MARKETING SCHEME

A. Seroquel XR® Health Risks

120. Seroquel XR®, like other SGAs, has numerous adverse and potentially fatal side effects. In addition to the specific risks to the elderly and those under the age of 18, discussed below, the package insert for Seroquel XR® warms of numerous severe health conditions associated with its use, including hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death; a potentially fatal symptom complex sometimes

referred to as Neuroleptic Malignant Syndrome; orthostatic hypertension associated with dizziness, teachycardia and, in some patients, syncope; leukopenia/neutropia, including fatal cases of agranulocytosis; Tardive Dyskinesia; cataracts; seizures; hypothyroidism; elevated cholesterol and triglyceride levels; hyperprolactinemia; transaminase elevations; potential for cognitive or motor impairment; priapism; inability to regulate body temperature; dysphabia; and acute withdrawal symptoms.

121. On April 11, 2005, the FDA required AstraZeneca and the makers of the other SGAs to place black-box warnings on the labels, indicating that older patients with dementia who are given these drugs are far more likely to die prematurely than those given a placebo. In 2003, the FDA had required the SGA makers to add a black box warning about an increased risk of diabetes. *See* Gardiner Harris, "Popular Drugs for Dementia Tied to Deaths," *New York Times,* April 12, 2005.

122. A package insert or prescribing information is a document provided along with a prescription medication to provide additional information about that drug. In the United States, the FDA determines the requirements for patient package inserts.

123. In the United States, a "black box warning" is a type of warning that appears on the package insert for prescription drugs that may cause serious adverse effects. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects.

124. The Seroquel XR® package insert contains a "black box warning" against its use in children and adolescents as well as use in the elderly for the treatment of dementia. The Seroquel XR® package insert warns, *inter alia*, of an "Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants for major depressive

disorder and other psychiatric disorders." The package insert further notes that the safety and effectiveness of Seroquel XR® in pediatric use has not been established. The black box warning elaborates, under the heading "SUICIDALITY AND ANTIDEPRESSANT DRUGS," that "Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults I short-terms studies of major depressive disorder (MDD) and other psychiatric disorders. In addition, there is a boxed warning against using Seroquel XR® in the treatment of the elderly with dementia: "Elderly patients with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) treated with this type of medicine are at an increased risk of death, compared to placebo (sugar pill). SEROQUEL is not approved for treating these patients."

125. In January 2009, a study published in the New England Journal of Medicine found that patients taking Seroquel® and other atypical antipsychotics were more likely to suffer sudden cardiac death than patients taking older antipsychotic drugs. Ray, et al., "Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death," NEJM 360:225-235 (January 15, 2009). The study was the first to systematically investigate the association between drugs like Seroquel and sudden cardiac death. For the study, scientists at the Vanderbilt University School of Medicine reviewed data on Tennessee Medicaid patients, comparing 44,218 people using older typical antipsychotics and 46,089 taking the newer atypical antipsychotics to 186,600 people who had never used the drugs. Overall, people taking typical antipsychotics were at 1.99-times greater risk of sudden cardiac death, while the risk for those on atypical antipsychotics was increased 2.26 times. The increased risk was greater for people on higher doses of the drugs. The researchers concluded that atypical antipsychotics are not a safer alternative to typical antipsychotics in preventing death from sudden cardiac causes.

B. AstraZeneca Gains FDA Approval of Seroquel® While Suppressing Negative "Study 15" and Engaging in Widespread Off-Label Promotion

126. Seroquel® (also called "Seroquel IR®," or "immediate release"), the predecessor to Seroquel XR®, is an antipsychotic drug (of the type commonly referred to as "atypical antipsychotic") originally approved by the FDA in 1997 for short-term use in treating schizophrenia only.

127. In January 2004, an indication FDA approved the addition of treatment for "short-term treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex."

128. In October 23, 2006, the FDA approved Seroquel® for the treatment of depressive episodes associated with bipolar disorder. *See* Medical News Today, October 23, 2006, http://www.medicalnewstoday.com/articles/54857.php (last checked on February 17, 2010).

129. The FDA finally approved Seroquel® for treating schizophrenia in 13 to 17 year olds as monotherapy and for the acute treatment of manic episodes associated with bipolar I disorder in children and adolescents between 10 and 17 years old. This limited approval was the first of any kind for the treatment of adolescents.

130. Since as early as 1999, AstraZeneca has illegally promoted Seroquel® for unapproved or "off-label" uses and for uses in children and adolescents as well as in the elderly population, where the efficacy and safety of the drug had not been established.

131. In 1997, the year Seroquel® was initially approved, AstraZeneca successfully suppressed a negative study called "Study 15," which showed that patients taking the drug experienced significant weight gain. The results of Study 15 were never published or shared with doctors, however, even as less rigorous studies that came up with positive results for

Seroquel® were published and used in marketing campaigns aimed at physicians and in television ads aimed at consumers.

132. Meanwhile, AstraZeneca employees expressed concerns regarding the results of Study 15. Internal documents show that company officials were worried because 45 percent of the Seroquel® patients had experienced what AstraZeneca physician Lisa Arvanitis termed "clinically significant" weight gain. In an e-mail dated August 13, 1997, Arvanitis reported that across all patient groups and treatment regimens, regardless of how numbers were crunched, patients taking Seroquel® gained weight: "I'm not sure there is yet any type of competitive opportunity no matter how weak."

133. In a separate note, company strategist Richard Lawrence praised AstraZeneca's efforts to put a "positive spin" on "this cursed study" and said of Arvanitis: "Lisa has done a great 'smoke and mirrors' job!"

134. Two years after those exchanges, in 1999, AstraZeneca presented different data at an American Psychiatric Association conference and at a European meeting. The conclusion: Seroquel helped psychotic patients lose weight.

135. Within the company, meanwhile, officials openly discussed their having misled physicians. The chief of a team charged with getting articles published, John Tumas, defended "cherry-picking" data. "That does not mean we should continue to advocate" selective use of data, he wrote on December 6, 1999, referring to a trial, called COSTAR, that also produced unfavorable results. But he added, "Thus far, we have buried Trials 15, 31, 56 and are now considering COSTAR."

136. Eight years after Study 15 was buried, an expensive taxpayer-funded study (the "CATIE Trial") pitted Seroquel® and other new drugs against another older antipsychotic drug.

The study found that most patients getting the new and supposedly safer drugs stopped taking them because of intolerable side effects. The study also found that the new drugs had few advantages. As with older drugs, the new medications had very high discontinuation rates.

137. The results caused consternation among doctors, who had been kept in the dark about trials such as Study 15. *See* Shankar Vedantam, "A Silenced Drug Study Creates An Uproar," *Washington Post*, March 18, 2009.

138. Since Seroquel®'s launch in July 1997, AstraZeneca has engaged in a nationwide, uniform marketing campaign involving fraudulent misstatements and deceptive conduct in the promotion of Seroquel®. Further, AstraZeneca misrepresented the comparative safety, efficacy and superiority of Seroquel® over other traditional/typical or atypical antipsychotics to the health care community, consumers, third-party payors, and others, with the common goal to increase sales of Seroquel® and the Defendants' profits.

139. On October 29, 2009, AstraZeneca announced it had reached a $520 million agreement to settle two federal investigations and two whistle-blower lawsuits over the sale and marketing of its blockbuster psychiatric drug Seroquel®. One of the investigations related to "selected physicians who participated in clinical trials involving Seroquel," AstraZeneca disclosed in a government filing. The other case related to off-label promotion of the drug. *See* Duff Wilson, "AstraZeneca Pays Millions to Settle Seroquel Cases," *New York Times,* October 29, 2009.

C. FDA Approvals of Seroquel XR®

1. May 17, 2007: The FDA Approves Seroquel XR® for Acute Treatment of Schizophrenia

140. On May 17, 2007, the FDA approved Seroquel XR® for the acute treatment of schizophrenia in adult patients. The basis for FDA's approval of Seroquel XR® in May 2007

was Study 132, which is also the basis for FDA's Advisory Board hearing about expanding Seroquel XR® approval for depression and anxiety.

141. The favorable findings of Study 132 were conducted off-shore in Bulgaria, Greece, India, Philippines, Romania, Russia, and South Africa. Study 132 findings were presented by Dr. Charles Schulz in two favorable poster reports at the annual American Psychiatric Association meeting in 2007: (a) Schulz, *et al.*, "Efficacy of Once-Daily Extended Release Quetiapine Fumarate in Patients with Acute Schizophrenia." Annual Meeting of the American Psychiatric Association, 2007, San Diego, California, research poster board NR04; and (b) Schulz, *et al.*, "Efficacy of Once-Daily Extended Release Quetiapine Fumarate across Symptom Domains in Schizophrenia." Annual Meeting of the American Psychiatric Association, 2007, San Diego, California, research poster board NR495. The published report, Kahn, *et al.*, "Efficacy and tolerability of once-daily extended release quetiapine fumarate in acute schizophrenia: a randomized, double-blind, placebo-controlled study," *Journal of Clinical Psychiatry*, 68(6):832-42 (June 2007), included the same results and was used to support the FDA approval for Seroquel XR®.

142. Dr. Schulz's promotional statements were quoted by PRN Newswire on May 18, 2007: "Clinical trial data demonstrate that Seroquel XR is a safe and effective treatment option for schizophrenia. . . . For many patients with schizophrenia, Seroquel XR may offer a viable once-daily treatment while decreasing the number of tablets needed to be taken each day." http://www2.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/ www/story/05-18-2007/0004591350&EDATE= (last checked on February 18, 2010)

143. AstraZeneca launched Seroquel XR® in July 2007 for sale in the United States.

144. On November 16, 2007, the FDA approved Seroquel XR® for maintenance treatment of schizophrenia in adult patients.

2. October 10, 2008: FDA Approves Seroquel XR® for Bipolar Depression, Bipolar I, and Bipolar Maintenance

145. On October 10, 2008, the FDA approved the use of Seroquel XR® for the acute treatment of the depressive episodes associated with bipolar disorder, the manic and mixed episodes associated with bipolar I disorder, and the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or Depakote® (divalproex sodium).

146. The approval of Seroquel XR® for treating bipolar depression was based primarily on two peer-reviewed, double-blind placebo-controlled studies in which patients taking Seroquel® were evaluated for 21 days. These studies were known as the "Bolder I" and "Bolder II" Studies.

3. AstraZeneca Applies for FDA Approval to Promote Seroquel XR® for the Treatment of MDD and GAD

147. Because of the huge market potential, AstraZeneca has long coveted the market for anti-depressant medications and has attempted to obtain FDA approval of Seroquel XR® as monotherapy for MDD and for GAD. In January 2008, AstraZeneca announced the submission of a sNDA to the FDA for approval to use Seroquel XR® as monotherapy for the treatment of MDD, adjunct therapy, and maintenance therapy. On May 8, 2008, AstraZeneca announced the submission of an sNDA for approval of Seroquel XR® for the treatment of GAD, including maintenance of anti-anxiety effect. It was the first time approval has been sought for an atypical antipsychotic medicine to treat GAD.

148. On May 5, 2008, AstraZeneca announced new study data on Seroquel XR® for the treatment of MDD and GAD in adult patients. The results from the studies were presented at the 161st Annual Meeting of the American Psychiatric Association ("APA") in

Washington, DC. In addition, the press release quotes the lead study authors touting the results. According to Dr. Richard Weisler, Adjunct Professor of Psychiatry at University of North Carolina School of Medicine, Adjunct Assistant Professor at Duke University Medical Center and lead investigator on the MDD short-term monotherapy study: "New MDD therapy options are clearly needed. Studies have shown that at least one-third of MDD patients who are treated with antidepressants fail to achieve a satisfactory response. . . . Additionally, for those patients who do achieve a response from treatment with antidepressants, it may often take a few weeks of treatment before a benefit is seen. In the short-term monotherapy study presented today at APA, patients taking Seroquel XR had a significant improvement in depressive symptom scores as early as the fourth day of treatment compared with patients taking placebo."

149. In addition, the press release quoted Professor Martin Katzman, Assistant Professor at the University of Toronto, and the Northern Ontario School of Medicine, and lead investigator on the GAD long-term study: "Given that many people suffering from generalized anxiety disorder do not achieve an adequate response from current treatments, new treatment options are needed; specifically for those who are not suited for existing therapies or who are simply not benefiting enough from the previously available approaches."

150. On December 24, 2008, AstraZeneca announced it had received a Complete Response Letter ("CRL") from the FDA, asking for additional information for the sNDA for Seroquel XR® for the treatment of MDD in adult patients.

151. On February 27, 2009, AstraZeneca announced it had received a CRL from the FDA, asking for additional information for the sNDA for Seroquel XR® for the treatment of GAD in adult patients.

152. On April 8, 2009, the FDA Psychopharmacologic Drugs Advisory Committee conducted a review of the safety and efficacy of supplemental new drug applications for Seroquel XR® for the treatment of MDD and for GAD. Although the Committee concluded that Seroquel XR® was effective to treat MDD as both monotherapy and adjunctive therapy, and effective in the treatment of GAD as monotherapy, the Committee expressed safety concerns over the use of Seroquel XR®.

153. The Committee found, by two separate votes of 9 to 0, that Seroquel XR® was not shown to be acceptably safe as monotherapy for broad treatment of MDD or for the treatment of GAD. By a vote of 6 to 2, the Committee also found that Seroquel XR® was not shown to be acceptably safe in certain instances as a treatment for GAD as monotherapy. Moreover, the Committee was undecided as to whether Seroquel XR® was shown to be acceptably safe in certain instances as a monotherapy treatment for MDD.

154. The FDA, however, declined to approve Seroquel XR® as monotherapy for the treatment of MDD and GAD.

4. December 4, 2009: FDA Approves Seroquel XR® For Adjunctive Treatment of MDD

155. On December 4, 2009, the FDA approved Seroquel XR® only as adjunctive treatment to antidepressants in adults suffering from MDD. The FDA did not approve Seroquel XR® for any uses for the treatment of GAD.

156. In addition to the FDA approval for the adjunctive indication in MDD, AstraZeneca received a CRL from the FDA, asking for additional information for the sNDAs for Seroquel XR® as acute monotherapy and maintenance monotherapy for the treatment of MDD in adult patients.

157. Also as part of the approval, the FDA required that AstraZeneca implement a Risk Evaluation and Mitigation Strategy ("REMS"). The REMS for Seroquel XR® required a Medication Guide and periodic assessments that will include a survey of patients' understanding of the potential risks of Seroquel XR®. The REMS applied to all approved indications and to both Seroquel® and Seroquel XR®.

D. July 2007: AstraZeneca Launches Seroquel XR® and Begins Fraudulent Marketing Scheme

158. Even though the FDA did not approve Seroquel XR® for bipolar depression until approximately one year after Seroquel IR® had received this same approval, AstraZeneca immediately started marketing Seroquel XR® for bipolar depression at its launch in July 2007. Prior to July 2007 (and later when it received the bipolar depression approval at meetings of the sales force), AstraZeneca conducted detailed sales training wherein it laid out the Fraudulent Marketing Scheme for the entire PSS sales force. From the outset, AstraZeneca's clear message in training its sales force for the launch of Seroquel XR® in July 2007 was to engage in widespread off-label promotion.

159. AstraZeneca Sales trainers directed the sales force to promote Seroquel XR® for the treatment of depression, an indication for which Seroquel XR® has never been approved (except recently, but only as adjunctive with SSRIs/SNRIs). The trainers instructed the sales force to conduct a "[d]epressive conversation every time."

160. In this regard, the trainers emphasized that "SSRI and SNRI share is in the Decile system" – *i.e.,* that AstraZeneca provided sales information to representatives to help identify "high decile" doctors who were high volume prescribers of SSRI/SNRI drugs, and whose business was worth more to AstraZeneca. AstraZeneca had purchased IMS prescribing data, and gave sales representatives lists of "high decile" physicians who primarily wrote

SSRIs/SNRIs (instead of Atypicals like Seroquel XR®) for the treatment of depression. The trainers emphasized the Seroquel XR® "must get in the SSRI and SNRI [market]" even though this market was off-label.

161. The training session concluded with the instructor telling the sales force to "[a]sk [the] customer to prescribe Seroquel XR® for bipolar depression to make a clinical assessment and discover for themselves that Seroquel XR® is proven effective as an antidepressant by itself in treating symptoms of bipolar depression." The trainers made this statement even though Seroquel XR® would not receive approval for the treatment of bipolar depression until October 2008.

162. Thus, AstraZeneca trained the sales force to begin actively promoting Seroquel XR® off-label for treatment of numerous conditions from its launch in July 2007, including for bipolar disorder, for the treatment of children, GAD, MDD, and for the treatment of dementia in the elderly.

163. AstraZeneca implemented its policy of promoting Seroquel XR® for multiple off-label uses on a nationwide basis. Off-label promotion of Seroquel XR® thus became ingrained in the sales force and AstraZeneca management.

E. Unsubstantiated Seroquel XR® Superiority Claims

164. From the launch forward, one of AstraZeneca's key goals was to increase sales of Seroquel XR® by converting as many Seroquel® prescriptions as possible to Seroquel XR® prescriptions, including those prescriptions that had been written for off-label uses as a result of AstraZeneca's prior illegal promotion of Seroquel®. To accomplish the IR to XR conversion goal, AstraZeneca promoted Seroquel XR® as being more effective than Seroquel®, when there were no adequate, head-to-head efficacy studies comparing the two drugs.

165. Despite the absence of any studies supporting a comparison of Seroquel® and Seroquel XR®, AstraZeneca developed promotional materials for its sales representatives claiming that Seroquel XR® was superior to Seroquel®. These materials were used as part of its Fraudulent Marketing Scheme to convert Seroquel® use to Seroquel XR® use, even the Seroquel® prescriptions for off-label use.

166. Sales representatives were to urge physicians to switch from Seroquel® to Seroquel XR®, claiming that Seroquel XR® was superior. For example, AstraZeneca's sales force were instructed to tell health care providers that Seroquel XR® would result in a better "patient experience" than Seroquel®, representing that Seroquel XR® causes less carbohydrate cravings, less sedation, lower triglycerides, less weight gain, and less orthostatic hypertension, and because Seroquel XR® has a "softer" peak.

167. In an attempt to support this representation, AstraZeneca sales personnel were directed to refer to a chart with the pharmacokinetic value purporting to show the peak at one hour for Seroquel® and at six hours for Seroquel XR®. AstraZeneca instructed its sales force to make this representation despite the absence of any adequate, well-controlled head-to-head studies supporting this claim.

168. At the training sessions regarding the sale and promotion of Seroquel XR® conducted prior to the launch in July 2007, AstraZeneca's sales trainers repeatedly encouraged its sales force to convince physicians and other health care providers to prescribe Seroquel XR® for off-label indications, including comparing Seroquel XR® to Abilify®.

169. As part of its effort to demonstrate Seroquel XR®'s supposed superiority over Abilify®, AstraZeneca trained the sales force to use scores from the Montgomery-Åsberg Depression Rating Scale ("MADRS"). The MADRS Scale is a ten-item diagnostic questionnaire

that psychiatrists use to measure the severity of depressive episodes in patients with mood disorders. AstraZeneca's sales materials regularly used MADRS scores from the non head-to-head trials comparing depression scores with Abilify®'s scores to create the misleading impression that Seroquel XR® was superior. The explicit goal was to create the false (and deliberately confusing) impression that Seroquel XR® could be used to treat the same conditions for which Abilify® had been approved.

170. AstraZeneca hoped to induce physicians and other prescribers to consider substituting Seroquel XR® for Abilify® for use in treating depression, even though Seroquel XR® would not receive the adjunctive use approval for MDD until December 2009.

171. After Seroquel XR® gained the bipolar depression indication in October 2008, for so-called "Non-Adopters" (*i.e.,* physicians resistant to switching patients from Abilify® to Seroquel XR®), the trainers instructed the sales force to emphasize that Abilify® is not approved for treatment of bipolar depression. The message was to be that, since Seroquel XR® was more effective than Abilify® at treating difficult-to-treat depression associated with bipolar disorder, it could be used to treat all forms of depression as well.

F. Off-Label Promotion of Seroquel XR® for the Treatment of Children and Adolescents

172. A key part of the Fraudulent Marketing Scheme has been the off-label promotion of Seroquel XR® for the treatment of children and adolescents even though (a) the drug carries a black box warning for such use and (b) Seroquel XR has never received FDA approval for the treatment of children and adolescents.

173. From the launch in July 2007, sales representatives had numerous child psychiatrists on their call lists, even though Seroquel XR® has never had any approvals for use in treating children and adolescents. AstraZeneca's official position was that sales

representatives were "allowed" to take child psychiatrists off call lists if they felt it was not appropriate because the child psychiatrists only treated children.

174. Since child psychiatrists were still in representatives' bonus potential, however, the majority of sales representatives have not removed child psychiatrists from their call lists and continue promoting Seroquel XR® off-label to these physicians.

175. As part of their sales details in the off-label promotion of Seroquel XR® in the treatment of children and adolescents, AstraZeneca's sales representatives regularly provided health care professionals with reprints of research studies funded by AstraZeneca, supporting the off-label use to treat children and adolescents. Among the key reprints were studies that had been prepared by teams headed by principal investigator, Dr. Melissa DelBello, M.D., a child and adult psychiatrist at the University of Cincinnati, using monies received from AstraZeneca. Dr. DelBello not only received significant research monies from AstraZeneca, she became a featured speaker on the use of Seroquel XR® for the treatment of children and adolescents throughout the United States. Rubenstein, "Sen. Grassley Knocks Psychiatrist's Funding from AstraZeneca," *Wall Street Journal Health Blog,* April 7, 2008, http://blogs.wsj.com/health/2008/04/07/sen-grassley-knocks-psychiatrists-funding-from-astrazeneca/?mod=WSJBlog (reporting Senator Grassley statement concerning Dr. DelBello's receipt of monies from AstraZeneca).

176. In one key study, DelBello, et al., "A double-blind, randomized, placebo-controlled study of quetiapine as adjunctive treatment for adolescent mania," Journal of American Academy of Child and Adolescent Psychiatry, 41(10):1216-23 (2002), Dr. DelBello and her research team tracked for six weeks the moods of 30 adolescents who had received diagnoses of bipolar disorder. Half of the teenagers took Depakote®, an anti-seizure drug used to

treat epilepsy and bipolar disorder in adults. The other half took Seroquel® and Depakote® together. *See* Gardiner Harris, et al., "Psychiatrists, Children and Drug Industry's Role," *New York Times,* May 10, 2007. The two study groups did about equally well until the last few days of the study, when those in the Seroquel® group scored lower on a standard measure of mania. By then, almost half of the teenagers getting Seroquel® had dropped out of the study because they missed appointments or the drugs did not work. Just eight of them completed the trial. Even though Dr. DelBello would later acknowledge that the study was therefore not conclusive, in the 2002 published paper, however, she and her co-authors reported that Seroquel® in combination with Depakote® "is more effective for the treatment of adolescent bipolar mania" than Depakote® alone. *Id.*

177. In January 2008, Plaintiff-Relator and her partner were directed by Doug Yarbrough, their District Manager, to use another DelBello study funded by AstraZeneca in marketing Seroquel XR® for off-label use in treating adolescents. *See* DelBello, "A 12-Week Single-Blind Trial of Quetiapine for the Treatment of Mood Symptoms in Adolescents at High Risk for Developing Bipolar I Disorder," Journal of Clinical Psychology, 68:5 (May 2007). The study was completely off-label as AstraZeneca did not have an indication for using Seroquel XR® in the treatment of children and adolescents. The DelBello study was used in details throughout the Iowa and Minnesota sales territories where representatives successfully used it to convince child psychiatrists use Seroquel XR® even though it was not indicated for children or adolescents.

178. One KOL that District Manager Yarbrough insisted they use as a speaker to grow off-label use in the treatment of children and adolescents was Sasha F. Khosravi, a Doctor of Osteopathy in West Des Moines, Iowa. Dr. Khosravi treats pediatric and adolescent patients, as

well as adult patients. AstraZeneca retained Dr. Khosravi to speak about the off-label use of Seroquel XR® in children.

179. For example, on June 25, 2008, Dr. Khosravi served as a "visiting professor" by meeting with a group of health care professionals in Fort Dodge, Iowa, where he discussed the off-label use of Seroquel XR® in the treatment of children, using case examples of two children he had treated with the drug. Later, on July 30, 2008, Dr. Khosravi conducted another visiting professorship with health care professionals in Leon, Iowa, about using Seroquel XR® to treat children based on his clinical experience and use of Seroquel XR® to treat children.

G. AstraZeneca Actively Marketed Seroquel XR® for Off-Label Use in Elderly Patients

180. The package insert for Seroquel XR® contains a black box warning against the use of this drug in elderly patients with dementia. The insert expressly warns, inter alia, that use of Seroquel XR® could cause "INCREASED MORTAILTY IN ELDERLY PATIENTS WITH DEMENTIA." Physicians considering use of Seroquel XR® for geriatric patients are admonished to "[c]onsider a lower starting dose (50 mg/day), slower titration, and careful monitoring during initial dosing period in the elderly."

181. The package insert does not mince words regarding the risks of Seroquel XR® in elderly patients. "Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death." The boxed warning noted that analyses of 17 placebo-controlled trials with a modal duration of 10 weeks largely in patients taking atypical antipsychotic drugs revealed a risk of death in the drug-treated patients of between 1.6 and 1.7 times the risk of death in placebo-controlled patients. Moreover, over the course of a "typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5 percent,

compared to a rate of about 2.6 percent in the placebo group." Although the causes of death varied, most appeared to be either cardiovascular or infectious.

182. The package insert makes clear that "Seroquel XR is not approved for the treatment of patients with dementia-related psychosis."

183. Despite the health risks and lack of FDA approval, AstraZeneca instructed and encouraged its sales force to market and promote Seroquel XR® for use in elderly populations.

184. AstraZeneca also employed its speakers to promote off-label use of Seroquel XR® in elderly patients. On August 28, 2007, after the FDA had approved Seroquel XR® for the acute treatment of schizophrenia in adult patients, Dr. M. Michael Ishii, the Site Psychiatrist at the Dean Medical Center in Madison, Wisconsin, hosted a regional Seroquel XR® teleconference. Even though the FDA has never approved the use of Seroquel XR® in elderly patients, Dr. Ishii included a slide entitled "Initiating Seroquel XR at Doses Lower Than 200 mg." This slide recommended the use of Seroquel IR® in, among others, the elderly suffering from schizophrenia. Dr. Ishii further recommended, for the elderly and patients with hepatic impairment, increasing the dosage of Seroquel IR® in increments of 25 to 50 mg per day and, when an effective dose had been reached, switching the patient to Seroquel XR® at an equivalent daily total dose.

185. Dr. Ishii's recommendation of use of Seroquel XR® in elderly patients was off-label, and violated FDA regulations and the requirements of the Federal Health Programs.

186. On May 12, 2008, Mr. Yarbrough forwarded to the Plaintiff-Relator an e-mail that informed its recipients Dr. Gordon Robinson "was back on AstraZeneca's speaker's bureau." In addition to engaging the crowd, the e-mail reported that Dr. Robinson "is a supporter for Seroquel and clearly sets it apart from the competition" and noted that Dr.

Robinson had "a wealth of experience in geriatric and adult psychiatry treating the mild mood disorders of the chronically ill schizophrenics."

187. Although Seroquel XR®, as of this date, had been approved for treatment of acute and maintenance treatment for adult schizophrenic patients, it had not at that time, and has never been, approved for treatment of geriatric patients. Therefore, AstraZeneca management was offering Dr. Robinson to serve as a speaker for an off-label indication.

188. Moreover, the sales representatives' call cycles for potential sales of Seroquel XR® include names of the physicians and health care providers who already had been Seroquel® writers, including numerous physicians and others who would have had no occasion to treat patients for the on-label conditions for which Seroquel XR® was approved (such as family physicians and neurologists). Numerous of these physicians are gerontologists treating elderly patients suffering from dementia. The majority of these practitioners worked in nursing homes and/or treated patients who were nursing home residents, where Seroquel XR® was used off-label to treat agitation, irritability, sleep disorders, and dementia in elderly patients. They were expected to promote Seroquel XR® to these physicians even though the majority of the use was for off-label treatment of dementia and related conditions in the elderly.

H. November 2008: AstraZeneca Push to Promote of Seroquel XR® as Monotherapy for the Treatment of MDD and GAD

189. In November 2008, in anticipation of the sought-after FDA approvals of the MDD and GAD indications, AstraZeneca began a company-wide promotional campaign, training all its sales representatives for these new indications and adding to its sales representatives' call lists numerous physicians and other health care providers who, based on the composition of their patient pools, would not prescribe Seroquel XR® for any on-label conditions.

190. Sales representatives were specifically trained to mention bipolar depression (for which Seroquel XR® had been approved in October 2008) at the beginning of their details and then instructed this opened the door so they could begin to discuss the use of Seroquel XR® for the treatment of the broader MDD and GAD indications.

191. In addition, sales representatives were instructed to use the depression and anxiety scores from the Bolder I and Bolder II studies to demonstrate that Seroquel XR® was effective in treating depression associated with MDD and GAD, using the Hamilton Depression Scale ("HAM-D"), a test measuring the severity of depressive symptoms in individuals, often those who have already been diagnosed as having a depressive disorder. The HAM-D test is often used as an outcome measure of depression in evaluations of antidepressant psychotropic medications and is a standard measure of depression used in research of the effectiveness of depression therapies and treatments.

192. Sales representatives were also instructed to use Bolder I and Bolder II anxiety scores using the Hamilton Anxiety Scale ("HAM-A"), a rating scale developed to quantify the severity of anxiety symptomatology, often used in psychotropic drug evaluation. They were to use the HAM-A scores as part of the off-label promotion of Seroquel XR® to treat GAD.

193. Among the sales pieces the representatives were to use was a brochure dated February 2009 (#270266), entitled "Discover something new about Seroquel XR: Now Approved for bipolar depression." Sales representatives were to use the bipolar depression indication and the diagram on page 2 of the sales brochure showing how the diagnostic criteria for bipolar depression and MDD "are identical" with one another. In this way, AstraZeneca intended to convince physicians that they should prescribe Seroquel XR® for the off-label treatment of MDD, and not just for bipolar depression.

194. The brochure contains sample patient stories that the sales force was to use as part of the detail. One example is of a 32-year-old patient with a "[t]entative diagnosis" of MDD, "still experiencing depressive symptoms" currently being treated with an SSRI. According to the sales piece, the treating physician for this patient suspected that the patient must have a "history of hypomanic or manic episodes, which prompts him to screen the patient for bipolar disorder." Sales representatives were instructed to explain to psychiatrists and family practice physicians that many patients were "misdiagnosed" as suffering from MDD, but who were actually suffering from bipolar depression. In this way, the sales representatives were to introduce the off-label prescribing of Seroquel XR® for the treatment of MDD, and not just for bipolar depression.

195. In addition, in December 2008 AstraZeneca disseminated new call lists to its nationwide sales force that included primary care doctors in addition to mental health practitioners. Primary care physicians would have no reason to treat any on-label conditions for which Seroquel XR® had been approved, and the only reason for these new physicians to be added was to "jump the gun" on the MDD/GAD promotion.

196. The AstraZeneca computer system that tracks the representatives' calling activities contains pre-loaded information on each doctor, including name, location, phone number, license number, DEA number, specialty, prescribing patterns, and health plans in which the doctors participate (and targeting government-funded programs). The database tracks a wealth of information on doctors' prescribing patterns through data purchased from third-party vendors who assemble this information for drug makers like AstraZeneca. This database is updated regularly, and provides the sales representatives with the names of the doctors they are to call on – their "call cycle." The representatives are then required to enter the results of their

calls as part of the tracking system for each doctor, any free samples given to the doctor, and sales information provided to the doctor.

197. When Plaintiff-Relator questioned Mr. Yarbrough, in early 2009, as to why these family practice doctors were added to her call list, he informed her that these providers were added because they wrote prescriptions for SSRI and SNRI anti-depressant medications, and thus were targets for promoting Seroquel XR® for the treatment of MDD and GAD.

I. January 2009: AstraZeneca Provided Free Samples of Seroquel XR® to Physicians Who Would Not Prescribe It For Any On-Label Indication and at Doses Intended for Off-Label Use

198. As part of its off-label promotional MDD/GAD campaign, beginning in 2009, AstraZeneca provided its sales force with samples of Seroquel XR® designed to promote off-label use of the drug for MDD and GAD. Plaintiff-Relator received three times the normal amount of 50 mg and 150 mg samples, which she was instructed to furnish to family practice physicians. These physicians would have no use for the free samples except for off-label use.

199. AstraZeneca's intent to use these samples for off-label marketing is apparent because the titration schedule for use of Seroquel XR® for treatment of MDD and GAD required these lower doses of 50 mg and 150 mg, whereas the drugs' on-label uses required higher doses. At the time, psychiatrists who would have used Seroquel XR® on label for schizophrenia and bipolar disorder expressed confusion as to why the company was no longer offering higher doses as samples, which would have been used to treat patients on-label.

200. AstraZeneca intended, through distribution of the lower-dose pills, to sell the "antidepressant" effects of Seroquel XR®, despite the absence of FDA approval for MDD and GAD. Indeed, AstraZeneca continues to include neurologists on its sales force's call lists and requires its sales personnel to provide them with low-dose samples of Seroquel XR®, even though neurologists do not treat psychiatric illnesses like MDD and GAD. The primary use

neurologists would have for Seroquel XR® is for the treatment of dementia in the elderly and to counteract the psychosis associated with medications commonly use to treat Parkinson's Disease, off-label uses and for which the drug has a "black box" warning.

J. AstraZeneca Sales Representatives Were Instructed to Use Unapproved, Off-Label Sales Materials

201. AstraZeneca's "Global Policy" on providing information about its products required that all sales materials must be approved before being used. AstraZeneca's Sales management regularly ignored this requirement, instead requiring sales representatives to use unapproved and "educational only" materials in their sales details. So, rather than these being unapproved materials, these were intended to be materials that would in fact be used in sales details, but that sales representatives should not get caught doing so.

202. One example of such an unapproved sales piece was a poster that had been presented at the APA convention, Bandelow, et al., "Results from a phase III study of once-daily extended release quetiapine fumarate (quetiapine XR) monotherapy in patients with generalised anxiety disorder." Another sales representative, Bill Schneider, in Plaintiff-Relator's district had obtained copies of the Bandelow poster at the 2008 APA convention, and provided copies to all of the other sales representatives in the district. They were directed by Regional Manager Steven Levandowski to use the Bandelow poster in their details to demonstrate that Seroquel XR® could be used off-label to treat GAD. The Bandelow poster had never been approved, and its use was completely off-label.

K. AstraZeneca Improperly Disguises Its Promotion of Seroquel XR® Through Paid Speakers Who Openly Discuss Off-Label Uses.

203. Promotional speaker programs funded and conducted by pharmaceutical companies are highly regulated by the FDA. Essentially, promotional educational presentations must be "on-label," presenting only information about FDA-approved uses contained in the

product's package insert. Promotional talks must also contain "fair balance"—*i.e.*, a discussion of the risks and benefits of the drug, including adverse effects, precautions, and warnings. Above all, promotional programs must be truthful and not misleading. All presentation slides, whether provided by the pharmaceutical company or developed by the speaker, should be designed to meet these requirements.

204. A narrow exception to the "on-label" rule exists for promotional programs. Speakers may answer questions about unapproved drug uses so long as the questions posed by the audience are unsolicited. Speakers should clearly advise the audience that the answer is outside the scope of approved labeling and that they are speaking from independent medical judgment. Questions should be answered briefly, to avoid unnecessary off-label discussion, and then the discussion should be guided back to the originally planned, on-label presentation.

205. AstraZeneca knows that the prohibition on initiating discussion of off-label uses of Seroquel XR® extends to AstraZeneca-sponsored promotional events at which healthcare providers speak to other healthcare providers.

206. A key component of AstraZeneca's Fraudulent Marketing Scheme is the use of paid local "experts" (also "thought leaders," "Key Opinion Leaders" or "KOLs") to influence other doctors to prescribe Seroquel XR® for their patients, including for off-label uses. This tactic is embedded in AstraZeneca's "Customer Engagement Career Ladder," which evaluates each Pharmaceutical Sales Specialists on, among other things:

- Influences Others . . . Degree to which the PSS persuades and convinces a targeted audience;
- Uses direct influence;
- Uses "experts" (e.g., local thought leaders) to effectively influence physicians' prescribing habits;

- Spends time with key influencers in advance of a key decision, so as to influence the outcome of that decision (e.g., assists physicians with preparing for P&T committee meetings); and

- Develops physicians and healthcare professionals to become speakers-cultivating advocates for AstraZeneca.

207. AstraZeneca, through its Pharmaceutical Sales Specialists, routinely pays certain preferred "Key Opinion Leader" doctors to make presentations to groups of other doctors in order to encourage them to prescribe Seroquel XR® for more of their patients, including for off-label uses. The presentations are offered under the guise of providing "fair and balanced" information, but AstraZeneca selects its speakers based largely on the volume of Seroquel XR® prescriptions they write (*i.e.,* the more they write, the more likely they are to be hired) and their willingness to talk about off-label uses of the product.

208. Paying lucrative speaker fees is a key part of AstraZeneca's marketing of Seroquel XR® to psychiatrists. AstraZeneca paid these speakers up to $1,500 per talk, without any annual limit (until recently). The current annual limit is now $75,000 per speaker, per year.

209. AstraZeneca recruited a nationwide network of paid speakers to promote Seroquel XR®, maintained lists of these speakers, tracked each speaker's effectiveness, including each speaker's success in growing off-label use of Seroquel XR®, and provided these lists to its sales force to track the success.

210. At all times material hereto, although it was AstraZeneca's official policy that investigational or unapproved uses could not be presented by an AstraZeneca-sponsored speaker, its sales force regularly used contracted speakers to make presentations that included unsolicited materials concerning investigational and/or unapproved uses of Seroquel XR®.

211. With knowledge and at the direction of senior management in Sales, AstraZeneca speakers touted unapproved uses for Seroquel XR®, both verbally and in written materials, such as Power Point slides. In addition, the speakers' written materials that included off-label uses were disseminated to AstraZeneca's sales force with AstraZeneca's knowledge and approval.

212. AstraZeneca sales personnel used speaker program monies to "buy" doctors' loyalty to the Seroquel XR® brand.

213. AstraZeneca's nationwide network of speakers included influential physicians who AstraZeneca knew would give unsolicited information about Seroquel XR® for unapproved uses to audiences across the country as part of AstraZeneca's Fraudulent Marketing Scheme.

214. Speakers who have promoted off-label uses of Seroquel XR® include:

1. Dr. M. Michael Ishii

215. M. Michael Ishii, M.D., the Site Psychiatrist at the Dean Medical Center's Sun Prairie Clinic in Madison, Wisconsin. Dr. Ishii is considered one of the most influential psychiatrists in the Madison, Wisconsin area and is well-known for speaking off label. Sun Prairie Clinic's patients include patients covered by Medicaid and Medicare. Dr. Ishii treats large numbers of children. AstraZeneca paid Dr. Ishii approximately $1,500 for each presentation.

216. For example, AstraZeneca invited and paid Dr. Ishii to speak at Mercy Psychiatric Services, in Des Moines, Iowa, on October 22, 2007, and at Broadlawns County Hospital in Des Moines where he spoke to health care professionals on May 19, 2009. In addition, Dr. Ishii conducted a visiting professorship with Dr. Bertroche and Dr. Kunze, both child psychiatrists in West Des Moines, Iowa, on March 31, 2008.

217. On October 14, 2009, Dr. Ishii gave a speaker program with several psychiatrists at Mercy Psychiatric Services, Des Moines, Iowa, and also that day gave a talk at Freedom

House, Iowa Falls, Iowa (a mental health and substance abuse hospital, treating a large volume of Medicaid patients), to the staff on the use of Seroquel XR®. Dr. Ishii included information, without prompting or in response to any questions from the audience, concerning off-label use of Seroquel XR® for elderly patients for so-called "sundowning" and to treat carbohydrate cravings in children. Seroquel XR® has never been approved for use in elderly patients and has never been approved for use in children or adolescents.

218. Dr. Ishii's audience at these AstraZeneca-sponsored speeches typically consisted of psychiatrists and other health care professionals who primarily worked at large state-funded clinics and county mental health facilities in Iowa, Wisconsin, and Illinois. The vast majority of the patients seen by the health care professionals in his audience were Medicaid beneficiaries.

219. AstraZeneca sales managers approved of Dr. Ishii's presentations. Following AstraZeneca's policy, Dr. Ishii based portions of his speaker programs on the MADRS scores (discussed *supra*), focusing on an off-label comparison of Seroquel XR® depression scores with other drugs, including Abilify®, when there is no adequate, head-to-head evidence supporting such comparisons.

220. AstraZeneca retained Dr. Ishii because he would give unsolicited off-label information about the use of Seroquel XR® in the treatment of GAD and MDD, as well as in treating children and adolescents and in the elderly. Thus, the use of Dr. Ishii furthered AstraZeneca's Fraudulent Marketing Scheme to attempt to convince health care providers that Seroquel XR® could be used off-label.

2. Dr. Michael Farnsworth

221. Michael Farnsworth, M.D., a forensic psychiatrist from Mankato, Minnesota, spoke frequently on behalf of AstraZeneca in Minnesota and Iowa, regarding his off-label use of Seroquel XR® in the treatment of the elderly. AstraZeneca paid Dr. Farnsworth approximately

$1500 per presentation. In Minnesota alone, according to data available from the State of Minnesota, during 2007 and 2008 Dr. Farnsworth received some $176,129 for 122 speaker programs where he regularly gave unsolicited information about using Seroquel XR® off-label for the treatment of the elderly.

3. Dr. Charles Scott Jennisch

222. Another frequent speaker is Charles Scott Jennisch, M.D., a psychiatrist from Des Moines, Iowa, who treats both adults and children. AstraZeneca regularly used Dr. Jennisch to promote Seroquel XR® in connection with then off-label treatment of bipolar depression before the FDA had approved Seroquel XR® for this indication. For example, Dr. Jennisch made a presentation to health care professionals in Fort Dodge, Iowa, on February 8, 2008, including unsolicited information concerning the then off-label use to treat bipolar depression. The presentation was promotional and off-label. On May 5, 2008, Dr. Jennisch gave the same talk to another group of health care professionals (including providers who treat primarily children) in Fort Dodge, Iowa. During the speech, Dr. Jennisch included unsolicited information on the use of Seroquel XR® to treat children and adolescents. As such, the talk was promotional and off-label.

223. On September 25, 2008, Dr. Jennisch gave a speaker program to health care professionals who primarily treat children, regarding the off-label use of Seroquel XR®. The entire discussion was promotional and off-label.

4. Dr. Dean Knudson

224. Dean Knudson, M.D., a geriatric psychiatrist in Eden Prairie, Minnesota and New Brighton, Minnesota, spoke frequently on behalf of AstraZeneca in Minnesota and Iowa, regarding his off-label use of Seroquel XR® in the treatment of the elderly. AstraZeneca paid Dr. Knudson approximately $1500 per presentation. In Minnesota alone, according to data

available from the State of Minnesota, during 2007 and 2008 Dr. Knudson received some $99,664 for 70 speaker programs where he regularly gave unsolicited information about using Seroquel XR® off-label for the treatment of the elderly.

5. Dr. John Luehr

225. Another speaker is John Luehr, M.D., a child and adolescent psychiatrist from St. Paul, Minnesota, who spoke frequently on behalf of AstraZeneca in Minnesota and Iowa, regarding his off-label use of Seroquel XR® in the treatment of children. AstraZeneca paid Dr. Luehr approximately $1500 per presentation. In Minnesota alone, according to data available from the State of Minnesota (one of only two states to make such data publicly available), during 2007 Dr. Luehr received some $43,270 for 28 different speaker programs where he touted Seroquel® and Seroquel XR® off-label for the treatment of children and adolescents. Because of Dr. Luehr's expertise is in the treatment of children, he was selected because the information he conveyed at speaker programs would include unsolicited information on the off-label use of Seroquel XR® to treat children and adolescents.

226. In June 2009, for example Dr. Luehr gave a speaker program to health care professionals which he included unsolicited information about using Seroquel XR® for off-label use as monotherapy treatment of MDD and GAD and his use of Seroquel XR® to treat children.

6. Dr. Azfar Malik

227. Another favorite off-label speaker is Azfar M. Malik, M.D., M.B.A., FAPA, a board-certified psychiatrist. He is the Chief of Staff and Chief Executive Officer of CentrePointe Hospital in St. Charles, Missouri, a hospital he owns along with his sister, brother, and a group of physicians. Dr. Malik is also the Chairman of the Board of Directors as well as the Principal Investigator and President of a clinical research enterprise, Psych Care, LLC. He is also an

Assistant Clinical Professor in the Psychiatry Department at St. Louis University Health Science Center. Dr. Malik has been on numerous speaker panels and advisory boards for AstraZeneca.

228. Because he (and his group) owned CentrePointe as well as a number of other clinics employing over thirty doctors, Dr. Malik was considered very important Key Opinion Leader by AstraZeneca.

229. In addition to regularly serving as a speaker, Dr. Malik also sought out and received compensation to conduct clinical research for AstraZeneca. For example, he is listed as an investigator on the clinical study, Weisler, et al., "Extended Release Quetiapine Fumarate Monotherapy for Major Depressive Disorder: Results of a Double Blind, Randomized, Placebo-Controlled Study, CNS Spectrums, 14(6):299-313 (June 2009), which was ghost-written by Complete Medical Communications with funding from AstraZeneca.

230. As part of his role as KOL for AstraZeneca, Dr. Malik agreed to speak about the off-label use of Seroquel XR®.

231. Dr. Malik's clinics treated numerous Medicaid patients where he regularly used Seroquel XR® off-label for the treatment of MDD and GAD.

232. On April 14, 2009, Dr. Malik gave speaker programs to health care professionals which included unsolicited information about off-label use of Seroquel XR® to treat MDD and GAD. Dr. Malik also later gave a speaker program to health care professionals in Carroll, Iowa where he gave unsolicited information about the off-label use of Seroquel XR® to treat GAD and MDD. Later that same day, he also gave a speaker program to health care professionals (including child psychiatrists), including unsolicited information about the off-label use of Seroquel XR® to treat MDD and GAD.

7. Dr. Gordon Robinson

233. Dr. Gordon Robinson, M.D. a psychiatrist from St. Louis, Missouri, also served as a paid speaker for AstraZeneca to promote the off-label use of Seroquel XR®. On information and belief, AstraZeneca terminated its relationship with Dr. Robinson due to violations of company policies on the content of speaker programs, but he was ultimately rehired.

234. Dr. Robinson gave an evening program on April 8, 2009, attended by several health care professionals in the Des Moines area, which included unsolicited information concerning use of Seroquel XR® to treat MDD and GAD, and as adjunctive therapy for the treatment of MDD. Dr. Robinson also gave this same off-label speaker program at Mercy Psychiatric Services in Des Moines, Iowa on April 9, 2009.

235. Dr. Robinson later gave a presentation at an evening program in Des Moines on October 5, 2009, at which he gave unsolicited information concerning the off-label use of Seroquel XR®. The next day on October 6, 2009, Dr. Robinson gave the same speaker program to health care professionals at Broadlawns County Hospital (primarily a Medicaid hospital in Des Moines, Iowa), providing unsolicited information on the off-label use of Seroquel XR® for the treatment of MDD and GAD.

8. Dr. Thomas Winegarden

236. Thomas Winegarden, M.D., a child and adolescent psychiatrist from Chanhassen, Minnesota, spoke frequently on behalf of AstraZeneca in Minnesota and Iowa, regarding his off-label use of Seroquel XR® in the treatment of GAD. AstraZeneca paid Dr. Winegarden approximately $1500 per presentation. In Minnesota alone, according to data available from the State of Minnesota, during 2007 and 2008 Dr. Winegarden received some $90,738 for some 73 speaker programs where he regularly gave unsolicited information about using Seroquel XR® off-label for the treatment of GAD.

237. When Plaintiff-Relator reported Dr. Winegarden's off-label speaker programs to AstraZeneca's compliance department, there was an investigation but nothing was done to correct in any way the widespread off-label promotional presentations he had given.

L. AstraZeneca Tracked Speaker "Return on Investment" – I.e., Whether Speakers Were Able to Increase Off-Label Prescribing for Seroquel XR®

238. AstraZeneca tracked the return on its investment associated with its speaker programs by measuring increases in its market share compared to other SGAs associated with these presentations. For example, of the twenty-one speaking engagements in 2009 tracked by the Plaintiff-Relator, AstraZeneca's average increase in market share was 5.49 percent. The most significant increases in market share included:

239. Devi Mikkilneni, M.D., who attended a lunch presentation by Dr. Jennisch on March 27, 2009, and a dinner presentation by Dr. Gordon Robinson on April 9, 2009, whose use of Seroquel XR® increased from 18 percent prior to these presentations to 35.46 percent after;

240. Jana Simmons, an Advanced Registered Nurse Practitioner, who attended a program with Dr. Robinson on April 9, 2009, whose use of Seroquel XR® use increased from 8.67 percent to 23.93 percent; and

241. Scott Eastin, M.D., who attended a program given by Dr. Ishii on October 14, 2009, whose use of Seroquel XR® increased from 6.43 percent to 18.94 percent.

242. At least six prescribers who attended the off-label speaker programs had not used Seroquel XR® prior to the presentations, but did so after.

243. On information and belief, at least 50 percent of the patients treated by the health care providers whose ROI increased following a speaker presentation had their prescriptions covered, in whole or in part, by Medicare or Medicaid programs.

M. AstraZeneca's Control of the CMEs Transformed Them into Promotional Events for Off-Label Use of Seroquel XR®

244. Another key source of drug information for doctors is continuing medical education ("CME") courses, usually medical lectures held locally featuring KOLs. Required to maintain medical licenses and to stay current with new developments to give patients the best medical care, many CME courses provide expert syntheses of clinical trial information.

245. The percentage of CMEs that are commercially funded increased significantly from forty-eight percent in 1998 to fifty-eight percent in 2002. Currently, sixty percent of CMEs have direct commercial sponsorship; indirect sponsorship (*e.g.*, via non-profits funded by company money) accounts for a large portion of the remainder. Total industry contributions towards continuing medical education is estimated to be seventy percent or higher and total in the hundreds of millions of dollars.

246. Survey data from the Accreditation Council for Continuing Medical Education ("ACCME") show that industry funding of accredited continuing medical education increased by more than 300 percent between 1998 and 2007 (ACCME, 2008). Moreover, profit margins increased substantially, from 5.5 percent in 1998 to 31 percent in 2006 (Steinbrook, 2008b).

247. The content of the CME programs is intended to be independent of drug companies. According to ACCME standards (*see* Accreditation Council for Continuing Medical Education Standards for Commercial Support, Adopted April 2004, approved Sept 2004. Available at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf) and FDA guidance (*see* U.S. Food and Drug Administration Center for Drug Evaluation and Research Guidance for Industry: Industry-Supported Scientific and Educational Activities. U.S. Department of Health and Human Services Food and Drug Administration Office of Policy, Nov 1997. Available at

http://www.fda.gov/cder/guidance/isse.htm), independent educational grants cannot be tied to the purchase, sale, prescription, or recommendation of the company's products. There cannot be price concessions to help offset a customer's purchase or reimbursement of drugs, and there cannot be any payment to ensure that the grant recipient markets the company's drugs during the educational program. Grants provided to customers of a pharmaceutical company (institutional pharmacies, retail chain pharmacies, pharmacy benefit managers, managed care organizations, and others) must be especially focused on educating health care professionals in order to avoid any appearance of price concession or quid pro quo arrangement. Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belong solely to the CME provider in accordance with their guidelines

248. AstraZeneca knows that its involvement in promotional speaker programs should be clearly disclosed, and that it should respect the independence of healthcare providers. Thus, its "Global Policy" on "Providing Information About our Products" states: "Engagements of Healthcare Professionals and Organisations for services must not be disguised promotion."

249. AstraZeneca's "Global Policy" on "Providing Information About our Products" also states: "Where the Company is providing support for third party programmes, we must . . . not exert any inappropriate influence over the content of presentations made by any speakers, whether or not the Company has sponsored the event at which the presentation is made."

250. AstraZeneca regularly violated the FDA guidance and its own policies governing CME events in that, although the programs offered through CME providers could ostensibly present off-label information, AstraZeneca manipulated the CME programs into events promoting off-label uses of Seroquel XR®. Therefore, even though the events highlighting the off-label use of Seroquel XR® were run through a CME provider, in fact, they were simply a

well-disguised AstraZeneca marketing message basically mimicking AstraZeneca's illegal promotional speaker programs that encouraged off-label use of Seroquel XR®.

251. One such CME funded by AstraZeneca was released online on December 24, 2008, by MedScape CME, Inc. entitled "Managing Mood and Anxiety Disorders in Primary Care Practice: A Focus on Complex and Difficult to Treat Patients" prepared by Dr. Larry Culpepper, M.D., Professor of Family Medicine, Department of Family Medicine Chair, Boston University School of Medicine, Boston, Massachusetts; Chief of Family Practice, Boston Medical Center, Boston, Massachusetts, which was sponsored by an educational grant from AstraZeneca. Dr. Culpepper discloses in the online CME that he serves as a consultant for AstraZeneca. Even though the presentation was accredited as a CME course (so product promotion was not allowed), the presentation was orchestrated by AstraZeneca as an off-label promotion of Seroquel XR® to treat GAD. During the online CME, Dr. Culpepper presents the case of Ms. S, a 43-year-old woman with a history of GAD who has been treated with SSRIs/SNRIs, but unresponsively. Dr. Culpepper then steers her to the off-label use of Seroquel XR®, which "may be effective for the treatment of anxiety and depressive symptoms." *See* http://cme.medscape.com /viewarticle/585333.

252. Another CME funded by AstraZeneca was released online on November 3, 2008, by MedScape CME, Inc. entitled "New Evidence in the Management of Major Mental Illness: Major Depressive Disorder and Generalized Anxiety Disorder" as a video CME panel with by Mark H. Rapaport, M.D.; Mark H. Pollack, M.D.; J. Craig Nelson, M.D. Dr. Rapaport is Vice Chair, Department of Psychiatry and Biobehavioral Sciences, UCLA School of Medicine and receives research grants from AstraZeneca. Dr. Pollock is a Professor of Psychiatry, Harvard Medical School, and is a consultant for AstraZeneca. Dr. Nelson Professor of Psychiatry and

Director of Geriatric Psychiatry, University of California at San Francisco. The CME was sponsored by an educational grant from AstraZeneca. Even though the presentation was accredited as a CME course (so product promotion was not allowed), the presentation was orchestrated by AstraZeneca as an off-label promotion of Seroquel XR® to treat MDD and GAD. During the video CME, the doctors discuss the off-label use of Seroquel XR® for the treatment of MDD and GAD. *See* http://cme.medscape.com/viewarticle/582811.

253. Another CME was released online on March 31, 2008, by MedScape CME, Inc. entitled "Bipolar Disorder in the Child and Adolescent" prepared by Christopher U. Cornell, M.D., Assistant Professor of Psychiatry, Albert Einstein College of Medicine, Bronx, New York. Dr. Cornell discloses in the online CME that he serves as a speaker for AstraZeneca. Even though the presentation was accredited as a CME course (so product promotion was not allowed), the presentation was orchestrated by AstraZeneca as an off-label promotion of Seroquel XR® to treat bipolar disorder in children and adolescents. During the online CME, Dr. Cornell presents the case of a 12-year-old girl with a history of ADHD and oppositional defiant disorder that has been treated with methylphenidate, but with no improvement in her symptoms. Dr. Cornell then describes the girl as having pediatric bipolar disorder and steers her to off-label use of Seroquel XR® in combination with Depakote®, based on the DelBello studies, discussed *supra*. The entire CME is little more than an off-label promotion of Seroquel XR® for the treatment of children and adolescents. *See* http://cme.medscape.com/viewarticle/572159.

N. AstraZeneca's Use of Tutorials, Preceptorships, and Professorships to Induce Physicians to Prescribe Seroquel XR® Off Label

254. In addition to speaking engagements, AstraZeneca openly promoted and encouraged sales representatives to set up tutorials and preceptorships, at which it paid KOLs to train the sales force on the nuances of off-label use of Seroquel XR®.

255. AstraZeneca knew that it could not directly pay doctors to induce them to prescribe Seroquel XR® or receive a sales pitch, and the doctors knew this as well. Nevertheless, several doctors would not meet with an AstraZeneca representative unless they were "wined and dined" in the process. Accordingly, AstraZeneca utilized "tutorials" and "preceptorships" to create an appearance that the compensation it provided to doctors was earned income.

256. As used by Defendant AstraZeneca, a "tutorial" was a presentation of at least one hour in duration by the doctor to a Pharmaceutical Sales Representative, generally on an AstraZeneca study selected by the PSS because it supported an off-label use of Seroquel XR®. Although the PSS already was fully familiar with the subject of the tutorial, the doctor typically was paid $150 or more for his time.

257. For example, Dr. Jennisch received conducted two such tutorials of sales representatives about the nuances of promoting the off-label use of Seroquel XR® to treat bipolar disorder and MDD long before those indications were approved by the FDA.

258. AstraZeneca also sought to disguise its improper compensation of doctors through the use of preceptorships. In a preceptorship, an AstraZeneca PSS would pay a "high volume" doctor (*i.e.,* a doctor who wrote a high number of SGA prescriptions, but not enough Seroquel XR®), typically a minimum of $250 to permit the PSS to follow the doctor during patient examinations for part or all of a day. In theory, the purpose of a preceptorship was to provide the PSS with insight into how the doctor decides which SGA drug to prescribe. In practice, since the PSS rarely stayed with the doctor for the entire day, the preceptorship was a thinly-veiled means of funneling cash gifts to doctors who AstraZeneca expected would reciprocate by writing more prescriptions for Seroquel XR®, including for off-label uses.

259. Moreover, until recently, preceptorships were part of each PSS's accountability. Each PSS was expected to participate in three preceptorships per year with high volume doctors not generally susceptible to AstraZeneca's other marketing practices.

260. Visiting professorships are one-on-one appointments with the AstraZeneca's hired speaker and a doctor it wishes to influence to prescribe more Seroquel XR®. The "professor" is generally a "Key Opinion Leader" and regular speaker for the company. The professor is supposed to stay on-label and use slides approved by AstraZeneca. In fact, these visiting professorships consist of informal meetings in the doctors' offices, at which the doctors can and do discuss any topics of interest, including off-label use of prescriptions medications, such as Seroquel XR®. Indeed, due to concerns that the professors were promoting Seroquel XR® off-label, the sales personnel were directed in or about July of 2009 that they were to provide the "professors" hard copies of slides they were to use in the promotions.

261. For example, in approximately August 2009, Dr. Khosravi conducted a visiting professorship that focused exclusively on the use of Seroquel XR® for the treatment of children. Plaintiff-Relator had been pressured by Mr. Yarbrough to retain Dr. Khosravi to serve on the speakers bureau because he was a board certified child psychiatrist. Yarbrough intended that Plaintiff-Relator to use Dr. Khosravi to speak to child psychiatrists who were not prescribing enough Seroquel® or Seroquel XR®. Even though Dr. Khosravi served as a speaker and professor for AstraZeneca, Yarbrough directed Plaintiff-Relator that she was to tell Dr. Khosravi that he was not writing enough Seroquel XR® prescriptions, given that he was a paid speaker for the company. Thereafter, Dr. Khosravi quit as an AstraZeneca speaker because he felt it was "quid pro quo" and did not like the pressure from AstraZeneca.

O. AstraZeneca Instructed Health Care Providers How to Circumvent Medicaid Regulations Concerning the Use of Seroquel XR®

262. AstraZeneca sales personnel coached health care providers on how to circumvent Medicaid restrictions on the prescription of Seroquel XR®.

263. For example, under current Iowa Medicaid regulations, prescribers must obtain prior approval before prescribing Seroquel XR®, but such prior approval is not needed for Seroquel®.

264. AstraZeneca sales specialists instructed health care providers to state on the forms that Seroquel® has side effects that the patient could not tolerate or that once-daily dosing with Seroquel XR® would assure that the patient would follow his or her prescription's instructions. Iowa Medicaid personnel learned of these instructions and now reject all prescription prior authorizations unless prescriber had first tried the patient on Seroquel®.

265. Undaunted, AstraZeneca sales personnel now routinely instruct Iowa health care providers to prescribe Seroquel® for one month and then switch the prescription to Seroquel XR®.

P. Using Quota and Credit Programs to Induce Sales to Doctors and Facilities Who Do Not Use Seroquel XR® On-Label

266. Moreover, AstraZeneca's national Seroquel XR® sales strategy included quota and credit programs that both penalized and created incentives to the sales force to sell to doctors who could not treat their patients using Seroquel XR® on-label. AstraZeneca knew that these programs created a working environment that was conducive to promoting Seroquel XR® for as many uses and as wide a patient base as possible. The quota and credit programs were instituted immediately upon Seroquel XR®'s approval in 2007, and applied to sales representatives, District Managers, Regional Managers and Vice Presidents.

267. AstraZeneca's quota system required Seroquel XR® sales representatives to detail any physician on their call list (regardless of specialty) and awarded them with bonuses based

on sales of Seroquel XR®. For example, Seroquel XR® sales representatives that exceeded quota of, for example, 105 percent, would be paid additional bonus dollars and additional chances of winning award trips.

268. The prescribers AstraZeneca included in its quota and credit programs were doctors that would not normally treat patients with Seroquel XR®'s approved indications. These doctors included child psychiatrists, primary care physicians, and geriatric physicians (including calling directly on nursing homes).

269. Included in the Seroquel XR® sales quotas were the following providers: 1- CNS Representatives in an assigned territory would have a quota for all psychiatrists (adolescent, adult and geriatric), state psychiatric hospitals, and other select hospitals (general, academic, and psychiatric (both state and private)) many of whom would have no reason to prescribe Serorquel XR® on label; 2 – Hospital Representatives would cover health care professionals at state hospitals and larger institutions which treated children and the elderly, many of whom who have no reason to use Seroquel XR® on label; and 3 – Primary Care Representatives would have a quota for all/most (10-40) primary care physicians, internal medicine specialists, and small rural hospitals not covered by the Hospital Representatives, many of whom would not prescribe Seroquel XR® on label.

270. Seroquel XR® sales quotas were based on several components: 1- the previous territory sales year revenue of Seroquel XR® for all assigned licensed medical professionals; 2 - the previous territory sales year revenue of all SGAs for all assigned licensed medical professionals (without regard to whether the SGAs were used to treat primarily off-label conditions); and 3 – a corporate growth component applied to the based quota. Once the quota was set for the semester, AstraZeneca rarely made any adjustments to the representative's quota.

271. The accumulative quotas of the district sales representatives (8 to 14 per district) generate the District Manager's quota. The quotas of the district sales managers (8 to 12 per region) generate the Regional Manager's quota. The quotas of the regional sales managers (six to eight nationally) feed into the Vice-President of Sales' quota and eventually up to the CEO/corporate quota. Thus, the entire Sales division was quota-driven based on success in sales to health care professionals who had little reason to prescribe Seroquel XR® for on-label uses.

272. AstraZeneca's quota and credit programs also influenced the selection of speakers. Speakers who spoke about unapproved uses and unapproved populations were selected by sales representatives, District Managers, Regional Managers and Vice Presidents for their ability to enhance quota and credit scores. For example, Plaintiff-Relator was instructed by her District Manager to retain Dr. Khosravi as a speaker due to his experience treating children with Seroquel XR® and in hopes that his being a speaker would increase off-label prescribing both by health care professionals in audience for the speaker programs, but also by Dr. Khosravi himself. Indeed, as discussed herein, speakers are retained to encourage their off-label use of Seroquel XR®.

273. Finally, AstraZeneca announced in July 2008, that child and adolescent psychiatrists designated as such by the AMA were to be deleted from the quota and credit programs. Despite this corporate decision, most sales representatives did not delete these practitioners from the program. AstraZeneca reversed this position in 2010, however, claiming that a third-party vendor had determined that many of these practitioners actually treat adults. This is often untrue. For example, Plaintiff-Relator still has at least one doctor on her call list in Des Moines who does not treat patients over the age of 18 years.

Q. October 7, 2009: AstraZeneca Notifies Sales Representatives to Cease Off-Label Promotion of Seroquel XR®

274. On October 7, 2009, Tom Viscount, National Sales Director for the Central Nervous System ("CNS") division, and Jonathan Walker, Commercial Brand Leader for the Seroquel Franchise, distributed an "Internal Communication" to all CNS Specialty Sales Representatives, which instructed them no longer to do exactly what they had been trained to do for months: "To clarify, it is not appropriate to simply reference bipolar disorder or bipolar depression once within a detail, and then allow the conversation to expand to 'depressed patients,' 'depressive episodes,' or 'depressive symptoms' (including sadness, loss of interest, and feelings of worthlessness), without grounding this conversation in the approved indication of bipolar disorder."

275. Moreover, for months (at least since November 2008) CNS Specialty Sales Representatives had been directed by AstraZeneca to tell the doctors on their call lists (including child psychiatrists and family practice physicians) that frequently patients with bipolar depression are "misdiagnosed" as having only depression and they should then promote Seroquel XR® as an appropriate alternative for the treatment of this type of patient.

276. In the October 7, 2009 memo from Viscount and Walker, the sales representatives were no longer to do exactly what the company had to this point instructed them to do: "You must not state or suggest that SEROQUEL XR would be an appropriate treatment choice for patients still experiencing depressive symptoms with their current SSRI/SNRI treatment, unless a positive diagnosis of bipolar disorder has been made." Again, the Viscount/Walker instruction is exactly counter to how AstraZeneca had since the launch in July 2007 instructed that the sales force was to promote Seroquel XR®.

277. And, beginning with the launch in July 2007, sales representatives had been instructed to tout Seroquel XR®'s superiority to Abilify® by making false comparisons

Abilify®'s depression trials and Seroquel XR® depression trials. Yet, the Viscount/Walker memo instructed that CNS sales representatives could no longer do what they had been trained to do: "You cannot . . . move beyond [highlighting the fact that Abilify failed two clinical trials in bipolar depression] and make comparisons between the Abilify bipolar depression trial, since this comparison does not involve a head-to-head clinical trial . . . ."

278. The Viscount/Walker e-mail constituted AstraZeneca's belated attempt to create the false appearance of compliance despite years of instructing (indeed, requiring) its sales force to promote and market aggressively off-label use of Seroquel XR®.

279. On December 7, 2009, the Plaintiff-Relator received an e-mail from Michael Walje, AstraZeneca – Kansas City, Executive District Sales Manager, who forwarded an e-mail from Mary Ann Warren on behalf of the CNS Sales Leadership and CNS Sales Training team. This e-mail alerted the recipients that they would be "required" to attend 10 modules on MDD disease state and disease management. The e-mail acknowledged that Seroquel XR® is not approved for MDD and it instructed the recipients not to "engage in any discussions with customers about Seroquel XR® for MDD," and prohibited discussing "the information you learn in this module with any customer."

280. AstraZeneca's training modules on MDD for an indication never approved by the FDA establishes AstraZeneca's motive to promote off-label use of Seroquel XR®. During the training modules, in a presentation given by Scott Weintraub, Brand Leader for Seroquel XR®, he explains their strategy would no longer include comparing the drug to Abilify®: "[W]e have to be competitive but not by being comparative. We have no head-to-head data versus Abilify and we have the same indication for adjunctive treatment of MDD. In 2010, we will be successful with Seroquel XR by establishing the benefits of Seroquel XR in its own right without

comparison to Abilify." Moreover, Weintraub informed the sales representatives they could no longer make superiority claims of Seroquel XR®'s efficacy compared to SSRIs/SNRIs: "You cannot state or imply the inclusion of Seroquel XR . . . would have changed the results or that Seroquel XR is any more effective than any given antidepressant . . . . Seroquel XR has not been studied in comparison to other antidepressant agents."

281. Despite efforts to make it appear that the company is now finally complying with the law and no longer allowing off-label promotion, AstraZeneca continues to instruct and require its sales force to promote off-label uses of Seroquel XR® in violation of FDA statutes and regulations and Federal Program statutes, regulations, and limitations.

X. ASTRAZENECA KNEW THE LEGAL RISKS RELATED TO OFF-LABEL PROMOTION OF SEROQUEL XR®

282. At all times relevant to this Complaint, AstraZeneca knew that it was prohibited from (i) initiating any promotion of Seroquel XR® for an off-label use, (ii) promoting Seroquel XR® through improper comparative marketing techniques, including unsubstantiated superiority claims, and (iii) compensating doctors in exchange for their decisions to prescribe Seroquel XR® for their patients.

283. AstraZeneca was well aware of the legal risks inherent in the unlawful marketing and promotion of its prescription drug products. On June 4, 2003, AstraZeneca entered into a Corporate Integrity Agreement ("CIA") with the United States Office of Inspector General of the Department of Health and Human Services. AstraZeneca signed the CIA in connection with the settlement of allegations that it engaged in illegal off-label marketing of its drug product Zoladex® (the "Zoladex CIA"). The Zoladex CIA expressly incorporated measures aimed at prohibiting AstraZeneca from future promotion of its products for off-label uses. AstraZeneca's

conduct as described herein constitutes flagrant, intentional and material breaches of the Zoladex CIA.

284. The Zoladex CIA also required AstraZeneca to certify compliance, and to report to the government "reportable events," which are defined in the Zoladex CIA as "anything that involves a matter, brought to the attention of senior management at AstraZeneca's New York headquarters, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the off-label promotion of drugs. . . ."

285. There is no doubt that, following the Zoladex criminal plea and the Zoladex CIA, AstraZeneca and its sales representatives have been clearly aware of the legal risks the Company takes if it chooses illegally to market its drug products.

286. Plaintiff-Relator alleges, upon information and belief, that AstraZeneca knowingly failed completely and truthfully to certify compliance with the Zoladex CIA, and failed completely and truthfully to report "reportable events," all as required by the Zoladex CIA. As a result, AstraZeneca has presented or caused to be presented to the United States a false certification or claim under 31 U.S.C. § 3729 *et seq.*

287. Plaintiff-Relator alleges, on information and belief, that AstraZeneca failed accurately and truthfully to report its improper Seroquel XR® marketing as described above, as required by the terms of the Zoladex CIA.

288. The failure by AstraZeneca truthfully and accurately to report, or the submission of a false report, to the United States, pursuant to the Zoladex CIA, was done knowingly and deliberately, without just cause.

289. Although AstraZeneca was clearly aware of its compliance obligations regarding sales and marketing of its products, AstraZeneca senior sales, marketing, and corporate executives did everything they could to get around any such limitations in order to sell Seroquel XR®.

290. AstraZeneca's pattern of off-label promotion, misbranding and purposeful targeting of vulnerable populations such as children and the elderly is all the more alarming and reprehensible given Seroquel XR®'s serious side effects, some of which could be fatal.

291. As a result of AstraZeneca's unlawful conduct, the United States has been damaged, and continues to be damaged, by Federal Program payments for off-label and falsely promoted Seroquel XR® prescriptions. Upon information and belief, Seroquel XR® off-label prescription payments made by Federal Programs total in the hundreds of millions of dollars.

XI. ASTRAZENECA'S FRAUDULENT MARKETING SCHEME VIOLATED FEDERAL PROGRAM LIMITATIONS

292. At all relevant times, AstraZeneca knew that Seroquel XR® was and is being paid or reimbursed by Federal Programs, including Medicaid and Medicare Part D, as well as by the *Qui Tam* States.

293. AstraZeneca knew or reasonably should have known and should have foreseen that its promotion of Seroquel XR® would lead to the submission by physicians, pharmacists and government-funded health plans of Seroquel XR® prescriptions ineligible for payment by Federal Programs.

294. When AstraZeneca decided to employ these illegal promotional practices, it knew or should have known that physicians, pharmacists, and federally-funded health programs would routinely and necessarily file claims with Federal Programs for reimbursement for Seroquel XR® prescriptions. But for AstraZeneca's illegal promotion, these off-label

and misbranded prescriptions for Seroquel XR® would not have been written. As a result, AstraZeneca caused the submission of false claims to Federal Programs for reimbursement of Seroquel XR®. AstraZeneca was the beneficiary of these false claims for reimbursement of Seroquel XR® prescriptions.

A. AstraZeneca Improperly Promoted Seroquel XR® for Off-Label Uses

295. AstraZeneca knows that it is prohibited under the FDCA from promoting off-label uses of Seroquel XR®. Thus, its "Global Policy" on "Providing Information About our Products" states:

> We must promote only licensed products and only for approved uses in accordance with the approved prescribing information. We must not initiate discussions on 'off-label' uses or unlicensed products in order to promote such use.

296. Similarly, AstraZeneca's policy on "Marketing to healthcare professionals" states: "Off-label promotion (the marketing of medicines for uses or for the treatment of patient groups not specified in the prescribing information) is illegal and not permitted by our policies." Although Pharmaceutical Sales Specialists receive annual online compliance training on these issues, that training routinely is countermanded by supervisors, such as Doug Yarbrough, District Sales Manager, Des Moines; Steve Levandowski, Regional Sales Director, Minneapolis; Mike Phaup, St. Louis; and Laura Schanen, Wisconsin. These supervisors direct their sales representatives to market Seroquel XR® for off-label use and have actual knowledge that the sales representatives follow their instruction and direction.

297. AstraZeneca at all times material hereto knew that its involvement in promotional activities should be clearly disclosed. Thus, its "Global Policy" states: "Engagements of Healthcare Professionals and Organisations for services must not be disguised promotion."

Yet AstraZeneca expected and encouraged its speakers to promote Seroquel XR® for off-label uses.

298. In fact, AstraZeneca routinely and intentionally has promoted off-label uses of Seroquel XR® on its own initiative (*i.e.,* not in response to inquiries received from physicians) and using improper means.

B. AstraZeneca's Fraudulent Marketing Scheme Violated Federal Program Limitations

299. In violation of federal law, AstraZeneca knowingly and deliberately promoted Seroquel XR® for non-FDA approved uses that AstraZeneca knowingly and deliberately knew, or could reasonably foresee, would lead to violations of federal Medicaid statutes and regulations designed to restrict reimbursement to Federal Programs such as Medicaid.

300. Federal Programs, including the Medicaid and Medicare Part D programs, rely on the FDA's findings regarding what uses for approved drugs are safe and effective. Whether a drug that is FDA-approved for a particular use will largely determine whether a prescription for that drug will be reimbursable under Federal Programs, including the Medicaid and Medicare Part D programs.

301. In 1990, Congress passed the Budget Reconciliation Act which limited reimbursement for prescription drugs to "covered outpatient drugs." Covered outpatient drugs only include drugs used for "medically accepted indications." A medically-accepted indication is a use which has been approved by the FDA or one which is supported by specific drug reporting compendia set forth in the Medicaid statute, 42 U.S.C. § 1396r-8(k)(6). Reimbursement by Medicaid is, with only one rare exception, prohibited if the drug is not being used for a medically accepted indication. 42 U.S.C. § 1396r-8(k)(3).

302. Congress has adopted a compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a "covered outpatient drug." Soc. Sec. Act § 1927(g)(1)(B)(i) and (k)(6) (permitting reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results"). Thus, the only way a prescription could be allowed under the Medicaid statute was if the particular off-label Seroquel XR® indication had been approved in one of the compendia identified in § 1927(g)(1)(B)(i) to be eligible for reimbursement under Medicaid, and other federal reimbursement programs.

303. The most commonly available of these compendia, DRUGDEX, does not support the off-label uses for Seroquel XR® promoted by AstraZeneca. The 2008 DRUGDEX does not support the use of Seroquel XR® in children or in elderly patients with dementia or for treatment of GAD or MDD. As such, all Medicaid reimbursements for Seroquel XR® prescriptions for these indications were not eligible for reimbursement and should not have been made.

304. Similarly, off-label indications qualify as "medically accepted indications" for Medicare reimbursement if they appear on the identified drug reporting compendia. Reimbursement under Medicare is only available to a physician if the services he or she provided were "medically required," and he or she certifies that the services performed were medically necessary. 42 U.S.C. § 1395n(a)(2).

C. AstraZeneca's Promotion of Seroquel XR® Caused Submission of Off-Label Claims to Federal Programs and the Qui Tam States

305. AstraZeneca has actual knowledge that its off-label marketing and promotion of Seroquel XR® gives rise to liability under the federal False Claims Act and similar laws of the *Qui Tam* States.

306. Defendant AstraZeneca promoted off-label indications and dosages of Seroquel XR®, knowing they were not eligible for reimbursement because the indication or dosage was neither listed on the drug reporting compendia or the relevant fiscal intermediary's Local Coverage Determination ("LCD"), nor was it included on Seroquel XR®'s FDA-approved product labeling.

307. Furthermore, Defendant AstraZeneca illegally promoted off-label uses without meeting the FDA requirements, and without resubmitting Seroquel XR® to the FDA testing and approval process as required by 21 U.S.C. § 360aaa *et seq.* Thus, claims for reimbursement of off-label Seroquel XR® prescriptions fail to meet the eligibility requirements of Federal Programs and the Qui Tam States. AstraZeneca's off-label promotion of Seroquel XR® resulted in reimbursement by Federal Programs and the Qui Tam States for numerous false claims.

XII. ASTRAZENECA'S RETALIATION AGAINST PLAINTIFF-RELATOR

308. Plaintiff-Relator suffered harassment and retaliation for her role in reporting to her human resources department her concerns over the manner in which AstraZeneca marketed and promoted Seroquel XR®.

309. In approximately March 2008, Plaintiff-Relator, along with her sales team partner, Emily Jensen, had informed AstraZeneca of illegal activity, including misleading efficacy promotion of Seroquel XR®, illegal off-label promotion and numerous compliance violations. The illegal activity included instructing Plaintiff-Relator to use an unapproved article in marketing Seroquel XR®; directing her to contact another sales representative in Minnesota to obtain guidance on how to use the article off-label; participating in a meeting at which direction was given to promote Seroquel XR® off label; providing ongoing updates of what representatives in Minnesota were doing to promote the product off-label and how to employ

these techniques in Iowa; and criticizing Plaintiff-Relator for being "too conservative" in her promotional activities -- *i.e.*, refusing to market Seroquel XR® off label.

310. In reporting this misconduct, Plaintiff-Relator followed AstraZeneca's procedures set forth in, among other places, AstraZeneca's Code of Conduct. The Code states, *inter alia*, that all employees must "promptly report any known, suspected, or observed violations of laws, regulations, this Code or supporting policies of which you become aware." Code at 2.

311. AstraZeneca's Code of Conduct further provides:

> ANYONE WHO RAISES A CONCERN ABOUT A POSSIBLE COMPLIANCE BREACH IN GOOD FAITH WILL BE SUPPORTED BY MANAGEMENT, AND WILL NOT BE SUBJECT TO RETALIATION. ANY ACT OR THREAT OF RETALIATION WILL IN ITSELF BE CONSIDERED A SERIOUS VIOLATION OF THIS CODE.

Code of Conduct at 3.

312. In derogation of the Code, Plaintiff-Relator was subject to harassment and retaliation as a result of raising a good faith compliance concern regarding off-label marketing and promotion of Seroquel XR®.

313. As a result of reporting her concern, and despite her exemplary performance, promotion to executive level sales representative (which had already been approved prior to the compliance investigation), and acceptable sales numbers, Plaintiff-Relator received a below-average review at the end of 2009. Mr. Yarbrough, Plaintiff-Relator's supervisor, exhibited hostility toward the Plaintiff-Relator during this review.

314. Moreover, Plaintiff-Relator was threatened as a result of having reported AstraZeneca's misconduct. At a "team building" meeting for the team of pharmaceutical sales representatives of which Relator was a part, held in Minneapolis on September 24, 2009, Mike Doran, PSS, slammed his fist down and stated that "he was ready to kill someone," when

Plaintiff-Relator had listed her self-perceived strengths as part of a scheduled exercise. Mr. Doran hastily left the room.

315. Although this incident occurred in the presence of Mr. Yarbrough, the supervisor to both Plaintiff-Relator and Mr. Doran, no action was taken against Mr. Doran as a result of his threats directed to the Plaintiff-Relator.

316. At the time, AstraZeneca did not institute any disciplinary action against either Mr. Yarbrough or Mr. Doran for the harassment directed at Relator.

COUNT I

VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, ET SEQ.

317. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

318. This is a civil action brought by Plaintiff-Relator, on behalf of the United States of America against Defendants under the False Claims Act, 31 U.S.C. §§ 3729(a)(1) and (2).

319. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, and may still be presenting or causing to be presented, to CMS, or other Federal Programs, false or fraudulent claims for payment, in violation of, inter alia, 31 U.S.C. § 3729(a)(1).

320. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, caused, or caused to be used, and may still be using or causing to be used, false or fraudulent records and/or statements to get false or fraudulent claims paid in violation of, inter alia, 31 U.S.C. § 3729(a)(2).

321. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information that supported claims to CMS, and Federal Programs, with actual knowledge of

the falsity of the information that supported these claims, caused, and may still be causing, the use of false or fraudulent materials or information to support claims paid by the government.

322. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Seroquel XR® prescribed to patients enrolled in Federal Programs.

323. As a result of Defendants' actions as set forth above in this complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT II

VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, *et seq.*

324. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

325. AstraZeneca's failure to report, or false reporting to the United States in accordance with the Zoladex CIA, was done deliberately, or in reckless disregard of the truth, and as a result, caused, and may still be causing, false or fraudulent records and/or statements resulting in false or fraudulent claims paid by the United States in violation of, inter alia, 31 U.S.C. § 3729 *et seq.*

326. As a result of Defendants' actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT III

VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3730(h)

327. Plaintiff-Relator hereby incorporates by this reference all allegations set forth in this Complaint, as though fully set forth herein.

328. As a result of Plaintiff-Relator's lawful acts in furtherance of protected activities investigating and reporting fraud, AstraZeneca retaliated against her.

329. The harassment and discrimination suffered by Plaintiff-Relator was a direct result of AstraZeneca's retaliatory acts, causing Plaintiff-Relator to suffer and continue to suffer substantial damage, in an amount to be proven at trial.

COUNT IV

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

330. Plaintiff-Relator hereby incorporates by this reference allegations set forth in this Complaint, as though fully set forth herein.

331. AstraZeneca's conduct toward Plaintiff-Relator was a calculated plan to cause her emotional harm. AstraZeneca's motive was retaliation for exposing AstraZeneca's violations of law and AstraZeneca's obligations under its Corporate Integrity Agreement.

332. All of the acts attributed to AstraZeneca, taken together, were so outrageous as to be utterly intolerable in a civilized community.

333. The emotional distress inflicted by AstraZeneca was severe, requiring Plaintiff-Relator to seek medical treatment.

334. AstraZeneca's extreme and outrageous conduct as alleged herein either intentionally or recklessly caused Plaintiff-Relator to suffer severe emotional distress.

335. Plaintiff-Relator was damaged as a result of suffering severe emotional distress, in an amount to be proven at trial.

336. Plaintiff-Relator is entitled to compensatory and punitive damages.

COUNT V

VIOLATION OF THE STATE OF CALIFORNIA FALSE CLAIMS ACT, CAL GOV'T CODE § 12650, *et seq.*

337. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

338. This is a civil action brought by Plaintiff-Relator on behalf of the State of California against Defendants under the California False Claims Act, CAL. GOV'T. CODE § 12652(c).

339. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of California or its political subdivisions false or fraudulent claims for payment, in violation of CAL. GOV'T. CODE § 12651(a)(1).

340. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of CAL. GOV'T. CODE § 12651(a)(2).

341. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California or its political subdivisions in violation of CAL. GOV'T. CODE § 1265 1 (a)(7).

342. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

343. As a result of Defendants' actions as set forth above, the State of California, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT VI

VIOLATION OF THE STATE OF CONNECTICUT FALSE CLAIMS ACT, 2009 CONN. PUB. ACTS NO. 09-5, *et seq.*

344. Plaintiff-Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

345. This is a civil action brought by Plaintiff-Relator on behalf of the State of Connecticut against Defendants under the Connecticut False Claims Act, 2009 Conn. Pub. Acts No. 09-5.

346. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of Connecticut or its political subdivisions false or fraudulent claims for payment, in violation of 2009 Conn. Pub. Acts No. 09-5 § 2(a)(1).

347. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of Conn. Pub. Acts No. 09-5 § 2(a)(2).

348. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut or its political subdivisions in violation of Conn. Pub. Acts No. 09-5 § 2(a)(1).

349. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

350. As a result of Defendants' actions as set forth above, the State of Connecticut, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT VII

VIOLATION OF THE STATE OF DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. CODE ANN. TIT. 6 § 1201, *et seq.*

351. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

352. This is a civil action brought on behalf of Plaintiff-Relator on behalf of the Government of the State of Delaware against Defendants under the State of Delaware's False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1203(b).

353. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented,

directly or indirectly, to an officer or employee of the Government of the State of Delaware false or fraudulent claims for payment or approval, in violation of DEL. CODE ANN. tit. 6, §1201 (a)(1).

354. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved, in violation of DEL. CODE ANN. tit. 6, §1201(a)(2).

355. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the Government of Delaware, in violation of DEL. CODE ANN. tit. 6, § 120l(a)(7).

356. The Government of the State of Delaware, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the Government of the State of Delaware.

357. As a result of Defendants' actions, the Government of the State of Delaware has been, and may continue to be, severely damaged.

COUNT VIII

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT, D.C. CODE A § 2-308.13, *et seq.*

358. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

359. This is a civil action brought by Plaintiff-Relator, in the name of the District of Columbia against Defendants under the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.15(a).

360. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, a false or fraudulent claim for payment or approval, in violation of D.C. CODE ANN. § 2-308.14(a)(l).

361. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records and/or statements to get false claims paid or approved by the District, in violation of D.C. CODE ANN. § 2-308.14(a)(2).

362. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, in violation of D.C. CODE ANN. § 2-308.14(a)(7).

363. The District of Columbia, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid,

and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

364. As a result of Defendants' actions, as set forth above, the District of Columbia has been, and continues to be, severely damaged.

COUNT IX

VIOLATION OF THE STATE OF FLORIDA FALSE CLAIMS ACT, FLA. STAT. 68-081, *et seq.*

365. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

366. This is a civil action brought by Plaintiff-Relator on behalf of the State of Florida against Defendants under the State of Florida's False Claims Act, FLA. STAT. ANN. § 68.083(2).

367. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Florida or one of its agencies false or fraudulent claims for payment or approval, in violation of FLA. STAT. ANN. § 68.082(2)(a).

368. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082(2)(b).

369. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082 (2)(g).

370. The State of Florida and its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

371. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT X

VIOLATION OF STATE OF GEORGIA MEDICAID FALSE CLAIMS ACT, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

372. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

373. This is a civil action brought by Plaintiff-Relator, in the name of the State of Georgia, against Defendants pursuant to the State of Georgia Medicaid Fraud False Claims Act, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

374. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Georgia Medicaid program, in violation of GA. CODE ANN. § 49-4-168 (2007).

375. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of GA. CODE ANN. § 49-4-168 (2007).

376. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of GA. CODE ANN. § 49-4-168 (2007).

377. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of GA. CODE ANN. § 49-4-168 (2007).

378. The State of Georgia or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

379. As a result of Defendants' actions, as set forth above, the State of Georgia or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XI

VIOLATION OF THE STATE OF HAWAII FALSE CLAIMS ACT FALSE CLAIMS TO THE STATE, HAWS REV. STAT. § 661-21, *et seq.*

380. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

381. This is a civil action brought by Plaintiff-Relator on behalf of the State of Hawaii and its political subdivisions against Defendants under the State of Hawaii's False Claims Act - False Claims to the State, HAW. REV. STAT. § 661-25.

382. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of HAW. REV. STAT. § 61-21(a)(l).

383. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(2).

384. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(7).

385. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

386. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XII

VIOLATION OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, IND. CODE § 5-11-5.5, *et seq.*

387. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

388. This is a civil action brought by Plaintiff-Relator on behalf of the State of Indiana against Defendants under the State of Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-4(a).

389. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(l 1.

390. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or

causing to be made or used, a false record or statement to obtain payment or approval of false claims by the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(2).

391. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(a)(6).

392. The State of Indiana, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

393. As a result of Defendants' actions, as set forth above, the State of Indiana has been, and may continue to be, severely damaged.

COUNT XIII

VIOLATION OF THE STATE OF ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT, 740 ILL. COMP. STAT. ANN. 175/1, *et seq.*

394. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

395. This is a civil action brought by Plaintiff-Relator on behalf of the State of Illinois against Defendants under the State of Illinois Whistleblower Reward and Protection Act, 740 ILL, COMP. STAT. ANN. 175/4(b).

396. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an

officer or employee of the State of Illinois or a member of the Illinois National Guard a false or fraudulent claim for payment or approval, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(I).

397. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(2).

398. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(7).

399. The State of Illinois, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

400. As a result of Defendants' actions, as set forth above, the State of Illinois has been, and may continue to be, severely damaged.

COUNT XIV

VIOLATION OF THE STATE OF LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. REV. STAT. § 46:437.1, *et seq.*

401. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

402. This is a civil action brought by Plaintiff, Relator, on behalf of the State of Louisiana's medical assistance programs against Defendants under the State of Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. § 46:439.1.

403. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of LA. REV. STAT. § 46:438.3(A).

404. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of LA. REV. STAT. § 46:438.3(B).

405. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of LA. REV. STAT, § 46:438.3 (D).

406. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

407. As a result of Defendants' actions, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XV

VIOLATION OF THE COMMONWEALTH OF MASSACHUSETTS FALSE CLAIMS ACT, MASS LAWS ANN. Ch. 12, § 5A, *et seq.*

408. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

409. This is a civil action brought by Plaintiff-Relator on behalf of the Commonwealth of Massachusetts against Defendants under the Massachusetts False Claims Act, MASS. LAWS ANN. ch. 12, § 5C(2).

410. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MASS. LAWS ANN, ch. 12, § 5B(1).

411. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts or its political subdivisions in violation of MASS. LAWS ANN. ch. 12, § 5B(2).

412. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts or one of its political subdivisions, in violation of MASS. LAWS ANN. ch. 12, § 5B(8).

413. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

414. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI

VIOLATION OF THE STATE OF MICHIGAN MEDICAID FALSE CLAIMS ACT, MICH. COMP. LAWS SERV. § 400.601, *et seq.*

415. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

416. This is a civil action brought by Plaintiff-Relator in the name of the State of Michigan against Defendants under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(l).

417. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of MICH. COMP. LAWS. SERV. § 400.603(1).

418. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit, in violation of MICH. COMP. LAWS. SERV. § 400.603(2).

419. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants are not entitled or in an amount greater than that to which Defendants are entitled, in violation of MICH. COMP. LAWS. SERV. § 400.603(3).

420. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly presented or made or caused to be presented or made, and may still be presenting or causing to be presented a false claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, in violation of MICH. COMP. LAWS. SERV. § 400.607(1).

421. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

422. As a result of Defendants' actions, as set forth above, the State of Michigan or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVII

VIOLATION OF STATE OF MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. § 17-8-401, *et seq.*

423. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

424. This is a civil action brought by Plaintiff-Relator on behalf of the State of Montana against Defendants under the State of Montana False Claims Act, MONT. CODE ANN. § 17-8-406(1).

425. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MONT. CODE ANN. § 17-8-403(l)(a).

426. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of MONT. CODE ANN. § 17-8-403(1)(b).

427. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of Montana or one of its political subdivisions, in violation of MONT. CODE ANN. § 17-8-403(l)(g).

428. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

429. As a result of Defendants' actions, as set forth above, the State of Montana or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII

VIOLATION OF STATE OF NEW HAMPSHIRE MEDICAID FALSE CLAIMS ACT, N.H. REV. STAT. ANN. § 167:61-b, et. seq.

430. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

431. This is a civil action brought by Plaintiff-Relator on behalf of the State of New Hampshire against Defendants under the State of New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-cII.(a).

432. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(a).

433. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to get a fake claim paid or approved, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(b).

434. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Hampshire or one of its political subdivisions, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(e).

435. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

436. As a result of Defendants' actions, the State of New Hampshire or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX

VIOLATION OF STATE OF NEW JERSEY FALSE CLAIMS ACT, N.J. STAT. ANN. § 265 (2007), *et seq.*

437. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

438. This is a civil action brought by Plaintiff-Relator, in the name of the State of New Jersey, against Defendants pursuant to the State of New Jersey Fraud False Claims Act, N.J. STAT. ANN. § 265 (2007), *et seq.*

439. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the New Jersey Medicaid program, in violation of N.J. STAT. ANN. § 265 (2007).

440. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of N.J. STAT. ANN. § 265 (2007).

441. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of N.J. STAT. ANN. § 265 (2007).

442. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of N.J. STAT. ANN. § 265 (2007).

443. The State of New Jersey or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

444. As a result of Defendants' actions, as set forth above, the State of New Jersey or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XX

VIOLATION OF STATE OF NEW MEXICO MEDICAID FALSE CLAIMS ACT, N.M. STAT. ANN. § 27-14-1, *et seq.*

445. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

446. This is a civil action brought by Plaintiff-Relator on behalf of the State of New Mexico against Defendants under the State of New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-7(B).

447. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false or fraudulent claim for payment under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4A.

448. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may be continuing to present or causing to be presented a claim for payment under the Medicaid program that is not authorized or is not eligible for benefit under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4B.

449. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved, in violation of N.M. STAT. ANN. § 27-14-4C.

450. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico or one of its political subdivisions, in violation of N.M. STAT. ANN. § 27-14-4E.

451. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

452. As a result of Defendants' actions, as set forth above, the State of New Mexico or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI

VIOLATION OF THE STATE OF NEW YORK FALSE CLAIMS ACT, N.Y. CLS. ST. FIN. § 187 *et seq.*

453. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

454. This is a civil action brought by Plaintiff-Relator on behalf of the State of New York against Defendants under the State of New York False Claims Act, N.Y. CLS St. Fin. § 190.2.

455. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.Y. CLS St. Fin. § 189(a).

456. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of N.Y. CLS St. Fin. § 189(b).

457. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York or one of its political subdivisions, in violation of N.Y.CLS St. Fin. § 189(g).

458. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

459. As a result of Defendants' actions, as set forth above, the State of New York or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXII

VIOLATION OF THE STATE OF NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT. ANN. § 357.010, *et seq.*

460. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

461. This is a civil action brought by Plaintiff-Relator on behalf of the State of Nevada against Defendants under the State of Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. ANN. § 357.080(1)

462. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of NEV. REV. STAT. ANN. § 357.040(l)(a).

463. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval for false claims in violation of NEV. REV. STAT. ANN. § 357.040(1)(b).

464. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of Nevada or one of its political subdivisions, in violation of NEV. REV. STAT. ANN. § 357.040(1)(g).

465. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

466. As a result of Defendants' actions, as set forth above, the State of Nevada or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII

VIOLATION OF THE STATE OF NORTH CAROLINA FALSE CLAIMS ACT, N.C. GEN. STAT. § 1-605, *et seq.*

467. Plaintiff-Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

468. This is a civil action brought by Plaintiff-Relator on behalf of the State of North Carolina against Defendants under the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605.

469. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented a false claim for payment or approval, in violation of N.C. GEN. STAT. § 1-607(a)(1).

470. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used false records or statements to obtain payment or

approval of claims by the State of North Carolina or its political subdivisions in violation of N.C. GEN. STAT. § 1-607(a)(2).

471. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, 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 to the State of North Carolina or one of its political subdivisions, in violation of N.C. GEN. STAT. § 1-607(a)(7).

472. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

473. As a result of Defendants' actions, as set forth above, the State of North Carolina or its political subdivisions have been severely damaged.

COUNT XXIV

VIOLATION OF STATE OF OKLAHOMA MEDICAID FALSE CLAIMS ACT, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

474. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

475. This is a civil action brought by Plaintiff-Relator, in the name of the State of Oklahoma, against Defendants pursuant to the State of Oklahoma Medicaid Fraud False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

476. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a

false statement or misrepresentation of material fact on an application for any benefit or payment under the Oklahoma Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

477. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

478. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

479. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

480. The State of Oklahoma or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

481. As a result of Defendants' actions, as set forth above, the State of Oklahoma or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXV

VIOLATION OF STATE OF RHODE ISLAND FALSE CLAIMS ACT, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*

482. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

483. This is a civil action brought by Plaintiff-Relator, in the name of the State of Georgia, against Defendants pursuant to the State of Rhode Island Fraud False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*

484. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Rhode Island Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

485. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

486. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

487. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

488. The State of Rhode Island or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

489. As a result of Defendants' actions, as set forth above, the State of Rhode Island or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVI

VIOLATION OF THE STATE OF TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE ANN. § 71-5-181 *et seq.*

490. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

491. This is a civil action brought by Plaintiff-Relator in the name of the State of Tennessee against Defendants under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-183(a).

492. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee a claim for payment under the Medicaid program knowing it was false or fraudulent, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(A).

493. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(B).

494. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, relative to the Medicaid program, with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(D).

495. The State of Tennessee, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and

may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

496. As a result of Defendants' actions, as set forth above, the State of Tennessee has been, and may continue to be, severely damaged.

COUNT XXVII

VIOLATION OF THE STATE OF TEXAS HUMAN RESOURCES CODE, TEX. HUM. RES. CODE § 36.001 *et seq.*

497. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

498. This is a civil action brought by Plaintiff-Relator in the name of the State of Texas against Defendants under the State of Texas Human Resources Code, Medicaid Fraud Prevention Chapter, TEX. HUM. RES. CODE § 36.101(a).

499. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for a contract, benefit or payment under a Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(1).

500. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact that is intended to be used, and has been used, to determine a person's eligibility for a benefit or payment under the Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(2).

501. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of TEX. HUM. RES. CODE § 36.002(4)(B).

502. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made a claim under the Medicaid program for a service or product that was inappropriate, in violation of TEX. HUM. RES. CODE § 36.002(7)(C),

503. The State of Texas, its political subdivisions or the Department, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

504. As a result of Defendants' actions, as set forth above, the State of Texas, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXVIII

VIOLATION OF THE COMMONWEALTH OF VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA CODE ANN. § 8.01-216.1, *et seq.*

505. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Complaint as though fully set forth herein.

506. This is a civil action brought by Plaintiff-Relator on behalf of the Commonwealth of Virginia against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.5, *et seq.*

507. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth, a false or fraudulent claim for payment or approval, in violation of VA. CODE ANN. § 8.01-216.3(A)(l).

508. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(2).

509. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(7).

510. The Commonwealth of Virginia, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

511. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXIX

VIOLATION OF THE STATE OF WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE, WIS. STAT. § 20.931 (2007), *et seq.*;

512. Plaintiff-Relator incorporates by this reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

513. This is a civil action brought by Plaintiff-Relator on behalf of the State of Wisconsin against Defendant under the State of Wisconsin False Claims for Medical Assistance, WIS. STAT. § 20.931 (2007), *et seq.*;

514. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the state, a false or fraudulent claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(a) (2007).

515. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(b).

516. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly conspired, and may still be conspiring, to defraud the state by obtaining allowance or payment of

a false claim for medical assistance; or knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program, in violation of WIS. STAT. § 20.931(2)(C).

517. The State of Wisconsin, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

518. As a result of Defendant' actions, as set forth above, the State of Wisconsin, its political subdivisions or the Department has been, and may continue to be, severely damaged.

WHEREFORE, Plaintiff-Relator pray for judgment against Defendants as follows:

a. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729, *et seq.*; ARK. CODE ANN. § 20-77-901, *et seq.*, CAL. GOV'T. CODE § 12650, *et seq.*, 2009 Conn. Pub. Acts No. 09-5, *et seq.*, DEL. CODE ANN. tit. 6, § 1201, *et seq.*, D.C. CODE ANN. § 2-308.13, *et seq.*, FLA. STAT. ANN. § 68.081, *et seq.*, GA. CODE ANN. § 49-4-168, *et seq.*, HAW. REV. STAT. § 661-21, *et seq.*, IND. CODE ANN. § 5-11-5.5, *et seq.*, 740 ILL. COMP. STAT. ANN. § 1751, *et seq.*, LA. REV. STAT. § 437.1, *et seq.*, MASS. LAWS ANN. Ch. 12, §5A, *et seq.*, MICH. COMP. LAWS SERV. § 400.601, *et seq.*, MONT. CODE ANN. § 17-8-401, *et seq.*, N.H. REV. STAT. ANN. § 167:61-b, *et seq.*, N.J. STAT ANN. § 265, *et seq.*, N.M. STAT. ANN. § 27-14-1, *et seq.*, N.Y. CLS ST. FIN. § 187, *et seq.*, NEV. REV. STAT. ANN. § 357.010, *et*

seq., N.C. GEN. STAT. § 1-605, *et. seq.,* OKLA. STAT. tit. 63, § 5053, *et seq.*, R.I. GEN. LAWS § 9-1,1-1, *et seq.*, TENN. CODE ANN. § 71-5-181, *et seq.*, TEX. HUM. RES. CODE § 36.001, *et seq.*, VA. CODE ANN. § 8.01-216.1, *et seq.*, and WIS. STAT. § 20.931 (2007), *et seq.;*

b. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

c. That Plaintiff-Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h), ARK. CODE ANN. § 20-77-911, CAL. GOV'T. CODE § 12652(g), 2009 Conn. Pub. Acts No. 09-5 § 5 (e), DEL. CODE ANN. tit. 6, § 1205, D.C. CODE ANN. § 2-308.15(f), FLA. STAT. ANN. § 68.085, GA. CODE ANN. § 49-4-168, HAW. REV. STAT. § 661-27, IND. CODE ANN. § 5-11-5.5-6(a), 740 ILL. COMP. STAT. ANN. 175/4(d), LA. REV. STAT. § 439.4, MASS. GEN. LAWS ch. 12, § 5F, MICH. COMP. LAWS SERV. § 400.610a(9), MONT. CODE ANN. § 17-8-410, N.H. REV. STAT. ANN. § 167:61-e, N.J. STAT ANN. § 265, N.M. STAT. ANN. § 27-14-9, N.Y. CLS St. Fin. § 190.6., NEV. REV.

STAT. ANN. § 357.220, N.C. GEN. STAT. § 1-607(a), OKLA. STAT. tit. 63, § 5053, R.I. GEN. LAWS § 9-1,1-1, TENN. CODE ANN. § 71-5-183, TEX. HUM. RES. CODE § 36.110, VA. CODE ANN. § 8.01-216.7, and WIS. STAT. § 20.931;

d. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Arkansas or its political subdivisions multiplied as provided for in ARK. CODE ANN. § 20-77-903(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by ARK. CODE ANN. § 20-77-903(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Arkansas or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

e. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in CAL. GOV'T. CODE § 12651(a), plus a civil penalty of no more than ten thousand dollars ($10,000) per claim as provided by CAL. GOV'T. CODE § 12651(a), to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

f. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the Government of the State of Connecticut multiplied as provided for in 2009 Conn. Pub. Acts No. 09-5 § 2(b), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Pub. Acts No. 09-5 § 2(b), to the extent such multiplied penalties shall fairly compensate the Government of the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

g. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the Government of the State of Delaware multiplied as provided for in DEL. CODE ANN. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five- hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Delaware False Claims and Reporting Act, as provided by DEL. CODE ANN. tit. 6, § 1201(a), to the extent such multiplied penalties shall fairly compensate the Government of the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

h. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. CODE ANN. § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. CODE ANN. § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

i. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in FLA. STAT. ANN. § 68.082, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by FLA. STAT. ANN. § 68.082, to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

j. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in GA. CODE ANN. § 49-4-168, plus a civil penalty of not less than fifteen (15) percent or more

than twenty five (25) percent of the proceeds per claim as provided by GA. CODE ANN. § 49-4-168.2, to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

k. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in HAW. REV. STAT. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by HAW. REV. STAT. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

l. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in IND. CODE ANN. § 5-11-5.5-2, plus a civil penalty of at least five thousand dollars ($5,000) as provided by IND. CODE ANN. § 5-11-5.5-2, to the extent such multiplied penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

m. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 ILL. COMP. STAT, ANN. 175/3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000), and the costs of this civil action brought to recover such damages and penalty, as provided by 740 ILL. COMP. STAT. ANN. 175/3(a), to the extent such multiplied penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

n. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in LA. REV. STAT § 438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by LA. REV. STAT § 438.6(B)(I), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by LA. REV. STAT § 438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by LA. REV. STAT. § 438.6(C)(l)(b), to the extent such

multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

o. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MASS. LAWS ANN. ch. 12, 65B, multiplied as provided for in MASS. LAWS ANN. ch. 12, § 5B, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to MASS. LAWS ANN, ch. 12, 5B, to the extent such multiplied penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

p. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MICH. COMP. LAWS SERV. §§ 400.603-400.606, 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants,

together with penalties for specific claims to be identified at trial after full discovery;

q. That judgment be entered in Plaintiff's favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MONT. CODE ANN. § 17-8-403(2), multiplied as provided for in MONT. CODE ANN. § 17-8-403(2), plus a civil penalty of up to ten thousand dollars ($10,000) for each false claim, pursuant to MONT. CODE ANN. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

r. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of New Hampshire or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.H. REV. STAT. ANN. § 167:6111, multiplied as provided for in N.H. REV. STAT. ANN. § 167:61II, plus a civil penalty of two thousand dollars ($2,000) for each false claim, pursuant to REV. STAT. ANN. § 167:61II, to the extent such multiplied penalties shall fairly compensate the State of New Hampshire or its political subdivisions for losses resulting from the

various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

s. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. STAT. ANN. § 265, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by N.J. STAT. ANN. § 265, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

t. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. STAT. ANN. § 27-14-4, multiplied as provided for in N.M. STAT. ANN. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after fill discovery;

u. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or

indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. CLS St. Fin. § 189.1., multiplied as provided for in N.Y. CLS St. Fin. § 189.1., plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. CLS St. Fin. § 189.l., to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

v. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in NEV. REV. STAT. ANN. 357.040, multiplied as provided for in NEV. REV. STAT. ANN. § 357.040(1), plus a civil penalty of not less than two thousand dollars ($2,000) or more than ten thousand dollars ($10,000) for each act, pursuant to NEV. REV. STAT. ANN. § 357.040, to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

w. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of North Carolina or its agencies multiplied as provided for in N.C. GEN. STAT. §

1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. GEN. STAT. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

x. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in OKLA. STAT. tit. 63, § 5053, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by OKLA. STAT. tit. 63, § 5053.4, to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

y. That judgment be entered in Plaintiff-Relator's favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. GEN. LAWS § 9-1,1-1, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by R.I. GEN. LAWS § 9-1,1-4, to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses

resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

z. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in TENN. CODE ANN. § 71-5-182, multiplied as provided for in TENN. CODE ANN. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) pursuant to TENN. CODE ANN. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

aa. That judgment be entered in Plaintiff-Relator's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in TEX. HUM. RES. CODE § 36.052(a)(l), multiplied as provided for in TEX. HUM. RES. CODE § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to TEX. HUM. RES. CODE § 36.052(a)(2), plus a civil penalty of not less than five thousand

dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to TEX. HUM. RES. CODE § 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

bb. That judgment be entered in Plaintiff's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in VA. CODE ANN. § 8.01-216.3(A), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by VA. CODE ANN. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

cc. That judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in WIS. STAT. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by WIS. STAT. § 20.931(2), to the

extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

dd. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

ee. That judgment be granted for Plaintiff-Relator against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Plaintiff-Relator in the prosecution of this suit; and

ff. That Plaintiff-Relator be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff-Relator demands a trial by jury of all issues so triable.

Dated: February 24, 2010

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