FILED UNDER SEAL

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PLAINTIFFS UNDER SEAL	)	Civil Action No. 07-10304
	)	Judge Nancy Gertner
v.	)	
	)	**FILED UNDER SEAL**
DEFENDANT UNDER SEAL	)	**JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
31 U.S.C. § 3729, ET SEQ.

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. DAVID FARBER and CASEY SCHILDHAUER, and on behalf of the STATES of ARKANSAS, CALIFORNIA, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, TEXAS, and VIRGINIA, Plaintiffs, v. PFIZER, INC., Defendant.	Civil Action No. 07-10304 Judge Nancy Gertner **FILED UNDER SEAL** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
31 U.S.C. § 3729, *et seq*.

This is an action brought on behalf of the United States of America and state and local governments, by David Farber and Casey Schildhauer, by and through their attorneys, Robins, Kaplan, Miller & Ciresi, L.L.P, against Defendant Pfizer Incorporated, pursuant to the *qui tam* and retaliation provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; the Arkansas Medicaid Fraud False Claims Act, ARK. CODE ANN. § 20-77-901 (2007), *et seq.*; the California False Claims Act, CAL. GOV'T CODE § 12650 (Deering 2000), *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 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. § 17-8-401 (2005), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New 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 Tennessee False Claims Act, TENN. CODE ANN. § 4-18-104(g) (2006), *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.*; and the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 (2006), *et seq.*, ("State *qui tam* statutes" or "*Qui Tam* States").

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345.

2. This Court has personal jurisdiction over the Defendant because, among other things, the Defendant transacts business in this District, and Defendant engaged in wrongdoing in this District.

3. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendant transacts business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

4. The causes of action alleged herein are timely brought because, among other things, of efforts by the Defendant to conceal from the United States their wrongdoing in connection with the allegations made herein.

II. PARTIES

5. Plaintiff/Relator David Farber ("Relator Farber") is a resident of Iowa City, Iowa, and is a former employee of Pfizer, Inc. In 1999, Faber joined Parke-Davis as a Territory Manager in Des Moines, Iowa. After the Parke-Davis and Pfizer merger in 2000, Relator Farber took a position with Pfizer as a Professional Healthcare Representative ("PHR"), a general sales representative responsible for promoting or detailing certain drugs to healthcare professionals. In 2003, Relator Farber became a Specialty Representative, responsible for detailing drugs such as Bextra® and Celebrex® to medical specialists (*e.g.*, neurologists, anesthesiologist, and orthopedic surgeons). During his almost eight (8) year tenure with Pfizer, Relator Farber was the recipient of numerous sales awards. Relator Farber has provided the government with information and documents prior to the filing of this complaint in accordance with 31 U.S.C. § 3730(b)(2). Relator Farber is an original source of this information, and this complaint is not based upon publicly disclosed information. Prior to filing this complaint, Relator Farber brought the wrongdoing described in this Complaint to the attention of Pfizer. As a result of Relator Farber's whistle-blowing activities, Pfizer retaliated against Relator Farber in violation of 31 U.S.C. § 3730(h).

6. Plaintiff/Relator Casey Schildhauer ("Relator Schildhauer") is a resident of West Hollywood, California, and is employed by Pfizer, Inc. Relator Schildhauer joined Pfizer on October 8, 2004 as a PHR promoting (or "detailing") Pfizer drugs to prescribers and pharmacies. Relator Schildhauer detailed a number of Pfizer drugs, including Bextra®, Celebrex® and Zoloft®, based out of the Iowa City, Iowa regional sales area, and later, Pfizer's Los Angeles regional sales area. Relator Schildhauer also detailed Lyrica® to physicians. Relator Schildhauer was relocated to Los Angeles in September, 2006, where he continued to detail Pfizer drugs, including Lyrica®. Relator Schildhauer has provided the government with information and documents prior to the filing of this complaint in accordance with 31 U.S.C. § 3730(b)(2). Relator Schildhauer is an original source of this information, and this complaint is not based upon publicly disclosed information. Prior to filing this complaint, Relator Schildhauer brought the wrongdoing described in this Complaint to the attention of Pfizer. As a result of Relator Schildhauer's whistleblowing activities, Pfizer retaliated against Relator Schildhauer in violation of 31 U.S.C. § 3730(h), transferred Relator Schildhauer to another state, and then terminated him on March 27, 2007.

7. Defendant Pfizer, Inc. ("Pfizer") is incorporated under the laws of Delaware, with its principal place of business in New York, New York. Pfizer is engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products throughout the United States. Throughout the relevant period, Pfizer manufactured and sold substantial quantities of its drugs products, including Lyrica®, in Massachusetts and in the United States, during which time Pfizer was operating under a Corporate Integrity Agreement entered into with the United States Department of Health and Human Services Office of Inspector General. Pfizer

employs approximately 12,000 sales representatives located across the United States whose function is to promote, market or otherwise sell Pfizer drugs.

III. SUMMARY OF PFIZER'S ILLEGAL CONDUCT

8. As described in greater detail below, Defendant Pfizer manufactures, markets and sells the brand-name prescription drug product Lyrica®, generic name pregabalin. From the outset of Lyrica®'s marketing and sales launch in 2005, Pfizer engaged in a deliberate and illegal marketing campaign to bolster sales by making unsubstantiated efficacy claims, comparing it to drugs like gabapentin and Keppra® although no head-to-head pharmacokinetic studies were conducted. Additionally, Pfizer promoted Lyrica® for non-FDA approved uses and made sales presentations that over-emphasized or exaggerated Lyrica's benefits while minimizing or neglecting to mention the drugs' substantial side effects.

9. Defendant Pfizer manufactures, markets and sells brand-name prescription drug products, including Lyrica®, 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 "federally funded health insurance programs" or "Federal Programs").

10. Following its launch in 2005, in 2006, Lyrica® quickly became a blockbuster drug for Pfizer, with sales revenue of $1.2 billion. At all relevant times, Pfizer knew that Lyrica® was and is being paid or reimbursed by Federal Programs. Lyrica® is Pfizer's follow-on brand-name drug product to Neurontin®, which began facing generic competition and decreased sales in 2004.

11. Pfizer may lawfully market Lyrica® in a number of ways, including the dissemination of truthful information that complies with federal law. Once a drug is approved by the FDA for a certain use, it must be promoted by the manufacturer for that use, and that use only. Pfizer obtained FDA approval of Lyrica® on December 30, 2004 to treat post-herpetic neuralgia (shingles) and diabetic peripheral neuropathy, and on June 10, 2005 as an add-on treatment for adult patients with partial onset seizures. After its approval, Pfizer could only promote Lyrica® to treat those FDA-approved conditions. At no time could Pfizer lawfully promote Lyrica® for any other non-FDA approved purpose.

12. In violation of federal law, Pfizer knowingly and deliberately promoted Lyrica® for non-FDA approved uses ("off-label" uses) that Pfizer knowingly and deliberately knew, or was reasonably foreseeable, would lead to violations of federal Medicaid statutes and regulations designed to restrict reimbursement to Federal Programs such as Medicaid. Pfizer knew, or it was reasonably foreseeable, that its promotion of Lyrica® would lead to the submission by physicians, pharmacists and government-funded health plans of Lyrica® prescriptions not eligible for reimbursement. For example, Pfizer provided its sales force with targeted literature describing Pfizer's "Lyrica Government Relation Managers," who were located at Pfizer headquarters and in the field. Not surprisingly then, for example, Pfizer promoted Lyrica® at the University of Iowa Hospitals and Clinics, where Pfizer knew a high density of Medicaid patients

were treated, and to the Veteran's Administration Hospital in Iowa City, Iowa, where Pfizer knew, or it was reasonably foreseeable, that Pfizer drugs such as Lyrica® would be reimbursed under the VA program, and promoted Lyrica® to numerous physicians such as Dr. Winthrop Risk, II and Dr. Mark Fortson in Cedar Rapids, Iowa, who treat a high density of Medicaid patients. Pfizer also specifically targeted VA Hospitals and Clinics.

13. In violation of federal law, Pfizer knowingly and deliberately falsely promoted Lyrica® by the use of unsubstantiated comparative claims, comparing Lyrica® with gabapentin and with Keppra®, an anti-epileptic drug manufactured by UCB Pharma, Inc. These unsubstantiated, comparative claims are prohibited by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 352, and 21 CFR 202.1(e)(6), as well as Pfizer's own internal sales policies. The use of unsubstantiated comparative claims renders a drug "misbranded" by the FDA. Pfizer promoted these Lyrica® falsehoods to physicians to induce physicians to prescribe Lyrica®. Once Lyrica® became "misbranded" it was no longer eligible for reimbursement by Federal Programs, including Medicaid.

14. Additionally, Pfizer was required to provide fair and balanced information whenever it engaged in promotional activities. Fair and balanced promotional activities include written materials, as well as, oral presentations. According to federal regulations and industry standards and practices, "fair and balanced" means that whenever Pfizer made representations about Lyrica's efficacy, they were required to also make statements about the drug's side effects. In addition, according to Pfizer's sales and marketing practices guide titled *The Field Guide*, in order to make claims concerning the superiority of Lyrica®, "the claims must have been supported by at least two adequate, well-controlled studies in which were compared head-to-head using comparable dosage regimens or a single, large, well-controlled study. . . . [I]t is not

appropriate to make comparative claims based on the data in the products' package inserts. Similarly, because of the differences in trial designs, inclusion criteria and other factors, it is not permissible to compare results from two non-comparable trials."

15. In violation of federal law, Pfizer, on innumerable occasions, knowingly and deliberately failed to give fair and balanced presentations on Lyrica®. These false superiority claims about Lyrica®'s efficacy were made without "substantial evidence" to support such claims. As such, any statements about Lyrica®'s effectiveness were false, misleading, distorted, inaccurate, unfair, imbalanced and omitted material facts Pfizer was required to disclose.

16. For example, Pfizer representatives have regularly engaged in "Compare and Win" presentations to physicians concerning Lyrica®'s superiority to gabapentin, to Keppra®, as well as comparisons to other competing products, by making false comparisons in the absence of any adequate, well-controlled head-to-head studies for such claims.

17. Pfizer is well aware of the legal restrictions placed on drug promotion. In 1995, its Warner-Lambert division pled guilty to distributing misbranded and unapproved new drugs related to good manufacturing practices ("GMP") violations. In the government Neurontin® settlement in 2004, Pfizer paid $430 million – the largest settlement for an off-label promotion case – to resolve charges related to marketing practices for Neurontin®. Although GMP issues are a distinct regulatory area from promotional policies, in both cases the company faced the same fundamental charge: violating the FD&C Act by introducing unapproved new drugs into commerce. According to the Neurontin® guilty plea: "After previously having been convicted of violating the FD&C Act, Warner-Lambert distributed Neurontin® intended for unapproved uses, causing the drug to be misbranded."

18. In January 2005, Pfizer was again reprimanded by the FDA because Pfizer promoted Celebrex® and Bextra® in materials that contained misleading claims of safety and unsubstantiated claims of superiority and effectiveness, and also omitted material facts, including indication and risk information. Pfizer has received additional warnings from the FDA for other products, such as Viagra®, Zyvox®, Zoloft®, Zyrtec®, and Geodon®. Coupled with its prior guilty pleas and misbranding violations, Pfizer's conduct as alleged in this complaint evidences a flagrant disregard for the FDA's rules and regulations.

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

20. Pfizer's illegal marketing campaign was in deliberate disregard of, violated, and continues to violate, the terms of the Corporate Integrity Agreement ("CIA").

21. Plaintiffs/Relators informed Pfizer's management and others of Pfizer's illegal activity. As a result of these whistle-blowing activities, Plaintiffs/Relators have been discharged, demoted, suspended, threatened, harassed and/or discriminated against.

IV. THE REGULATORY SCHEME THAT RESTRICTS THE PROMOTION AND REIMBURSEMENT OF LYRICA®

22. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the pharmaceutical has proven to the Food and Drug Administration (FDA) that the drug is safe and effective for specific indications at specified dosages. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to prescribe approved drugs for

indications or at dosages different than those set forth in a drug's labeling, The Food, Drug, and Cosmetic Act prohibits drug companies from marketing or promoting approved drugs for uses other than those set forth in the drugs' approved labeling. This regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body.

23. Federal Programs, including the Medicaid program, also rely on the FDA's findings regarding what uses for approved drugs are safe and effective. Whether a drug 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 program.

24. 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 compendia set forth in the Medicaid statute. 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). Subsection (k)(6) goes on to define a medically accepted indication as one which is approved under the Food, Drug, and Cosmetic Act.

25. Violation of FDA's restrictions on misleading and off-label promotion may result in governmental action. In May, 2004, Pfizer entered into a CIA with the United States Office of Inspector General of the Department of Health and Human Services. Pfizer signed the CIA in connection with the settlement of allegations that it engaged in illegal off-label marketing of its drug product Neurontin® (the "Neurontin CIA"). In October, 2002, Pfizer had earlier entered into another CIA that, like the Neurontin CIA, incorporated compliance with federal law

measures. The Neurontin CIA expressly incorporated measures aimed at prohibiting Pfizer from future promotion of its products for off-label uses. Pfizer's conduct as described herein constitutes flagrant, intentional and material breaches of the Neurontin CIA. Moreover, the Neurontin CIA also required Pfizer to certify compliance, and to report to the government "reportable events" which is defined in the Neurontin CIA as:

> anything that involves a matter, brought to the attention of senior management at Pfizer'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. . . .

Plaintiffs/Relators allege upon information and belief that Pfizer knowingly failed to completely and truthfully certify compliance with the Neurontin CIA, and failed to completely and truthfully report "reportable events," all as required by the Neurontin CIA. As a result, Pfizer has presented or caused to be presented to the United States a false certification or claim under 31 U.S.C. § 3729 et seq.

26. As described below, Pfizer began its off-label promotion and misbranding of Lyrica® immediately after it began selling the drug in August, 2005, and upon information and belief continues to illegally promote Lyrica®, thereby intentionally and knowingly violating the regulatory schemes described above, as well as intentionally and knowingly violating the terms of the Neurontin CIA. When Pfizer decided to employ these illegal marketing 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 Lyrica® prescriptions. But for Pfizer's illegal promotion, these off-label and misbranded prescriptions for Lyrica® would not have been written. As a result, Pfizer caused the submission of false claims

to Federal Programs for reimbursement of Lyrica®. Pfizer was the beneficiary of these false claims for reimbursement of Lyrica® prescriptions.

27. In addition, the federal Medicare and Medicaid Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), also regulates the promotion of prescription drugs that are reimbursed by Federal Programs. Under the Anti-Kickback Act, any form of remuneration, in cash or in kind, paid by Pfizer to an individual such as a physician to induce the use of Pfizer drug products that are reimbursed by Federal Programs, including Medicare or Medicaid, is illegal. But for the payment of a kickback, Federal Programs would not have otherwise paid for the product tainted by the kickback, thereby causing financial loss to the United States. Pfizer violated the Anti-Kickback Act as described below.

V. PFIZER'S ILLEGAL PROMOTION OF LYRICA®.

28. Pfizer knew from its Neurontin® experience that promoting a drug product for as many indications as possible would result in dramatically increased sales of its follow-on drug product, Lyrica®. In the case of Neurontin®, approximately 70% to 90% of its sales were reportedly for off-label use, and had resulted in annual sales of nearly $3 billion per year at the time the first generic came on the market in 2004. Upon information and belief, Pfizer intended to replicate its Neurontin® success with Lyrica®, Neurontin's follow-on branded drug product in the anti-epileptic drug ("AED") class.

29. Replacing the revenue lost by competition to Neurontin® was critical for Pfizer once Neurontin® lost its patent protection, and generic gabapentin started flooding the market beginning in 2004. Thus, Pfizer developed Lyrica® to replace the revenue lost by Neurontin®.

30. On August 18, 2004, generic manufacturer Ivax announced it had launched "at risk" its generic version of Pfizer's Neurontin®, gabapentin, in 100 mg, 300 mg and 400 mg

strengths. Pfizer had originally intended to launch Lyrica® prior to generic competition for gabapentin. However, according to reports in the "Pink Sheet" dated August 23, 2004, the Lyrica® New Drug Application ("NDA") filing had been delayed at least three years by a number of issues, including carcinogenicity and toxicological data, FDA's determination that Lyrica® would be a Schedule V controlled drug (due to its potential for euphoric effects, abuse, and dependence), and whether the FDA would approve Lyrica® generalized anxiety disorder (*i.e.*, "GAD"). The FDA gave Pfizer a not-approvable for GAD in 2004.

31. On December 31, 2004, the FDA approved Lyrica® for treating two conditions: (1) Diabetic Peripheral Neuropathy ("DPN" -- diabetic nerve pain); and (2) Post Herpetic Neuralgia ("PHN" -- pain associated with shingles). According to the Pfizer Lyrica® website, these two conditions were to be treated with Lyrica® "just to treat the burning, stabbing, shooting symptoms of nerve pain caused by diabetes or shingles." On June 13, 2005, Lyrica® was approved by the FDA as an adjunct therapy to treat partial onset seizures in adults with epilepsy. The most common side effects of Lyrica® include dizziness, somnolence, dry mouth, peripheral edema, blurred vision, weight gain, and difficulty with concentration/attention.

32. Not only did Pfizer face the challenge of getting physicians to prescribe Lyrica® instead of the gabapentin, which began flooding the market, it faced a new challenge with the introduction by competitors of products in the category, particularly Eli Lilly's drug Cymbalta®, which was approved by the FDA for major depressive disorder and diabetic peripheral neuropathy on August 3, 2004, and UCB's drug Keppra®, which is FDA-approved as an adjunctive treatment for partial onset seizures in adults and children four (4) years of age, myoclonic seizures in adults, and primary generalized tonic-clonic seizures in adults and children six (6) years of age and older with idiopathic generalized epilepsy. There were also reports that

Lilly was pursuing fibromyalgia and generalized anxiety disorder indications for Cymbalta® as well. *See* "Pink Sheet," December 20, 2004, p.19.

33. In addition, by 2004, the company had experienced a series of failed drug product launches with the Geodon® launch in 2001, the Relpax® launch in 2003, the Inspra® launch in 2003 all failing miserably. In order to deal with these series of failed launches, as well as declining revenues, Pfizer began an austerity program, including closing manufacturing plants around the world. Moreover, in December, 2004, the company faced a loss of $14 billion due to loss of patents on key products during 2005 through 2007.

34. On information and belief, it thus became vitally important for Pfizer to have a very successful launch of Lyrica®, not only to shore up lost revenues and move market share from its loss of patent exclusivity for Neurontin®, but also to fend off the challenge from Cymbalta® and Keppra®, particularly for new indications for which Pfizer had attempted, but failed, to receive FDA approval -- *i.e.*, fibromyalgia and generalized anxiety disorder.

35. Armed with FDA approval, Pfizer placed Lyrica® on the market. However, given the limited indications approved by the FDA and intense competition, Pfizer faced only limited market potential for Lyrica®'s approved uses. Nonetheless, the company made the calculated business decision to replicate Neurontin®'s success by the illegal off-label marketing and misbranding of Lyrica®. Thus, Pfizer implemented its illegal Lyrica® promotional programs with the formal launch of the drug in September 2005.

36. One of Pfizer's goals to increase Federal Program payments for Lyrica®, which Pfizer communicated to Relators and the rest of the Pfizer sales force, was to convert every gabapentin prescription to a Lyrica® prescription, including those Neurontin® prescriptions that were written for off-label uses as a result of Pfizer's prior illegal promotion of Neurontin®. To

accomplish the Lyrica® for gabapentin conversion goal, Pfizer deliberately promoted Lyrica® as being more effective than gabapentin, knowing no head-to-head efficacy studies comparing the two drugs were available. Beginning shortly after the launch in 2005, Pfizer disseminated false and misleading promotional literature to its sales force and the medical community, including marketing materials, comparing Lyrica® to gabapentin, and thereby misbranded Lyrica® in violation of the FD&C Act.

37. Similarly, Pfizer deliberately promoted Lyrica® as being more effective in reducing seizures than Keppra® although no head-to-head pharmacological studies comparing the drugs have been conducted. What makes this promotion even more egregious is that Keppra® is FDA-approved as adjunctive therapy to treat several different forms of epilepsy in adults as well as children (as explained above), while Lyrica® is only approved as adjunctive treatment for one form of epilepsy in adults.

38. Pfizer instructed representatives they were not to mention, or in any way highlight or draw attention to the fact, that the Lyrica® study on which Pfizer relied to make it its unsubstantiated and deliberately misleading head-to-head comparisons, was a study for partial onset seizures in adults, the only epileptic condition for which Lyrica® is an FDA-approved treatment. In this way, Pfizer used deception to purposefully and intentionally mislead doctors and other healthcare professionals to believe that Lyrica® treated the same types of epilepsy as Keppra®. Pfizer representatives were trained to, and did, use "Pfizer math" to intentionally create the false impression that there had been head-to-head comparisons between Keppra® and Lyrica® showing Lyrica®'s superiority when there were no such studies.

39. Moreover, Pfizer's illegal promotion also included off-label promotion of Lyrica® through the use of various programs. These programs included (1) targeting physicians

who do not treat the FDA-approved uses, such as psychiatrists and orthopedists; (2) explicit and implicit directions to Pfizer's sales representatives to market Lyrica® off-label; (3) providing free Lyrica® vouchers to induce physicians to prescribe Lyrica® off-label; and (4) payments to speakers and Pfizer medical specialists to promote Lyrica® off-label.

40. In addition to directing sales representatives to promote Lyrica® for the treatment of any kind of pain, some of the conditions which Pfizer has promoted Lyrica® for off-label use include migraine headaches, spinal pain, and fibromyalgia.

41. To bolster its illegal promotion of Lyrica® to physicians, Pfizer paid monies to its identified "thought leaders" – *i.e.*, heavy Neurontin® prescribers who were also Pfizer speakers in order to induce them to recommend Lyrica® for addition to formularies, including Medicaid formularies.

42. Pfizer's illegal promotional campaign included the following:

a. Directing sales representatives to discuss with physicians Lyrica®'s efficacy relative to gabapentin and other drugs in the absence of pharmacokinetic, peer-reviewed studies supporting such claims;

b. Using promotional materials provided to all Pfizer sales representatives with improper and unsupported side-by-side claims of the efficacy of Lyrica® in comparison with gabapentin in the absence of pharmacokinetic, peer-reviewed studies supporting such claims;

c. Using Pfizer-sponsored studies (including the *Dworkin* and *French* studies) which raised additional non-FDA approved indications ("secondary endpoints"), as additional uses for Lyrica®, including as an aid for sleep disorders;

d. Directing sales representatives to contact orthopedists, reconstructive surgeons, psychiatrists, and numerous other physicians who do not treat patients with any of the conditions for which Lyrica® is approved, and whose only reason for being contacted was that they had been off-label prescribers of Neurontin®;

e. Using a sales pitch which "required" sales representatives to tout Lyrica® for treatment of "any kind of pain" despite it only being FDA-approved for neuropathic pain associated with PHN and DPN, and as adjunct therapy for adult onset epilepsy;

f. Using relationships with "thought leaders" (many of who had been heavy off-label prescribers of Neurontin®) who were recipients of significant speaker fees, research grants, and other Pfizer monies to influence their recommendations for the addition of Lyrica® to formularies, including Medicaid formularies;

g. Providing "Do Not Detail" off-label materials to marketing representatives, which Pfizer intended would in fact be used in the off-label promotion of Lyrica®, including materials touting the use of Lyrica® for the treatment of fibromyalgia;

h. Directing off-label sales promotion to psychiatrists not be logged into the Pfizer sales databases so they could not be tracked as off-label sales promotions;

i. Using "insell" off-label marketing pitches to hospital physicians, including psychiatrists for treatment of pain, which cannot be tracked as being off-label in the Pfizer databases; and

j. Paying speakers and "medical specialists" to promote Lyrica® off-label.

VI. SPECIFIC ALLEGATIONS

Sales and Marketing Claims: Off-Label Promotion of Lyrica® and Unsupported Comparative Claims of Superiority to Gabapentin.

1. The Company Knew the Risks Related to Off-Label Promotion of Lyrica®.

43. There is no doubt that, following the Neurontin® criminal plea and Neurontin CIA, Pfizer and its sales representatives have been clearly aware of the legal risks the Company takes if it chooses to illegally market drug products. For example, Pfizer has issued to all its sales representatives a compliance manual entitled *The Field Guide*, the Pfizer drug representative's "bible" on all compliance issues (also called the "Orange Manual" by company

employees). *The Field Guide* describes how the sales force is expected to conduct itself when marketing a product, including what constitutes a clear violation of Pfizer policy and federal law.

44. *The Field Guide* again specifically makes clear that sales representatives must stay on-label:

> As discussed in the Overview of this Guide, our May 2004 Corporate Integrity Agreement (CIA), arose from allegations concerning the off-label promotion of Neurontin®. Off-label promotion is taken very seriously by Pfizer and the government. In fact, Pfizer is obligated under our CIA to proactively report any instance of off-label promotion to the Office of the Inspector General (OIG).

On the issue of comparative marketing claims, *The Field Guide* states:

> [The] FDA considers promotional materials to be false and misleading if they state or suggest that a drug's safety or effectiveness is comparable or superior to another drug's without 'substantial evidence' to support the claim. A comparative claim generally must be backed up by at least two adequate, well-controlled studies in which the drugs were compared head-to-head using comparable dosage regimens or a single, large, well-controlled study.

With respect to fair and balanced presentation, *The Field Guide* directs:

> All presentations on Pfizer products must include a summary of the relevant safety information in order to "balance" the statements on the product's efficacy. The FDA requires such "fair balance" and it is necessary to make such disclosures to maintain your credibility. The more robust the efficacy statements, the more risk information that needs to be provided in order to balance the information. This means providing the relevant warnings, precautions, side effects and other material information, such as relevant clinical trial exclusion criteria, that are necessary for a prescriber to make an informed decision about whether to prescribe the product.

45. While Pfizer was clearly aware of its compliance obligations regarding sales and marketing of its products, Pfizer senior sales executives deliberately evaded and/or ignored any such limitations in order to increase sales of Lyrica®.

46. As a result of profit pressures related to, among other factors, Pfizer's 2005-2006 loss of patent protection on Zoloft® and Zithromax®, two blockbuster Pfizer drugs in the last

year, and with the recent announcement that the Pfizer pipeline successor to Lipitor®, torcetrapib, had been withdrawn during Phase II studies (due to the deaths of some 88 patients during the trial), Pfizer's senior sales executives were determined to aggressively market Lyrica®, even if it meant engaging in off-label promotion and misbranding.

47. Although sales representatives themselves were provided materials discouraging off-label marketing of Lyrica®, they were encouraged (in fact, required) by the district managers, regional managers, and Pfizer Corporate Sales to engage in company-wide promotions of Lyrica®, which (a) have made unsupported, comparative claims with gabapentin, (b) have made unsupported, comparative claims with Keppra® and (c) have engaged in off-label promotion of Lyrica® for the same off-label uses that made Neurontin®, a blockbuster drug for the Company.

2. The Lyrica® Launch (August 23-September 19, 2005): Making Comparative Efficacy Claims of Lyrica® to Gabapentin.

48. Although, as described above, Lyrica® had been approved for the treatment of PHN and DPN on December 30, 2004 and on June 10, 2005 as an adjunctive therapy for the treatment of adult patients with partial onset of seizures, Pfizer did not choose to launch Lyrica® for widespread marketing and sales until September 12, 2005. Notwithstanding the formal launch date, the Lyrica® sales force began marketing the drug to physicians as early as August 23, 2005, urging them to switch from gabapentin.

49. On or about August 23, 2005, for example, the Cedar Rapids, Iowa region held what is known as a Plan of Attack ("POA") meeting at the Collins Plaza Hotel in Cedar Rapids. POA meetings are sales meetings generally arranged by the district manager. The purpose of these meetings, among other things, is to inform the sales team of new product details, to give

direction regarding strategies and best practices to employ in the sale and marketing of Pfizer drugs, and to focus each individual sales representative on the region's sales goals and how the doctors on the representative's call list fulfill the purposes of the sales strategy. In addition to Relators, in attendance at the meeting were Tracy Lucas ("Lucas"), the district manager of Pfizer's Cedar Rapids office, Kris Beardsley, Mary Callahan, Laurie Russell, Tyler Sondrol, Karen Shields and Jerry McLaughlin.

50. At the meeting, Lucas asked that three local "thought leaders" present their views on the launch of Lyrica®. The three physician-presenters were Dr. Udaya Kabadi, a University of Iowa Hospitals and Iowa City Veteran's Administration Medical Center Endocrinologist (and a frequent speaker on Pfizer products), Dr. Basem Hamid, a frequent lecturer on Pfizer products, and Dr. Mark Fortson.

51. At this pre-launch meeting, Lucas instructed the sales force to talk about how effective Lyrica® was compared to gabapentin (even though no studies had been conducted to prove the drug's efficacy in relation to gabapentin), to talk about the bioavailability of Lyrica® as compared to gabapentin, and to work hard at getting Lyrica® on key formularies.

52. Since this was a pre-launch meeting, the Pfizer-provided marketing materials (other than the package insert) were not yet available. Instead, Lucas provided a copy of the package insert, which the sales team was instructed to use prior to the formal launch date which was on September 12, 2005. According to the Pfizer *Field Guide*, "[t]he only comparison that can be made between package inserts are those based on the fixed properties of the products." However, superiority claims using the package insert were not permissible unless they had been "clinically proven by adequate and well-controlled head-to-head clinical trials." Because no

such trials have ever been completed, Pfizer's pre-launch use of the package insert was a violation of Pfizer's own policy and FDA regulations.

53. Government formularies were key for a successful launch of Lyrica®. Such government formularies included the State of Iowa Medicaid, the University of Iowa Hospitals, and the Iowa City VA Medical Center, because these programs had been heavy users of Neurontin® and (after the generic launch in 2004) of gabapentin, their formularies were very influential in "bandwagon" promotion to other formularies and prescribers.

54. Pfizer sales management from the outset instructed sales representatives to use false and misleading side-by-side "Compare and Win" detail pieces to launch Lyrica®. For example, in the Cedar Rapids, Iowa region, Lucas directed the marketing team that they should use side-by-side promotional "panels" comparing the efficacy profile of Lyrica® to gabapentin. During the pre-launch meeting in August 2005, Relator Schildhauer raised concerns about using the unsubstantiated comparative panels, to which Lucas responded that representatives were to tout that Lyrica® was a "better agent" than gabapentin despite lack of any head-to-head adequate and well-controlled clinical trials.

55. The articulated goals of the August 2005 POA was thus to ensure that the sales representatives were to make sure as many doctors as possible would switch their gabapentin patients to Lyrica® and that representatives were immediately to undertake focused efforts to obtain formulary status on key government formularies – *e.g.*, the University of Iowa and the State of Iowa Medicaid formularies.

56. At the end of the meeting, Lucas instructed the Cedar Rapids sales force to go out and begin selling Lyrica® immediately. Lucas thus directed the team to go after the gabapentin

market share with Lyrica®, using side-by-side comparisons from the package inserts only, misbranding Lyrica® as superior to gabapentin.

57. Two-and-a-half weeks after the POA meeting, on September 12-15, 2005, Pfizer formally launched Lyrica® for widespread sales and marketing. In particular, the Relators attended a meeting in Anaheim, California, with the entire Western Region sales force, with some 4,000 other Pfizer sales representatives in attendance. Pfizer spared no expense for the Lyrica® launch, staging numerous presentations. Among other elaborate presentations, on the stage in one of the conference rooms where the meeting was being held, there was a mammoth fountain of boiling water where singers sang a song called the "Power of Pain." Throughout the meeting, speakers touted the comparison of Lyrica® to gabapentin, telling those present that Lyrica® is "so good it can sell itself."

58. During the launch meeting, Lyrica® launch binders were distributed, which were customized with targeted marketing for each representative, listing particular physicians they were to call on, including:

- "Thought leaders" who included "Lyrica® speakers, Investigators, and Key Opinion Leaders who are experts" on the approved conditions;
- Top 20 account information, sorted by total market sales from May 2004 through April 2005 for Neurontin®;
- "Insell" opportunities for sales to community hospitals – *i.e.*, which provide opportunities to sell off-label to hospitals without the sale being traced in the Pfizer Sherlock database;
- Sales opportunities with governmental accounts such as correctional facilities, Medicaid and VA Hospitals;
- Pain clinics within the representative's region; and

- An "opportunity report" of the top 25 specialty physicians, tracking the gabapentin usage for each.

59. The message from the Anaheim launch meeting to the Pfizer sales force was clear. Representatives were expected to work diligently to get Lyrica® on prominent formularies (especially government formularies), and sell Lyrica® to doctors who had been prescribing gabapentin.

60. This computer system that tracks the representative's calling activity is called "Sherlock" and includes the doctor's name, location, phone number, license number, DEA number, specialty, prescribing patterns, and health plans in which the doctors participate. The Sherlock 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 Pfizer. The Sherlock database is updated regularly, and provides the representatives with the doctors they are to call on – the "call cycle." The representatives enter the results of their calls on Sherlock as part of the tracking system for each doctor, any free samples given to the doctor, information provided to the doctor.

61. Following the Anaheim launch, sales representatives had included on their call cycles in the Sherlock system physicians including psychiatrists who had been Neurontin® writers for potential off-label sales of Lyrica®. Each marketing representative's pre-loaded Pfizer computer included physicians who would have no occasion to treat patients for the on-label conditions for which Lyrica® was approved, including numerous orthopedists, rheumatologists, and psychiatrists. Relator Farber's Pfizer computer, for example, included some 286 doctors, including over 50 orthopedists and numerous psychiatrists.

62. As such, Pfizer planned the call cycles by capturing its actual off-label Neurontin® sales and recycling this as potential off-label sales for Lyrica®.

63. In addition, the sales force was given a generous supply of side-by-side comparative Lyrica® v. gabapentin marketing materials called "Compare and Win" pieces. The marketing pieces presented each drug's indications, the bioavailability of each drug as compared to the other, and Lyrica's efficacy as opposed to gabapentin, even though no studies comparing Lyrica's efficacy to Neurontin's have been conducted.

64. When these pieces were presented to the sales force at the Anaheim meeting, Pfizer sales executives represented to use them immediately because they were unsure how long they would be approved, thus demonstrating that Pfizer knew exactly that use of these materials violated Pfizer policy concerning false and misleading comparative marketing, but that using them was critical to the success of the launch. Thus, it is clear Pfizer supplied these materials for the purpose of having the sales force use them to promote the misbranding of Lyrica®.

3. Making Comparative Efficacy Claims of Lyrica® to Keppra®.

65. Notwithstanding that Lyrica® had been FDA-approved as adjunctive therapy for the treatment of partial onset of seizures in adults, shortly after the Lyrica® launch, Pfizer realized that neurologists who were the most likely to be prescribing Lyrica® on-label were rarely prescribing the drug and instead were using a competing manufacturer's product, Keppra®. In fact, for the treatment of seizures, Keppra® was the drug of choice among many treating neurologists. With this in mind, Pfizer undertook a concerted effort through the use of POA meetings and conference calls to develop specific strategies aimed at unseating Keppra® as the leading treatment for seizures and increasing Lyrica's market share in this area.

66. In furtherance of this strategy, for example, on May 9, 2006, at the Technology Park Hilton in Denver, Colorado, Pfizer's senior sales management directed the Therapeutic Specialty Representatives ("TSRs"), that they were to undertake a "Compare and Win" detail, comparing the purported efficacy of Keppra® to Lyrica®. To do this, Pfizer instructed representatives they were to use seizure reduction data from two separate studies (one for Lyrica® and one for Keppra®) to illustrate Lyrica®'s superiority. According to the directives given, even though there had not been a head-to-head trial, sales representatives were to create the impression for doctors that there had been such a head-to-head trial.

67. According to senior Pfizer sales management (and Pfizer Medical), representatives were to inform doctors the Lyrica® control group experienced a 51% reduction in seizures as opposed to the Keppra® control group which only experienced a 37% reduction in seizures. Not only were these studies not head-to-head, there was no evidence to suggest comparable dosing regimens, common study protocols, trial designs, or inclusion criteria. Because of the differences in trial designs, inclusion criteria and other factors, per *The Field Guide* and FDA regulations, it was "not permissible to compare results from two non-comparable trials."

68. Moreover, by telling doctors Lyrica® was more efficacious than Keppra®, Pfizer was representing that the 51% reduction in seizures in Lyrica® was across the board, meaning the same results would be experienced by *any* patient who was currently taking Keppra®, even if that patient was taking Keppra® for one of the seizure indications for which Lyrica® was not approved.

69. Further, during a conference call with TSR's in October 2006, Pfizer senior sales managers again instructed their sales representatives to emphasize the 51% vs. 37% seizure

reduction as a means to tout Lyrica's improved "efficacy" as opposed to its competitor, Keppra®. Pfizer Medical also participated in this conference call and articulated the company's position that, while Pfizer sales representatives could not "officially" tell doctors that Lyrica® was more efficacious than Keppra®, they could imply it by using the 51% vs. 37% seizure reduction rate information.

70. Pfizer thus engaged in a scheme of deliberate, misleading comparisons between Keppra® and Lyrica® when there were no such head-to-head studies available, in violation of Pfizer policy and FDA regulations.

4. Using Secondary Endpoints to Off-Label Promote Lyrica®.

71. One of the most aggressive off-label schemes developed shortly after the launch was the promotion of the "secondary endpoints" from several Lyrica® studies and the unapproved uses of Lyrica® from those studies. At the launch meetings in September 2005, Pfizer senior sales executives instructed its sales force, including Relator Farber, to market Lyrica®'s purported "secondary endpoints." These secondary endpoints had been mentioned in two Pfizer studies, *Dworkin*[1] and *Rosenstock*[2] as possible additional beneficial endpoints reached other than those intended in the study, including as a sleep medication, and for its use in reducing anxiety and total mood improvement. These secondary endpoints indications are not FDA-approved.

a. American Society of Anesthesiologists ("ASA") Meeting in Atlanta on October 10, 2005.

[1] According to the *Dworkin* study, the secondary endpoints included additional pain ratings, sleep interference, quality of life, mood, and patient and clinician ratings of global improvement.

[2] According to the *Rosenstock* study, the secondary endpoints included additional pain ratings, sleep interference, quality of life, mood, and patient and clinical ratings of global improvement.

72. On October 12, 2005 Pfizer's Rick Burch, Vice President of Arthritis, Pain and Metabolic-West ("APM"), sent an e-mail to the sales force, stating that the sales force could begin referring to the secondary endpoints discussed in the *Dworkin* and *Rosenstock* studies. The Burch e-mail, sent to the entire Pfizer sales force, instructed the sales force to off-label market the Lyrica® secondary endpoints, and reads:

> APM Field Force,
>
> We promised at the Lyrica® launch meeting that we would provide clarification on the use of secondary endpoints within the Dworkin and Rosenstock papers. I am pleased to announce that effective immediately, representatives can refer to the secondary endpoints as long as the following guidelines are followed.
>
> Lyrica® is off to an outstanding start capturing 2.3% market share two weeks after the launch!
>
> Good Selling,
>
> Rick

73. Copied on the Burch email are numerous members of senior management in the Pfizer Sales Division, including: Carl D. Wilbanks, Executive VP of Sales, Bruce Fleischman, Kathleen M. Dowd, Lyrica® Product Manager, Everett Cunningham, David C. Cogan, and others. The attached guidelines to the Burch email from Terry Griesling, Medical Team Leader for Lyrica®, state that the sales force could discuss the secondary endpoints in sales pitches to doctors. The guidelines thus allow Pfizer sales representatives to tout these unapproved uses of Lyrica®.

74. The Burch email was sent just before the start of the American Society of Anesthesiologists ("ASA") meeting in Atlanta where 100 TSR's were staffing the Pfizer Lyrica® interactive booth.

b. District Manager Lucas Directs Use of Secondary Endpoints in Marketing Lyrica® Off-Label to Doctors.

75. This marketing of Lyrica®'s secondary endpoints became pivotal in the marketing plan. For example, at a POA meeting in Cedar Rapids following the Atlanta ASA meeting at the end of October 2005, the Cedar Rapids sales team was directed to discuss Lyrica®'s secondary endpoints. During this meeting, Tracy Lucas, Pfizer's district manager, directed the Cedar Rapids sales representatives to include secondary endpoints when marketing Lyrica® to health care professionals. Lucas responded to off-label concerns by saying that there it was okay to proceed with marketing secondary endpoints, and if anyone got in trouble, the sales team could "blame it on Stuart," meaning Stuart Smith, the Regional Manager, who had directed the sales representatives to use the secondary endpoints as part of the marketing pitch.

76. Lucas had detail binders for the representatives created which included non-approved uses such as sleep improvement, highlighting the *Rosenstock* sleep interference secondary endpoint scores, which sales representatives were to use in marketing these off-label uses of Lyrica®.

c. Sales Calls Using Secondary Endpoints.

77. Shortly after the Lyrica® launch meeting in Anaheim, Pfizer representative Karen Shields on a sales call with Dr. Farid Manshadi, a rehabilitation doctor in Waterloo, Iowa, told Dr. Manshadi that Lyrica® was a much more efficacious drug than gabapentin, that gabapentin had poorer bioavailability compared to Lyrica®, and that for whatever conditions he had prescribed gabapentin, he could substitute Lyrica®. Moreover, Shields discussed known secondary endpoints, additional indications for which a drug may be used that are not necessarily FDA-approved, including improved sleep, additional pain ratings, and improvement in mood,

none of which are FDA-approved indications. In response, Dr. Manshadi stopped Shields, and said: "I don't like what you're saying."

5. Use of "Do Not Detail" Materials: The *Freeman, et al.* Abstract in Off-Label Sales for Treatment of Fibromyalgia.

78. Pfizer's not-so-subtle message to its sales force to off-label market Lyrica® included the supply of materials by Pfizer to its sales force labeled "Do Not Detail." Although Pfizer labels these materials in such a way to make it appear that they are not to be used in sales presentations, Pfizer makes clear to all sales representatives that this is not the intention. Sales representatives are supposed to use the materials, but not get caught doing so.

79. In one example, Pfizer used a *Freeman, et. al* abstract presented to the 58th American Academy of Neurology ("AAN") meeting to begin an off-label marketing campaign for the treatment of fibromyalgia with Lyrica®. The *Freeman* abstract was very significant because there is no approved treatment for fibromyalgia, thus having Lyrica® as a treatment option would open up a huge potential market for Lyrica®.

80. In an email dated April 17, 2006, Regional Manager, Stuart Smith, sent the abstract to the sales team with an admonition "Do Not Detail." In actuality, the use of "Do Not Detail" was meant by Lucas and Pfizer to mean exactly the opposite: Pfizer intended that its sales representatives use the materials.

81. For example, on May 30, 2006, during a POA meeting held in Galena, Illinois, Lucas presented materials provided by the Pfizer Sales Department, which touted the significant number of Lyrica® prescriptions that were already being written for fibromyalgia. In particular, Lucas showed them a Power Point pie chart demonstrating that a significant number of doctors

were writing Lyrica® off-label for fibromyalgia, for which Lyrica® had not been approved by the FDA.

82. In another example, in an email from Jake Friedman, a Senior Vice President of Sales in the Pfizer Arthritis, Pain, and Metabolic Department in New York, dated November 10, 2006, he both passes on the good news about the fibromyalgia work and purportedly warns representatives not to off-label market for fibromyalgia:

> APM Sales Team:
>
> I am very pleased to inform you that Pfizer will be presenting data on LYRICA's efficacy in fibromyalgia at the upcoming American College of Rheumatology annual meeting in Washington D.C. from November 11-15. ACR has decided to highlight these results in a press release.
>
> As you are already aware, Pfizer does not and cannot promote LYRICA for fibromyalgia as it is not an approved indication. Pfizer is under a tremendous amount of scrutiny for its sales and promotional activities surrounding LYRICA, so it's very important that we do things right and do not engage in discussions with customers on off-label uses of the drug. Therefore, please do not bring up these data with physicians and other health care providers.
>
> If the physicians have questions on these data and/or on the LYRICA fibromyalgia program, please ask them to contact Pfizer US Medical Information.

6. Failure to Engage in Fair and Balanced Lyrica® Promotional Activities Downplaying Lyrica®'s Reported Side Effects When Marketing.

83. The FDA requires Pfizer sales representatives to provide fair and balanced information when promoting Lyrica®, including safety issues. However, from the outset of the launch of Lyrica®, sales representatives were told to tout the fact that, by comparison to gabapentin, which required titration of up to three weeks to reach an effective dose, Lyrica® was effective immediately. This ability to titrate patients immediately on Lyrica® was an important selling point for Lyrica® in getting doctors to switch from gabapentin, which required more active involvement of doctors titrating patients to an effective dose. The titration difference

became a key selling point in driving the launch of Lyrica®, and one which the sales force was told should be marketed heavily to doctors.

84. Shortly after the launch, however, Relators and others on the Cedar Rapids sales team began getting reports from doctors that patients were suffering from serious side effects when they started on Lyrica®. There were numerous reports from doctors who complained their patients starting out on Lyrica® suffered from severe dizziness and edema. One doctor complained that a patient reported a weight gain of over 30 pounds after suffering from peripheral edema caused by starting on Lyrica®. In another example, Mary Callahan, raised concerns with District Manager Lucas regarding a report from Dr. Janda from Hiawatha, Iowa that one of his patients became extremely hostile, agitated, and delusional after starting on Lyrica®. And, Dr. Andrew Peterson from Cedar Rapids reported that one of his patients almost died due to taking Lyrica®. In addition, Relator Farber reported to Lucas that he had received a complaint from Dr. Fortson, a neurologist from Cedar Rapids, that Pfizer "better do something" about the dosing of Lyrica® "before the government does something."

85. In response to the reports of side effects and doctor pushback, Lucas told sales representatives they should tell doctors to continue the recommended dosing and that the side effects go away. Nonetheless, concerned that patients might become so dizzy they would fall and be injured or that they could not drive a call, many doctors titrated patients starting at a lower dose and working up to the prescribed dose over several weeks. As a result, Relator Farber began telling doctors they should carefully titrate patients onto Lyrica® to avoid these side effects.

86. When District Manager Lucas learned that Relator Farber was telling doctors to titrate patients onto Lyrica®, he was upset and told him to "stay on message." According to Lucas' Field Ride Coaching Guide report from January 23, 2006:

> One area for improvement would be in covering the dose of Lyrica® with physicians. Be sure to clearly communicate the Lyrica® dose on each call. I know that we see different starting doses of Lyrica® utilized, but it is important for each doctor to know exactly how to start each patient on this great product.

The message from Lucas and from Pfizer Corporate was clear: the dosing of Lyrica® is an important part of the sales message to get doctors to switch patients from gabapentin. Pfizer thus deliberately wanted its sales force to stay on message, and downplay safety concerns.

7. January 2006 Cogan Field Ride and Off-Label Claims.

87. Similarly, at Pfizer's annual "Fast Start" meeting in Cedar Rapids on January 5, 2006, David Cogan, a senior sales manager from Pfizer headquarters in New York City, attended the meeting and spoke to the sales force for a refresher concerning Lyrica®. The day after this meeting, Cogan joined Relator Farber on a field ride. During this field ride, Cogan commented that Relator Farber was not aggressive enough in his sales presentations, and that he was not "going in for the kill" or "getting the sale at any cost."

88. Later that day, Relator Farber and Cogan met over lunch in Cedar Rapids with Dr. Winthrop Risk II and his partner Dr. Mark Fortson, both neurologists. During the lunch, Cogan commented that Lyrica® is more efficacious than gabapentin, and that Pfizer "believes in Lyrica®'s potency" compared with gabapentin. At the time, the Iowa Medicaid Pharmacy & Therapeutics ("P&T") Committee had just approved use of Lyrica® without a prior authorization requirement, and Drs. Risk and Fortson had a practice in which they were treating a high percentage of Medicaid patients, so Cogan's comments were aimed at capturing more Medicaid

claims for Lyrica®. In addition, Cogan told the doctors that Pfizer was investigating other uses of Lyrica®.

89. Cogan's statements support the misbranding of Lyrica® (a) because there were no peer-reviewed, pharmacokinetic studies which indicated that Lyrica® was more efficacious than gabapentin, so Cogan's statements were false, and a violation of the Pfizer *Field Guide*, and (b) because the *Field Guide* instructs them not to mention any uses for drug products except for FDA-approved uses.

8. Use of Side-By-Side Promotional Materials With Unsupported Comparative Claims.

90. One of the key means that Pfizer used to rapidly increase the off-label prescribing of Lyrica® was the use of comparative marketing materials which it disseminated to doctors, touting Lyrica®'s superiority to gabapentin. From the launch forward, this became the cornerstone to the Pfizer strategy for moving business from gabapentin to Lyrica®. Pfizer's goal was to have every Neurontin® and gabapentin prescription switched to a Lyrica®. At the Lyrica® Anaheim launch meeting in September 2005, for example, Pfizer prepared a marketing brochure showing the one-page comparison of Lyrica® and gabapentin.

91. In late March 2006, Pfizer adopted aggressive marketing materials it provided to physicians, making unsupported side-by-side comparisons of Lyrica®'s superiority to gabapentin.

92. Shortly after these materials were adopted, in March 2006 at a meeting for newly hired sales representatives at Pfizer's Arrowwood training facility in upstate New York, Pfizer senior sales executive Nick Corsine told the trainees that they should use the side-by-side presentations now because Pfizer has concerns with it and would likely withdraw the materials

soon. The obvious benefit of using these materials was that they gave the explicit message that, if doctors were already prescribing gabapentin off label, they would prefer prescribing Lyrica® since it was a better product. Pfizer was thus leveraging the unsupported comparative claims into additional off-label sales of Lyrica®.

93. In May 2006, Lucas gave a presentation at the POA in Galena, Illinois to the team, in which they were directed to do side-by-side comparisons between gabapentin and Lyrica® in spite of the fact there were no studies that made such comparisons. The sales force was given stacks of these side-by-side comparisons with the heading "The pharmacology facts" and the statement, "Welcome to predictability and consistency."

94. Later, in September 2006, Pfizer issued a new, two-page side-by-side promotional materials, which again compared gabapentin and Lyrica®, and included reprints of clinical studies for each drug, including the *Dworkin* study with its secondary endpoints discussion.

95. Relators Farber and Schildhauer on numerous occasions raised concerns about Pfizer's off-label and unsupported comparative marketing claims to district manger Lucas and others at Pfizer.

9. May 30, 2006 Galena, Illinois POA Meeting and Off-Label Marketing.

96. Pfizer provided specific training to its sales force to refine the off-label pitch during a POA Meeting in Galena, Illinois on May 30-31, 2006. During the second day of the Galena meeting, when the meeting focused on Lyrica® sales and marketing strategies, the Cedar Rapids region was given a training document that required the sales force to "gain agreement that Lyrica® is different and more potent as an AED when compared to gabapentin and others" when meeting and pitching Lyrica® to neurologists.

97. Moreover, the sales team was told that the goal of its meetings with neurologists was to "gain commitment from the physician that Lyrica® is better than gabapentin." During this meeting the sales force was also directed to close its meetings with neurologists by gaining a commitment from the doctor to prescribe Lyrica® to any new patients who present with DPN or PHN *and* "for those patients on other therapies who are not pain-free or who are suffering side effects that limit their ability to enjoy a reasonable quality of life."

98. The message was clear: get doctors to choose Lyrica® for all pain conditions. During the Galena meeting, the sales representatives practiced this same off-label sales presentation, in which they were to tell doctors if you can treat DPN and PHN (two of the toughest pain conditions to treat) with Lyrica®, they could use Lyrica® to treat any kind of pain condition.

99. During the course of the Galena meeting, Pfizer management discussed a sales instruction chart entitled "Lyrica® Presentation – Cedar Rapids MAX," which instructed Pfizer sales representatives on how to pitch Lyrica® to physicians. These instructions included misleading and off-label promotion, such as the following: "Lyrica® is better than gabapentin." Pfizer's instructions to its Lyrica® sales force to tell physicians that Lyrica® is better than gabapentin were a deliberate directive to misrepresent Lyrica®'s efficacy.

100. At all relevant times, no scientific, clinical studies had been completed to support Pfizer's comparative claims.

10. Using Lyrica® Off-Label Claims in Speaker Programs to Leverage Sales.

101. Pfizer aggressively used speeches by its "thought leaders" to promote Lyrica®, even in instances when those speakers made presentations of off-label uses. For example, Dr.

Lorelei Rayburn from Texas Tech gave a Pfizer-sponsored speech to a group of doctors, including Dr. Winthrop Risk, II, which included unsolicited off-label representations of prescribing Lyrica® to treat migraine headaches.

102. Dr. Rayburn's speech was another instance of off-label marketing as well as a violation of corporate sales guidelines. This action is expressly against Pfizer policy. According to *The Field Guide*: "Pfizer is held responsible for the conduct and content of its promotional speaker programs." *The Field Guide* at 97. In addition, *The Field Guide* states that

> [a]ll information proactively presented must be consistent with labeling. A physician speaking for Pfizer at a promotional program represents Pfizer and must follow the same promotional policies as a member of the Pfizer sales force, with two exceptions:
>
> - He or she may provide off-label information only in response to a specific, unsolicited questions;
> - He or she may create and use his or her own non-product disease state and case study slides for a promotional program; and
> - Since the unapproved clinical reprint contains off-label information, the speaker may not include the study in his or her presentation, but may cite it only if appropriate in response to a specific unsolicited question.

103. The Rayburn lecture was yet another example of the apparent disconnect between what Pfizer corporate said constituted permissible marketing as opposed to what sales management was instructing the sales force to do.

104. Off-label Pfizer-sponsored presentations are very effective in inducing physicians to write Lyrica® off-label. For example, as a result of the off-label migraine claims made in the Rayburn lecture, Dr. Risk (a neurologist from Cedar Rapids who treats a large number of Medicaid patients) later solicited information regarding using Lyrica® for migraines based on

statements from the Rayburn lecture, advocating the off-label use of Lyrica® for migraine. On information and belief, based on the off-label representations in the Rayburn lecture, Dr. Risk prescribed Lyrica® off-label as a first-line medicine for the treatment of migraines, including to his Medicaid patients.

11. Marketing Lyrica® To Doctors Who Do Not Treat Patients With Conditions Requiring the On-Label Use Of Lyrica®.

105. Yet another off-label marketing method employed by Pfizer is to market Lyrica® to doctors who do not treat DPN, PHN, or partial onset of adult epilepsy, but may be able to be influenced by Pfizer to prescribe Lyrica® off-label. In November 2005, Lucas left a voicemail for Relator Farber requesting that Relator Farber leave marketing materials, including the *Dworkin* and *Rosenstock* studies, with Dr. Michael Flaum, a psychiatrist at the University of Iowa Hospital who chairs the Iowa Medicaid P&T committee. On information and belief, there is no reason to call on Dr. Flaum because he would have no reason to prescribe Lyrica® for any of its indicated uses as he does not treat patients for DPN, PHN, or seizures. Thus, the only reason Dr. Flaum would prescribe Lyrica® to anyone would be for an off-label use.

106. The solicitation of doctors (psychiatrists, orthopedists, rheumatologists, spine surgeons, general surgeons, etc.) who did not treat patients with conditions related to Lyrica®'s FDA-approved uses was common. For example, Relator Farber had numerous orthopedists included in his Lyrica® call-cycle as well as psychiatrists to whom he was expected to sell Lyrica®. This was common for other sales representatives as well. Moreover, Relator Farber knew other colleagues were asked to market, and that those colleagues did in fact market, Lyrica® to doctors who would not in the normal course prescribe Lyrica® for its indicated uses

including but not limited to orthopedic surgeons (Dr. Jerry Joachims) and spine surgeons (Dr. Mitchell Paul, Dr. Brent Overton).

107. As another example, in late 2006, while visiting a podiatrist in Los Angeles, Relator Schildhauer's district manager told the podiatrist that Lyrica® could be used for pre-operative, post-operative, and operative uses. None of these uses is approved by the FDA. The district manager acknowledged after the sales pitch that the promotion was off-label.

108. In addition to the off-label promotions, Pfizer directed its sales representatives to use Lyrica® vouchers to further help sway physicians to prescribe Lyrica® for off-label uses. These vouchers represented a free seven day prescription for Lyrica®. The voucher program was intended to accomplish Pfizer's goal of switching all gabapentin prescriptions to Lyrica®, and to further encourage off-label prescribing by enticing physicians.

12. Using Off-Label "Insell" to Hospitals to Avoid Detection.

109. Another key to Pfizer's success was the concept of "insell" and how "inselling" a product at a hospital which allows a sales representative to market off-label without Pfizer Legal becoming aware of the sale. "Insell" involves sales of Pfizer drugs for prescriptions filled at a hospital pharmacy as opposed to an external pharmacy like CVS. The benefit of "inselling" a drug at a hospital is that it is very easy to off-label market a drug, like Lyrica®, within the hospital because the department that dispenses the drug is not tracked. When the sale is recorded, the hospital will be listed as the purchaser, but the department will not be listed.

110. District Manager Lucas talked extensively about this concept and how to use "inselling" as a means to increase Lyrica® sales at the University of Iowa Hospital, in particular. For example, Lucas directed Relator Farber, while he was at the hospital making his normal sales visits, to stop at the Psychiatric Clinic to encourage the doctors there to write Lyrica® scripts.

He advised Relator Farber not to log such visits into Sherlock as every sales representative was required to do. As previously mentioned, because psychiatrists would have no reason to prescribe Lyrica® as the drug is not indicated for any psychological conditions, such representations were off-label.

111. In another example in the fall of 2006, Pfizer sponsored a Continuing Medical Education ("CME") talk on Arthritis and Pain at Los Angeles Metropolitan Hospital ("L.A. Metro"). L.A. Metro has a large inpatient psychiatric unit and outpatient orthopedic surgery department. The L.A. district manager informed Relator Schildhauer that if a psychiatrist in the hospital prescribes Lyrica® for any reason, the L.A. sales team would receive credit for the prescription, and subsequently be compensated by Pfizer, and directed him to sell Lyrica® off-label in this way.

13. Pfizer Speaker Payments to "Thought Leaders" to Influence Formulary Addition of Lyrica®.

112. Pfizer purportedly uses speakers "to present topic experts to educate healthcare professionals (HCPs) about Pfizer, Pfizer products or particular disease states. Any time you engage an expert to speak to HCPs on Pfizer's behalf, you are engaging in a promotional act. . . . [W]henever an HCP is paid to speak for Pfizer, the transaction is subject to scrutiny under anti-kickback and other healthcare laws." *The Field Guide* states that the selection of Pfizer speakers is "solely to engage the [healthcare professional] for speaking services." It is specifically not permissible to hire a speaker to:

- "Build a relationship with that HCP;
- Gain or improve access to that HCP; [and]
- Reward past prescribing or induce future prescribing; . . ."

Despite Pfizer's clearly articulated policies against such activity, the company regularly uses its Lyrica® speakers program in order to improve relationships with the HCP, gain access to HCPs, reward past prescribing, or induce future prescribing.

113. According to *The Field Guide*, "[a]t no time should it appear Pfizer is engaging in a concerted effort to influence an upcoming formulary decision." It is specifically prohibited to link "financial transactions . . . to P&T Committee decisions. Outside of certain limited exceptions, anti-kickback laws prohibit manufacturers from providing anything of value in order to influence formulary decisions." Moreover, "[a]lthough [sales representatives] may ask for [the healthcare professional's] support [to influence P&T decisions], in no event should the [healthcare professional] be compensated or otherwise rewarded for this activity."

114. Interactions with VA physicians are subject to scrutiny under both the anti-kickback laws and specific rules such as the Veterans Health Administration Directives and Office of Government Ethics Rules. These rules limit the range of allowable interactions with healthcare professionals employed by the government. As a result, sales activities that are permissible when conducted with healthcare professionals who do not work for the government may be prohibited under these specific federal rules when conducted with government healthcare professionals. It is specifically against these laws, for example, for the healthcare professional to accept speaker fees on a matter pending before the government agency.

115. On information and belief, Dr. Kabadi is highly regarded by the University of Iowa Hospitals P&T committee members, although he himself is not on the committee. Dr. Kabadi's ability to influence his peers was not lost on Lucas. In fact, he relied on Dr. Kabadi's ability to exert some influence over the committee's decision-making. Lucas heard from

colleagues that Dr. Kabadi was a tremendous fan of Neurontin®, so thought it important to meet with Dr. Kabadi to gain and build support for Lyrica® at the University of Iowa.

116. As early as July or August of 2005, Lucas had met with Dr. Udaya Kabadi (an endocrinologist at the Iowa City VA Medical Center, who was also on staff at the Iowa City VA Medical Center and a frequent speaker for a number of Pfizer drugs) to seek his support for adding Lyrica® to the University of Iowa Hospitals formulary.

117. On information and belief, during this initial meeting, Lucas asked for Dr. Kabadi's help in having Lyrica® added to the University of Iowa's formulary. Dr. Kabadi agreed to help, but did not complete a formulary recommendation form at that time. Dr. Kabadi, did, however, request that he be added to the speaker's list for Lyrica®, which Lucas agreed to put in place. Thereafter, Dr. Kabadi was later flown to Boston to attend Lyrica® speaker training. Upon completion of his training, Dr. Kabadi became a frequently-used speaker for Lyrica®.

118. In addition, shortly after the Lyrica® launch, Lucas made clear that it was important for Relator Farber to also meet with influential University of Iowa Hospital physicians like Dr. Kabadi to see if they would recommend Lyrica® to the University of Iowa Hospital P&T Committee. Gaining acceptance on the University of Iowa Hospital formulary was extremely important to Pfizer because, not only did the University use a great deal of gabapentin (and thus was a potentially large Lyrica® customer), if Lyrica® were adopted on the University formulary, Pfizer could use that to leverage adoption on numerous other formularies in the region. Pfizer use of speaker monies to establish relationships with these influential doctors demonstrates how it used financial relationships to gain wide acceptance of Lyrica®.

119. On or about September 16, 2005, Lucas again asked Dr. Kabadi for help in having Lyrica® added to the University of Iowa's formulary. Dr. Kabadi, once again, agreed to assist. This time Dr. Kabadi completed the recommendation form while Lucas was in his office. A little over a month later, in November 2005, Lyrica® was added to the University of Iowa formulary for the neurology and anesthesiology departments.

120. Additionally, in January 2006 David Cogan, a senior sales manager from Pfizer headquarters in New York City, met with Dr. Kabadi during a sales call. During the meeting, Dr. Kabadi mentioned that he would reach his honorarium cap within a few months. Cogan responded that Pfizer was relying on Dr. Kabadi to speak in support of Exubera® which was going to launch in July of that year. Thus, given Dr. Kabadi's influence at the University of Iowa, that he was well-respected by members of the P&T committee, that he had been instrumental in having Lyrica® added to the University of Iowa's formulary, and that Dr. Kabadi would be instrumental in helping Pfizer get Exubera® added to the University of Iowa's formulary, Cogan requested that Dr. Kabadi's honorarium limit be raised.

121. Upon information and belief, Dr. Kabadi's honorarium limit was raised from $50,000 to $150,000 within weeks of the doctor's request.

122. In short, Pfizer engaged in influence pedaling to get Lyrica® on the University of Iowa formulary. In exchange for his support and assistance in getting Lyrica® on the University of Iowa's formulary, Lucas agreed to have Dr. Kabadi trained as a Lyrica® speaker. Further, as a reward for his help in getting Lyrica® added to the University of Iowa formulary and to encourage his future assistance in getting Exubera® added to the formulary, Cogan had Dr. Kabadi's honorarium raised to $150,000. Not only does this exchange of a favor for a favor violate the federal Anti-Kickback Act, such transactions are strictly forbidden by Pfizer policies.

123. Additionally, Pfizer also employed a strategy in which it required sales representatives to recruit doctors who were not prescribing Lyrica® and entice those doctors to become paid Pfizer speakers in exchange for prescribing Lyrica®. The strategy required sales representatives to enlist doctors as speakers many of whom, on information and belief, were heavy Medicaid prescribers. Once the speakers were accepted into Pfizer's speaker program, they were then trained by Pfizer to speak on a variety of drugs and paid an honorarium for each speaking engagement. In exchange for the opportunity to make additional money through speaking events, on information and belief, the doctors would tacitly agree to prescribe Lyrica®.

124. In one instance, for example, Pfizer District Manager Lucas directed that the Relators were to pursue a neurologist in Burlington, Iowa, Dr. Nidel Alkurdy. Based on research conducted by Pfizer, Lucas had learned that Dr. Alkurdy wrote very little or no Lyrica® prescriptions, although he treated conditions for which Lyrica® is indicated and FDA-approved. During telephone conversations, POA meetings, and in emails, Lucas explained to the Relators that he wanted Dr. Alkurdy to become a Lyrica® speaker in order to increase the number of prescriptions Dr. Alkurdy and the doctors at Alkurdy's clinic wrote. At all times material hereto, Dr. Alkurdy treated large numbers of Medicaid recipients.

125. Pursuant to Lucas' instructions, Relator Schildhauer met with Dr. Alkurdy in Fort Maddox, Iowa and gained Dr. Alkurdy's agreement to become a Lyrica® speaker in exchange for his agreement to prescribe more Lyrica®. This use of speaker fees to influence Lyrica® prescribing is an express violation of law and Pfizer policy.

14. Pfizer's Payments to Physician's Assistants to Promote Lyrica.

126. Pfizer also pays speakers to tout Lyrica®, including deceptively double-paying physician's assistants. For example, Pfizer has four to five speakers approved in each of its

regional sales areas. If one of the approved physicians is unable to speak at a given event, Pfizer allows physician assistants ("PAs") to speak. Because of a fair market value assessment conducted by Pfizer related to the proper compensation to speakers, Pfizer determined that PAs should be paid less than the physician speakers. As a result, PAs were reluctant to agree to act as a speaker. Because Pfizer needed PAs to fill in as speakers, Pfizer management secretly agreed to pay PAs double what Pfizer had earlier determined to be the fair market value of PAs' speaking services. The double-pay scheme was accomplished by generating two checks for the PA. The double-pay scheme resulted in PAs being paid more than fair market value, violating Pfizer's own internal guidelines, the Neurontin CIA and the Anti-Kickback Act.

15. Payments to RMRSs to Promote Lyrica® Off-Label

127. Pfizer also pays regional medical research specialists, also known as RMRSs, to promote Lyrica® off-label. For example, in November, 2006, every district in the nation conducted a regional POA. Most regions are made up of multiple states, but in densely populated Southern California, the regional POA was made up of all districts in the Los Angeles metropolitan area, Orange County, San Diego, and Palm Springs. In this POA meeting in Relator Schildhauer's district, the Pfizer district manager introduced their RMRS, a pharmacist.

128. The Los Angeles district manager insisted that their RMRS "go out in the field" with each representative, for the purpose of promoting Lyrica® off-label. It was common practice for Pfizer managers to encourage the use of speakers, and Pfizer-employed medical professionals working for or paid by Pfizer, to promote Pfizer products, including Lyrica®, for non-FDA approved indications. The off-label promotion of Lyrica by Pfizer's paid speakers and medical specialists constitutes illegal promotion of a drug for unapproved uses.

129. As noted above, in the fall of 2006, Pfizer sponsored a Continuing Medical Education ("CME") talk on Arthritis and Pain at Los Angeles Metropolitan Hospital ("LA Metro"). L.A. Metro has a large inpatient psychiatric unit and outpatient orthopedic surgery department. The speaker was being sponsored by a medical grant from Pfizer. Pfizer grant speakers are not allowed to promote Pfizer products at CME's.

130. Pfizer's payments to speakers and medical specialists who in turn promote Lyrica® to physicians for the purpose of inducing the prescribing of Lyrica® for off-label uses, which prescriptions are paid or reimbursed by Federal Programs, including Medicaid, is a violation of the Federal Food, Drug and Cosmetic Act and the federal Anti-Kickback Act.

16. The Lyrica® "Upgrade" Scheme – Pfizer's Strategy to Defraud the Medi-Cal Program

131. Although Pfizer's strategy for off-label and deceptive marketing of Lyrica® was company-wide, different sales regions developed unique ways to work around state and federal Medicaid regulations, thereby, defrauding those programs.

132. For example, in Los Angeles, Relator Schildhauer was told by his district manager that the promotion of Lyrica® as a replacement to gabapentin was critical to the reimbursement of Lyrica® by a large government third party payer such as Medi-Cal. During a team conference call and also in a broadcast voicemail message, Relator Schildhauer's district manager instructed representatives in a false prescription scheme, euphemistically referred to as "the Lyrica® upgrade strategy," to ensure Lyrica® was reimbursed by Medi-Cal. At that time, Medi-Cal had not placed Lyrica® on its formulary and required patients to have failed on gabapentin before Medi-Cal would approve the use of Lyrica®. Sales representatives were

instructed to encourage prescribing doctors to write two prescriptions whenever gabapentin was prescribed. One prescription would be for gabapentin, the other for Lyrica®.

133. The sales representatives were then directed to request that the doctor date the Lyrica® prescription for exactly one week or 7 days following the date written on the gabapentin prescription. Further, the doctor was to give the patient a free 7-day trial of Lyrica® and send the patient to the pharmacist, instructing the patient to give the pharmacist both the gabapentin and Lyrica® prescriptions. The sales representatives would then talk to those pharmacists with whom they were most closely aligned and instruct them to fill both prescriptions. The patient would come back to the pharmacist to pick up the Lyrica® prescription and although it was filled, never take the gabapentin. Once put into use, this sham gabapentin prescription strategy was so effective that the L.A. Confidential team began to use it for managed care patients as well.

17. Pfizer's Strategy to Work Around State Limits that Govern Pharmaceutical Expenditures Per Physician.

134. Many states in which Pfizer conducts business have regulations that limit the amount of money pharmaceutical companies can spend per person for meals with doctors or dinners with doctors. Upon information and belief, notwithstanding these regulations, Pfizer many times ran afoul of the preset limits and employed various ways to hide its non-compliance. For example, sales representatives are required to send the names of all participants at a Pfizer sponsored dinner to Pfizer corporate. However, rarely did all confirmed guests attend the event. This posed a problem as most of the restaurants at which such functions were held required the representatives to pay a minimum charge. Since the minimum was fixed and there was a fee that was assessed on top of the number of attendees, representatives were often over the predefined

state limit. In order to give the appearance of compliance, representatives would submit names of individuals who did not attend such that the cost per participant was not exceeded.

135. Additionally, in order to appear to be in compliance with the state regulations described above, participants would have restaurants code any preset minimum food charge as a room rental charge. Like the scheme described above, this would keep the costs of meals per head at the state prescribed maximum making it seem as if Pfizer was in compliance with state regulations.

VII. PFIZER'S FALSE REPORTING IN CONNECTION WITH THE NEURONTIN® CIA.

136. Although comparisons of the efficacy of Lyrica® to gabapentin (Neurontin®) and to other products, including Keppra® had been the cornerstone of the Lyrica® launch, on or about November 27, 2006, Pfizer announced that making such comparisons (particularly in the absence of head-to-head studies supporting such representations) was no longer permissible.. Both Relators Farber and Schildhauer had complained on numerous occasions that were a violation of Pfizer policy and FDA fair and balanced regulations. Only after Pfizer representatives had been directed that they were to make such representatives, in a stunning reversal, in an email to all sales employees, Kathleen Dowd, the Pfizer Lyrica® team leader, stated that:

> APM RMs, DMs, PHRs, and TSRs,
>
> As we recently communicated to you, product features reflected in the side-by-side Lyrica® / Neurontin chart in the Lyrica® promotional materials are the only appropriate bases for comparing Lyrica® to Neurontin/gabapentin. These product features are molecular structure, FDA-approved indications, oral bioavailability, dose potency, time to reach an effective dose, and dosing schedule. Statements comparing the efficacy or safety of Lyrica® to Neurontin/gabapentin are not substantiated by head-to-head studies and, therefore, are not acceptable.

> In order to ensure that we stay focused on promoting the approved benefits of Lyrica® while at the same time maintaining an unimpeachable focus on compliance, we have decided to cease using and distributing the stand-alone side-by-side Lyrica® / Neurontin profiler containing the following Neurontin clinical reprints: "Gabapentin as add-on therapy in refractory partial epilepsy -- A double-blind, placebo-controlled, parallel-group study" (reprinted from Neurology) and "Gabapentin for the treatment of postherpetic neuralgia -- A randomized controlled trial" (reprinted from JAMA). AS A RESULT, EFFECTIVE IMMEDIATELY, YOU ARE TO STOP USING AND DISTRIBUTING THE PROMOTIONAL PIECES WITH THE FOLLOWING CONTROL NUMBERS PRINTED ON THE BACK:
>
> PB271524
> PB271524A
>
> The Neurology and JAMA clinical reprints discussing Neurontin, which were included in the pocket of the side-by-side Lyrica® / Neurontin profiler, are no longer approved and are not to be used.

137. As such, Pfizer admitted that its systematic unsupported comparisons and claims of Lyrica® superiority were illegal, and thus should have been reported to the United States under the Neurontin CIA.

138. Relators/Plaintiffs allege, on information and belief, that Pfizer failed to accurately and truthfully report its improper Lyrica® marketing as described above, as required by the terms of the Neurontin CIA.

139. Relators/Plaintiffs allege, on information and belief, that Pfizer falsely reported to the United States a true and accurate account of its improper Lyrica® marketing as required by the terms of the Neurontin CIA.

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

141. Pfizer’s deliberate omissions and false statements as described above caused and may continue to be causing Federal Programs to reimburse for Lyrica® prescriptions which were prescribed for off-label uses or prescribed as a result of Pfizer’s illegal comparison marketing.

142. But for Pfizer's deliberate omissions and false statements as described above, on information and belief Federal Programs, including Medicaid, would not have paid or reimbursed for Lyrica® prescriptions filled as a result of Pfizer's illegal marketing activities.

VIII. PFIZER RETALIATION AGAINST RELATORS

143. Relators informed Pfizer of Lyrica®'s illegal promotion. Pfizer's response was aimed at containing any adverse impact caused by Relators' whistleblowing, rather than seeking to uncover and remedy the illegal conduct.

144. As a result of Relators' whistleblowing activities, each has been the subject of retaliation. Pfizer has discharged, demoted, suspended, threatened, harassed or discriminated against Plaintiffs/Relators by virtue of their lawful acts in bringing to light Pfizer's illegal and potentially harmful actions.

1. David Relator Farber

145. Relator Farber was constructively discharged on or about January 19, 2007.

146. Preceding his discharge, Relator Farber informed Pfizer of illegal activity, including misleading efficacy promotion of Lyrica®, as well as illegal off-label promotion. This illegal activity included: (1) directives from his district manager, Tracy Lucas, including a voicemail message left on his telephone to leave sales materials for a doctor who would never prescribe Lyrica® in the normal course of business; (2) directives from Pfizer management to market non-FDA approved indications known as "secondary endpoints;" (3) directives from his district manager to never discuss the drug's side effects; (4) sales calls involving the discussion of secondary endpoints with physicians; and (5) use of side-by-side promotional materials to demonstrate the comparative advantages of Lyrica® as opposed to gabapentin or Keppra®, absent supporting, peer-reviewed studies.

147. Relator Farber made his first report of off-label marketing on or about March 2006. Over the course of the next several months, Farber expressed his concerns to his district manager, Pfizer Human Resources ("HR") representatives, as well as others.

148. Relator Farber expressed concerns to Pfizer management that Pfizer would retaliate against him for reporting the off-label marketing scheme.

149. During the following months, Relator Farber continued to inform Pfizer of off-label marketing activities in which the sales force is directed by Pfizer management to participate.

150. As a result of Relator Farber's whistleblowing activities, on or about January 19, 2007, he was constructively discharged.

2. Casey Schildhauer

151. Relator Schildhauer first complained to Pfizer management regarding Pfizer's promotion of Lyrica® in or around the time of Lyrica®'s launch, including at a meeting in Denver, Colorado on February 23, 2006. These complaints were made to Pfizer management, including Schidhauer's district managers, Pfizer Human Resources, Pfizer corporate, and others.

152. For example, at a meeting held at Pfizer's Denver office on February 23, 2006, Relator Schildhauer informed Pfizer management of illegal sales activity, including the off-label promotion of Lyrica®, the unsubstantiated comparison promotion of Lyrica® with gabapentin and Keppra®, as well as the excessive payment of speakers.

153. Subsequent to the Denver meeting, Relator Schildhauer was accorded pariah treatment, including additional false accusations that he had violated Pfizer policies.

154. In September, 2006, Pfizer initiated a relocation of Relator Schildhauer to one of Pfizer's Los Angeles-based sales teams, where he was employed as a sales representative until

March 27, 2007 whereupon he was terminated for refusing to subject himself to further retaliation stemming from his whistleblowing activities.

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

155. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

156. This is a civil action brought by Plaintiffs/Relators, on behalf of the United States of America against Defendant under the False Claims Act, 31 U.S.C. §§ 3729(a)(1) and (2).

157. Defendant, 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).

158. Defendant, 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).

159. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information which 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.

160. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements,

paid and may still be paying or reimbursing for Lyrica® prescribed to patients enrolled in Federal Programs.

161. As a result of Defendant's 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*.

162. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

163. Pfizer's failure to report, or false reporting to the United States in accordance with the Neurontin 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.

164. As a result of Defendant's 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)

165. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

166. As a result of Plaintiffs/Relators' whistle-blowing activities, Pfizer has discharged, demoted, suspended, threatened, harassed, and discriminated against Plaintiffs/Relators by virtue of his lawful acts.

167. Plaintiffs/Relators are entitled to all the relief afforded by 31 U.S.C. § 3730(h), including, without limitation, double back pay, front pay, and special damages.

COUNT IV

ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT, ARK. CODE ANN. § 20-77-901, *et seq.*

168. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

169. This is a civil action brought by Plaintiffs/Relators, in the name of the State of Arkansas, against Defendant pursuant to the State of Arkansas Medicaid Fraud False Claims Act, ARK. CODE ANN. § 20-77-901, *et seq*.

170. 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 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 Arkansas Medicaid program, in violation of ARK. CODE ANN. § 20-77-902(1).

171. 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 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 ARK. CODE ANN. § 20-77-902(2).

172. 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 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 ARK. CODE ANN. 20-77-902(3).

173. 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 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 ARK. CODE ANN. § 20-77-902(7)(A)(ii).

174. The State of Arkansas or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT V

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

176. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

177. This is a civil action brought by Plaintiffs/Relators on behalf of the State of California against Defendant under the California False Claims Act, CAL. CODE § 12652(c).

178. 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, 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. CODE § 12651(a)(1).

179. 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, false records or statements to get false or fraudulent claims paid in violation of CAL. CODE § 12651(a)(2).

180. 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, 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. CODE § 12651(a)(7).

181. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

182. As a result of Defendant's 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 DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. CODE ANN. TIT. 6, § 1201, *et seq*.

183. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

184. This is a civil action brought on behalf of Plaintiffs/Relators on behalf of the Government of the State of Delaware against Defendant under the State of Delaware's False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1203(b).

185. 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, 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).

186. 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, 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).

187. 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, 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, § 1201(a)(7).

188. The Government of the State of Delaware, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT VII

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

190. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

191. This is a civil action brought by Plaintiffs/Relators, in the name of the District of Columbia against Defendant under the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.15(b).

192. 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 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)(1).

193. 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 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).

194. 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 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).

195. The District of Columbia, 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 health insurance programs funded by the District.

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

COUNT VIII

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

197. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

198. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Florida against Defendant under the State of Florida's False Claims Act, FLA. STAT. ANN. § 68.083(2).

199. 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 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).

200. 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, 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).

201. 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, 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).

202. The State of Florida and its agencies, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT IX

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

204. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

205. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Hawaii and its political subdivisions against Defendant under the State of Hawaii's False Claims Act – False Claims to the State, HAW. REV. STAT. § 661-25.

206. 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 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. § 661-21(a)(1).

207. 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 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).

208. 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, 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).

209. The State of Hawaii, or its political subdivisions, 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.

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

COUNT X

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

211. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

212. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Indiana against Defendant under the State of Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-4(a).

213. 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 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)(1).

214. 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 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).

215. 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 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(b)(6).

216. The State of Indiana, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XI

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

218. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

219. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Illinois against Defendant under the State of Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. 175/4(b).

220. 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 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)(1).

221. 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 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).

222. 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, 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).

223. The State of Illinois, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XII

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

225. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

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

227. 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, false or fraudulent claims, in violation of LA. REV. STAT. § 46:438.3(A).

228. 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 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).

229. 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 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).

230. 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 Defendant, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendant's claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

231. As a result of Defendant's 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 XIII

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

232. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

233. This is a civil action brought by Plaintiffs/Relators on behalf of the Commonwealth of Massachusetts against Defendant under the Massachusetts False Claims Act, MASS. LAWS ANN. ch. 12, § 5C(2).

234. 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, a false claim for payment or approval, in violation of MASS. LAWS ANN. ch. 12, § 5B(1).

235. 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, 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).

236. 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, 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).

237. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XIV

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

239. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

240. This is a civil action brought by Plaintiffs/Relators in the name of the State of Michigan against Defendant under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(1).

241. 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 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).

242. 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 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).

243. 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 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 Defendant has applied for or is receiving a benefit

with intent to obtain a benefit to which Defendant is not entitled or in an amount greater than that to which Defendant is entitled, in violation of MICH. COMP. LAWS. SERV. § 400.603(3).

244. Defendant, in possession of facts under which it is aware or should be aware of the nature of its conduct and that its 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).

245. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XV

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

247. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

248. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Montana against Defendant under the State of Montana False Claims Act, MONT. CODE ANN. § 17-8-406(1).

249. 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, a false claim for payment or approval, in violation of MONT. CODE ANN. § 17-8-403(1)(a).

250. 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, false records or statements to get a false claim paid or approved, in violation of MONT. CODE ANN. § 17-8-403(1)(b).

251. 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, 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(1)(g).

252. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XVI

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

254. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

255. This is a civil action brought by Plaintiffs/Relators on behalf of the State of New Hampshire against Defendant under the State of New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-cII.(a).

256. 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, a false claim for payment or approval, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(a).

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

258. 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, 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).

259. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XVII

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

261. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

262. This is a civil action brought by Plaintiffs/Relators on behalf of the State of New Mexico against Defendant under the State of New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-7(B).

263. 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, a false or fraudulent claim for payment under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4A.

264. 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 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.

265. 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, false records or statements to get a false or fraudulent claim paid or approved, in violation of N.M. STAT. ANN. § 27-14-4C.

266. 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, 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.

267. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XVIII

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

269. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

270. This is a civil action brought by Plaintiffs/Relators on behalf of the State of New York against Defendant under the State of New York False Claims Act, N.Y. CLS St. Fin. § 190.2.

271. 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, a false claim for payment or approval, in violation of N.Y. CLS St. Fin. § 189(a).

272. 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, false records or statements to get a false claim paid or approved, in violation of N.Y. CLS St. Fin. § 189(b).

273. 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, 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).

274. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XIX

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

276. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

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

278. 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, a false claim for payment or approval, in violation of NEV. REV. STAT. ANN. § 357.040(1)(a).

279. 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, false records or statements to obtain payment or approval for false claims in violation of NEV. REV. STAT. ANN. § 357.040(1)(b).

280. 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, 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).

281. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XX
VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT, TENN. CODE ANN. §§ 4-18-101, *et. seq.*

283. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

284. This is a civil action brought by Plaintiffs/Relators, on behalf of the State of Tennessee against Defendant under the Tennessee False Claims Act, TENN. CODE ANN. § 4-18-104(c).

285. 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 an officer or employee of the State of Tennessee, or its political subdivisions, false claims for payment or approval, in violation of TENN. CODE ANN. § 4-18-103(a)(1).

286. 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, false records or statements to get false claims paid or approved by the state or its political subdivisions in violation of TENN. CODE ANN. § 4-18-103(a)(2).

287. 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, false records or statements to conceal, avoid, or decrease an obligation to pay money to the State of Tennessee or its political subdivisions, in violation of TENN. CODE ANN. § 4-18-103(a)(7).

288. 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, any false or fraudulent conduct, representation, or practice in order to procure anything of value directly or indirectly from the state or its political subdivisions, in violation of TENN. CODE ANN. § 4-18-103(a)(9).

289. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, 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 funded health insurance programs.

290. As a result of Defendant's conduct, as set forth above, the State of Tennessee or its political subdivisions has been, and may continue to be, severely damaged.

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

291. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

292. This is a civil action brought by Plaintiffs/Relators in the name of the State of Tennessee against Defendant under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-183(a).

293. 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 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)(1)(A).

294. 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, 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)(1)(B).

295. 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, 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).

296. The State of Tennessee, unaware of the falsity of the claims and/or statements made by Defendant, 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.

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

COUNT XXII

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

298. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

299. This is a civil action brought by Plaintiffs/Relators in the name of the State of Texas against Defendant under the State of Texas Human Resources Code, Medicaid Fraud Prevention Chapter, TEX. HUM. RES. CODE § 36.101(a).

300. 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 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).

301. 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 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).

302. 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 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).

303. 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 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).

304. The State of Texas, its political subdivisions or the Department, unaware of the falsity of the claims and/or statements made by Defendant, 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.

305. As a result of Defendant's 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 XXIII

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

306. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

307. This is a civil action brought by Plaintiffs/Relators on behalf of the Commonwealth of Virginia against Defendant under the Commonwealth of Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.5, *et seq*.

308. 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 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)(1).

309. 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, 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).

310. 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, 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).

311. The Commonwealth of Virginia, 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.

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

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

A. That Defendant 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. CODE § 12650, *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.*, HAW. REV. STAT. § 661-21, e*t seq.*, IND. CODE ANN. § 5-11-5.5, e*t seq.*, 740 ILL. COMP. STAT. ANN. 175/1, *et seq.*, LA. REV. STAT § 437.1, *et seq.*, MASS. LAWS ANN. Ch. 12, §5A, *et seq.*, MICH. COMP. LAWS SERV. § 400.601, e*t seq.*, MONT. CODE ANN. § 17-8-401, *et seq.*, N.H. REV. STAT. ANN. § 167:61-b, *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.*, TENN. CODE ANN. § 4-18-101, *et seq.*, TENN. CODE ANN. § 71-5-181, e*t seq.*, TEX. HUM. RES. CODE § 36.001, *et seq.*, and. VA. CODE ANN. § 8.01-216.1, *et seq.*

B. That judgment be entered in Plaintiffs' favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

C. That Plaintiffs be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h), ARK. CODE ANN. § 20-77-911, CAL. CODE § 12652(g), DEL. CODE ANN. tit. 6, § 1205, D.C. CODE ANN. § 2-308.15(f), FLA. STAT. ANN. § 68.085, 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.M. STAT. ANN. § 27-14-9, N.Y. CLS St. Fin. § 190.6., NEV. REV. STAT. ANN. § 357.220, TENN. CODE ANN. § 4-18-104(g)(1), TENN. CODE ANN. § 71-5-183(c), TEX. HUM. RES. CODE § 36.110, and VA. CODE ANN. § 8.01-216.7.

D. that judgment be entered in Plaintiff's favor and against Defendant 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)(1), 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)(1), 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

E. that judgment be entered in Plaintiff's favor and against Defendant in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in CAL. CODE § 12651(a), plus a civil penalty of no more than ten thousand dollars ($10,000) per claim as provided by CAL. 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

F. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

G. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

H. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

I. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

J. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

K. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

L. that judgment be entered in Plaintiff's favor and against Defendant 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)(1), 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)(1)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of s. 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)(1)(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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

M. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant' unlawful acts, as provided for in MASS. LAWS ANN. ch. 12, § 5B, 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

N. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant' 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

O. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant' 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

P. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant' unlawful acts, as provided for in N.H. REV. STAT. ANN. § 167:61II, 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 N.H. 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 Defendant, 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 Defendant 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 Defendant' 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

R. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant' 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. § 189.1., 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

S. that judgment be entered in Plaintiff's favor and against Defendant for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

T. that judgment be entered in Plaintiff's favor and against Defendant for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in TENN. CODE ANN. § 4-18-103(a), multiplied as provided for in TENN. CODE ANN. § 4-18-103(a), plus a civil penalty of not less than two thousand five-hundred dollars ($2,500) or more than ten thousand dollars ($10,000) for each false claim, pursuant to TENN. CODE ANN. § 4-18-103(a), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

U. that judgment be entered in Plaintiff's favor and against Defendant for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in TENN. CODE ANN. 71-5-182, multiplied as provided for in TENN. CODE ANN. § 71-5-182(a)(1), 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)(1), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

V. that judgment be entered in Plaintiff's favor and against Defendant for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in TEX. HUM. RES. CODE § 36.052(a)(1), 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

W. that judgment be entered in Plaintiff's favor and against Defendant 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 Defendant, together with penalties for specific claims to be identified at trial after full discovery;

X. that Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

Y. That judgment be granted for Plaintiffs against Defendant for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Plaintiffs in the prosecution of this suit; and

Z. That Plaintiffs be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: June 12, 2007.

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