FILED
IN CLERKS OFFICE
2007 AUG 13 P 4: 25
U.S. DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA ex rel. BLAIR COLLINS, and

THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, and TEXAS, ex rel. BLAIR COLLINS,

THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA ex rel. BLAIR COLLINS, and

THE DISTRICT OF COLUMBIA, ex rel. BLAIR COLLINS,

Plaintiffs,

v.

PFIZER INC.,

Defendant.

CIVIL ACTION NO.

04-11780 DPW

FILED IN CAMERA and UNDER SEAL

RESTATED AND AMENDED FALSE CLAIMS ACT COMPLAINT

I. INTRODUCTORY STATEMENT

The Plaintiff, BLAIR COLLINS, by and through his counsel of record, brings this action on behalf of the United States of America against PFIZER INC. (the "Defendant") pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA"), and on behalf of the above named States under their respective State False Claims Acts ("State FCAs") (together referred to herein as "*Qui Tam* Action"). Pursuant to 31 U.S.C. § 3730 (b)(2), and comparable provisions in State FCAs, this action is brought *in camera* and under seal. Plaintiff Blair Collins also brings this action on his own behalf under the FCA,

31 U.S.C. section 3730(h), seeking redress for Defendant's wrongful and unlawful retaliation and termination of his employment.

Plaintiff alleges that Defendant PFIZER INC. has violated numerous laws, including the Federal and State FCAs, the Federal Food, Drug, and Cosmetic Act and the Medicare-Medicaid Anti-Kickback Act (and comparable state laws), and has violated the terms of two Corporate Integrity Agreements between it and the government, by engaging in unlawful promotional and pricing activities in the marketing of numerous drugs manufactured and/or sold by Defendant from at least 1998 to at least 2005. Pfizer's actions and omissions have caused physicians to prescribe and administer such drugs to their patients over competitor's drugs, have caused Pfizer's drugs to be listed on formularies over competitor's drugs, have caused Pfizer's more expensive brand name drugs to be prescribed and listed on formularies in lieu of less expensive generic drugs, have caused physicians to prescribe Pfizer's drugs for "off-label" purposes, and at dosages that are unnecessary and adversely affect patient quality of care, and have caused Government Health Care Programs to receive and pay false or fraudulent bills submitted to such programs, and to pay higher prices and to receive lower rebates for such drugs.

Plaintiff/Relator further alleges that Defendant PFIZER INC. has violated the whistleblower's protection section of the FCA, 31 U.S.C. section 3730(h), by subjecting him to adverse actions and ultimately terminating plaintiff's employment in retaliation for his attempts to report and correct the illegal conduct described herein.

Pfizer's illegal activities are each violations of law, but together demonstrate a concerted and well-organized national corporate strategy to use kickbacks, off-label promotion, pricing "incentives" and other illegal tactics directed from the highest levels of the company to assure that Pfizer's drugs would not only compete, but would receive preferential treatment, thereby

putting Pfizer's competitors at an unfair disadvantage, depriving certain providers and consumers of a fair and informed choice, and causing Government Health Care Programs (as defined below) to expend excessive amounts of money to reimburse the cost of Pfizer's drugs. All of this has been done despite two Corporate Integrity Agreements, the Department of Health and Human Services Office of Inspector General's Guidelines, and internal complaints from employees such as Relator who instead of being treated with respect, are unfairly and illegally retaliated against.

II. JURISDICTION AND VENUE

1. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. § 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730, and has supplemental jurisdiction over the State FCA claims pursuant to 31 U.S.C. section 3732(b) and 28 U.S.C. § 1367.

2. Venue is appropriate as to the Defendant in that PFIZER INC. can be found in, resides in, and/or transacts business in this judicial district. Therefore, within the meaning of 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a), venue is proper.

3. To Relator's knowledge, jurisdiction over this action is not barred by 31 U.S.C. Section 3730(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party; there has been no "public disclosure" of these allegations or transactions; and, in any event, Relator is the "original source" of the information on which these allegations are based.

III. THE PARTIES

4. Plaintiff Blair Collins is a citizen of the United States of America and a resident of Utah. From October 1998 until August 2003, he was employed by Defendant PFIZER INC. He brings this *Qui Tam* Action based upon direct, independent and unique information obtained during the period of his employment as a pharmaceutical sales representative for the Defendant.

As characterized by the Federal False Claims Act, Plaintiff will often be referred to as "Relator" hereafter. Mr. Collins has made several disclosures to the government regarding the allegations and information in his original Complaint and in this Restated and Amended Complaint, and will be providing the government plaintiffs with further disclosures as well.

5. Defendant PFIZER INC. ("PFIZER"), a publicly-traded corporation, is one of the world's largest drug companies. It develops, manufactures and markets a wide array of top selling prescription drugs including, for example, LIPITOR, VIAGRA, NORVASC, CADUET, ZYRTEC, ZITHROMAX, ZOLOFT, GLUCOTROL XL, CELEBREX, ARICEPT, DIFLUCAN (and the new version, VIRACEPT), RELPZX, DETROL LA, and NEURONTIN. Pfizer is incorporated in Delaware, and headquartered in New York, New York. It has operations in the United States and several other countries, and maintains its principal place of business in the United States at 232 East 42nd Street, New York, New York. Pfizer conducts business in the Commonwealth of Massachusetts and every state within the United States. In 2003, the year Relator's Complaint was filed, Pfizer had revenues of some $45.2 billion and 122,000 employees around the world; in the most recent past year (2006), Pfizer's revenues topped $52.5 billion dollars.

IV. FEDERAL AND STATE HEALTH INSURANCE PROGRAMS

6. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 *et seq*., (hereinafter "Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services through it Centers for Medicare and Medicaid Services ("CMS"). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons

over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, including under Part D of the Medicare Program, the Medicare Prescription Drug Benefit effective in about January 2004.

7. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§. 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States (and territories) and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services through CMS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid. States also use taxpayer revenue to fund other health insurance programs for children and/or adults, including, for example, the so-called S-CHIPS program, see 42 U.S.C. section 1397dd(a)-(c), and in Massachusetts the so-called Uncompensated Care Pool.

8. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

9. The federal government, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126; 42 U.S.C. § 256b.

10. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described in paragraphs 6-10 shall be referred to as "Government Health Care Programs").

V. RELEVANT FEDERAL AND STATE LAWS

A. The Federal Food, Drug and Cosmetic Act

11. The Federal Food, Drug and Cosmetic Act ("FFDCA") prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe *and* effective for its intended use. 21 U.S.C. § 355 (a) and (d). An approved drug may be prescribed by doctors for uses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or "off-label" uses. 21 U.S.C. § 331(d). If the manufacturer intends to promote the drug for a new unapproved use, the drug must be resubmitted to the FDA for testing and

approval (or the manufacturer must obtain an exemption therefrom) and the promotional materials must meet certain statutory requirements. 21 U.S.C. § 360aaa, *et seq*.

12. Whether a drug is FDA-approved for a particular use is a key factor in whether a prescription of the drug is reimbursed under Government Health Care Programs. For example, reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id. §1396r-8(k)(3). A medically accepted indication includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in a specified drug compendia. Id. §1396r-8(k)(6). There is a single exception: in certain circumstances Medicaid will reimburse the prescription of certain single-source or multi-source innovator drugs for an "off-label" use where the individual State has determined, *inter alia*, that the drug is essential to the health of beneficiaries. 42 U.S.C. § 1396r8(a)(3).

13. The Federal Food, Drug, and Cosmetic Act also prohibits, and provides criminal penalties for, the dissemination of certain written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug that is not described in the FDA approved labeling of the drug. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa(b) which include:

> (1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) or section 355 of this title or a biologics license issued under section 262 of Title 42:
>
> (2) the information meets the requirements of section 360aaa-1 of this title;
>
> (3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it were derived from research conducted by another

> manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;
>
> (4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary-
> (A) a copy of the information to be disseminated; and
> (B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;
>
> (5) the manufacturer has complied with the requirements of section 360aaa-3 of this title (relating to a supplemental application for such use);
>
> (6) the manufacturer includes along with the information to be disseminated under this subsection –
> (A) a prominently displayed statement that discloses –
> (i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;
> (ii) if applicable, that the information is being disseminated at the expense of the manufacturer;
> (iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;
> (iv) the official labeling for the drug or device and all updates with respect to the labeling;
> (v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1) of this section; and
> (vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or devise for which such information is being disseminated; and
> (B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

In addition, a manufacturer may disseminate written information on a new use of a drug only if the information is about a clinical investigation with respect to the drug and is contained in an article published in a scientific or medical journal, which is peer-reviewed by experts, or in a reference publication. 21 U.S.C. §360aaa-1 states in part:

> (a) Authorized information – A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information –

(1) is in the form of an unabridged –

(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which were published in a scientific or medical journal (as defined in section 360aaa-5(5) of this title), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or
(B) reference publication, described in subsection (b) of this section that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation ….

14. The FFDCA and its implementing regulations further treat drug "price lists" as "labeling" subject to FDA restrictions. *See* 21 U.S.C. § 321(k) and (m); 21 C.F.R. § 202.1(l)(2). These restrictions require price lists to conform to the regulations on labeling, *see* 21 C.F.R. § 201.100(d), or else fit within certain exemptions therefrom, *see* 21 C.F.R. § 200.200 and 201.100(f). It is therefore illegal for a drug manufacturer to market a drug using a price list which does not meet these requirements.

B. Federal and State False Claims Acts

15. The Federal FCA, 31 U.S.C. § 3729(a)(1) makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

16. The Federal FCA, 31 U.S.C. § 3729(a)(2) makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of

between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

17. The Federal FCA, 31 U.S.C. sec. 3729(a)(3) makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

18. The Federal FCA, 31 U.S.C. § 3729(a)(7) makes it illegal for any person to "knowingly" make, use or cause to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

19. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

20. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Georgia State False Medicaid Claims Act,

49 Ga. Code Ann. Chapter 4 at 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*, New Hampshire False Claims Act, N.H. RSA §§ 167:61-b, *et seq.*, New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468), New York False Claims Act 2007, New York Laws 58, section 39, article 13, section 189 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

C. Federal and State Anti-Kickback Laws

21. The Medicare Medicaid Anti-Kickback Act ("AKA"), 42 U.S.C. §1320a-7b (b), makes it illegal to offer, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Government Health Care Program. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient

having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services. Many States have similar laws pertaining to the Medicaid Program.

VI. FACTS AND ALLEGATIONS

A. Defendant Pfizer's Drugs and Sales

22. At all or some of the times relevant to this action, Pfizer manufactured, marketed and/or sold numerous brand name prescription drugs, including those with the trademark names of LIPITOR, VIAGRA, NORVASC, ZYRTEC, ZITHROMAX, ZOLOFT, GLUCOTROL XL, and CADUET ("the Drugs"). At various times relevant to this action, the Drugs were approved by the Food and Drug Administration for certain indications as described below.

(a) **LIPITOR (atorvastatin calcium)**. LIPITOR was originally manufactured by Warner Lambert Company ("WL") and co-marketed by WL and Pfizer from 1997-2000 when WL, and its subsidiary Parke-Davis, were acquired by Pfizer. LIPITOR was first approved to reduce elevated total cholesterol, low density lipids (LDL) and triglyceride levels in patients with primary hypercholesterolemia (i.e. elevated cholesterol levels). When introduced into the market in 1997, LIPITOR faced several competitors, including two, Zocor (manufactured by Merck) and Pravachol (manufactured by Bristol Myers Squibb) which had broader approved indications (i.e. to reduce fatal and non-fatal strokes and heart attacks) than LIPITOR. Nevertheless, by April 2000, LIPITOR was the number one prescribed cholesterol lowering medication and indeed the number one selling brand name drug in the United States.

It was not until late July 2005, that LIPITOR was granted approved for any additional indications, at that time for the reduction of cardiovascular events (heart attacks and strokes), but *only in* patients with coexisting elevated cholesterol levels *and* hypertension (i.e. high blood pressure).

In March 2007, the FDA approved additional indications for LIPITOR, in specific: (1) reducing the risk of nonfatal Myocardial Infarction; (2) reducing the risk for fatal and non-fatal strokes; (3) for use during certain types of heart surgery (or in lieu thereof); (4) reducing the risk of hospitalization for heart failure (congestive heart failure; and (5) to reduce chest pain in patients with heart disease.

Notably, LIPITOR *has not been approved* to reduce fatal and non-fatal strokes or heat attacks in patients with diabetes or atherosclerosis.

(b) **VIAGRA (sildenafil citrate)**, created by Pfizer, was launched and sold by Pfizer beginning in April 1998. It was approved for the treatment of erectile dysfunction and to date is not approved for any other indication.

(c) **NORVASC (amlodipine besylate)**, a calcium channel blocker, was created and manufactured by Pfizer. It was originally launched in 1991 and replaced Pfizer's earlier blockbuster blood pressure lowering medication called Procardia XL. NORVASC quickly became the dominant blood pressure medication in a market with some 50 competitors. At all relevant times, NORVASC was approved for the treatment of hypertension, chronic stable angina and vasospastic angina. NORVASC is not approved to treat coronary artery disease ("CAD"), although Pfizer details it for that use and even promotes it for that use on the

company's web site.

(d) **ZYRTEC (cetirizine hydrochloride)** was created by UCB Pharma and was sold by Pfizer starting in 1996. This drug was first approved for treatment of seasonal and perennial allergic rhinitis and for certain skin allergies in adults, and was later approved for use in children. It carries a post-marketing adverse events warning in its label/package insert, including for suicide and suicidal ideation.

(e) ZITHROMAX (azithromycin) was launched and sold by Pfizer beginning in 1991. It is an antibiotic which was at all relevant times approved/indicated for the treatment of patients with certain enumerated mild to moderate infections/disease states caused by certain susceptible strains of microorganisms (i.e. bacteria);

(f) ZOLOFT (sertraline hydrochloride) was also launched and sold by Pfizer in 1991. It is indicated for the treatment of *adults* with depression, obsessions and compulsions, and panic disorder (with or without agoraphobia). Zoloft's *only approved use in children* is for the treatment of obsessions and compulsions.

(g) GLUCOTROL and GLUCOTROL XL (glipizide) was launched and sold by Pfizer starting in 1984. Its delivery system was changed in 1990 to the XL formulation and delivered through the gastro-intestinal therapeutic system ("GITS") by way of extended release tablets. The drug is indicated as an adjunct to diet for the control of hyperglycemia and its associated symptomatology in patients with non-insulin dependent diabetes mellitus (i.e. Type 2 diabetes).

(h) CADUET is a single/fixed dose pill prescription drug consisting of 10 mg. of LIPITOR (the leading branded prescription drug for lowering cholesterol) and 5 mg. of

NORVASC (the leading branded prescription drug for high blood pressure). It was approved by the FDA on January 30, 2004 for the reduction of cholesterol and high blood pressure, and launched by Pfizer in May 2004. CADUET effectively extended the patent protection of both NORVASC and LIPITOR (which would face generic competition when their patent protection expired). CADUET is indicated for patients for whom *both* LIPITOR and NORVASC are approved/indicated. CADUET does not compete head to head with any other drug. Rather, its competitors are those drugs that compete individually against LIPITOR and NORVASC.

23. Each of the Drugs is or is among the top sellers in its field (or in the United States), and generates large revenues for Pfizer. For example, PFIZER'S approximate revenues from United States' sales of LIPITOR were $7.6 billion in 2003, $8.6 billion in 2004, $9.2 billion in 2005, and $10.3 billion in 2006. By way of comparison, for 2003 United States sales: for NORVASC were $2.2 billion; for ZYRTEC were $1.05 billion; for ZITHROMAX were $1.05 billion; for VIAGRA were $1.4 billion; for ZOLOFT were $2.3 billion; and for GLUCOTROL XL were $530 million. Each of the Drugs is not only included, but is a "preferred" drug (i.e. physicians are encouraged or required by the health plans to write prescriptions for these drugs over competing drugs in their class unless there is a generic version of the drug) on many, if not most, private insurance formularies, and has a preferred status as well for Medicaid, Department of Defense and Veteran's Administration Health Plans and, on information and belief, on federal and state employees health benefit plans, and under Medicare Part D.

24. In addition to the above enumerated Drugs, Pfizer has at all relevant times sold numerous other brand name instruction drugs implicated by this Complaint and the allegations

herein, including without limitation, Diflucan, Aricept, Trovan, Celebrex, Bextra, Viracept, Relpax and Detrol LA among others.

B. Pfizer's Corporate Structure

25. At all times relevant to this case, Pfizer marketed its drugs in the United States through U.S. Pharmaceuticals. During Relator's tenure with Pfizer, U.S. Pharmaceuticals was organized through two "Clusters": "Cluster X" which emphasizes cardiovascular drugs and includes all of the Drug described in paragraph 22 above, except for Zoloft; and "Cluster A" which emphasizes central nervous system drugs, including Zoloft. Each Cluster was headed by a Senior Vice President of Sales, and in turn had several Sales Divisions across 8 Regions of the country. Each Region had a Regional Manager, and within each Region there were twelve districts, each with a District Manager and nine or ten sales representatives, including specialty representatives such as IHR's (institutional healthcare representatives), CHSRs (cardiovascular healthcare representatives), and RHRs (renal/urology healthcare representatives).

26. The drugs at issue in this action were in all cases marketed/sold by more than one division within a Cluster, depending on, for example, the specialty of the physician customer or institution, and sometimes were even sold across a Cluster. For example, LIPITOR, NORVASC, and VIAGRA were sold by every sales division in Cluster X, while ZOLOFT was sold by every sales division within Cluster A. Pfizer labeled this corporate approach to marketing "copromotion." According to Pfizer, copromotion enhanced the quality of detailing minutes in physicians' offices and increased the writing of prescriptions. Copromotion ensured that every doctor was called on at least once per week by both a Cluster X representative and a Cluster A representative, and that the high writers and key influencers would be called on at least 2-3 times per week.

27. Pfizer has over the years acquired various other drug companies and their products. Most notably, in June 2000, Pfizer acquired competitor Warner-Lambert Co. and its subsidiary Parke-Davis Labs, and in April 2003, Pfizer acquired competitor, Pharmacia.

C. Pfizer's 2002 LIPITOR Settlement and Corporate Integrity Agreement

28. In late October 2002 Pfizer and its subsidiaries, Warner-Lambert and Parke-Davis, agreed to pay $49 million to settle allegations that the company violated the False Claims Act, by fraudulently avoiding paying fully the rebates owed to the state and federal governments under the national drug Medicaid Rebate program for the cholesterol-lowering drug LIPITOR. Defendant, Parke-Davis Labs, then a subsidiary of Warner-Lambert, which was subsequently acquired by Pfizer in 2000, allegedly overstated the LIPITOR best price in the first and second quarters of 1999 by concealing $250,000 of cash discounts that were given to a key managed care customer in Louisiana in exchange for favorable status on the managed care organization's drug formulary. These unreported discounts to the managed care organization allowed Parke-Davis/Warner-Lambert unlawfully to retain over $20 million in Medicaid Rebates. In addition to the $49 million settlement, Pfizer entered into a five-year corporate integrity agreement with the United States Department of Health and Human Services' ("HHS") Office of Inspector General ("OIG"). The Corporate Integrity Agreement ("CIA") included requirements that Pfizer certify its best price processes and maintain internal procedures designed to prevent future problems in compliance with the Medicaid program.

29. In response to the LIPITOR settlement, Pfizer stated: "Pfizer acquired Warner-Lambert in June 2000, after the transactions at issue…In addition, Pfizer has entered into a corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which is consistent with Pfizer's existing voluntary compliance

program. .. 'We are pleased to bring this legacy Warner-Lambert matter to a conclusion,' said Jeffrey B. Kindler, Senior Vice President and General Counsel of Pfizer.' In addition, because integrity is one of Pfizer's core values, we look forward to working with the HHS Inspector General on continuously improving our compliance programs."

30. Prior to this, in August 2002, Pfizer had sent out new directives to its entire U.S. sales force, including Relator/Plaintiff Mr. Collins, regarding each employee's duty to report any illegal conduct within the company immediately upon discovery under a so-called "Open Door Policy." Pfizer's "Open Door Policy" states, in relevant part: "Freedom from retaliation. The Open Door Policy expressly prohibits any type of retaliation as a result of raising an issue or being involved in the open door process. If a colleague feels that he or she has experienced retaliation, he or she should contact the person responsible for the fact-finding investigation, local Human Resources or Global Diversity."

31. As detailed below, during 2003, Mr. Collins, in accordance with this Pfizer Open Door Policy and the requirements of the Pfizer LIPITOR Corporate Integrity Agreement, brought to the attention first of his District Manager and then to Corporate Compliance in New York, New York, illegal conduct that was occurring in the Utah District, the Rocky Mountain Region, and elsewhere among the Pfizer sales force. Contrary to assurances provided to employees and the government on paper, Mr. Collins was met with harsh retaliation and then firing in August 2003, despite his stellar record as a Pfizer employee.

D. Pfizer's Internal Healthcare Law Compliance Program and its *Key Principles Guide*

32. In the latter part of 2002, Pfizer also began sending to the field sales force various communications relating to compliance with federal laws as part of it s new "Healthcare Law Compliance Program." In January 2003, Hank McKinnel, the CEO of Pfizer distributed Pfizer's

Key Principles Guide accompanied by a cover letter acknowledging important new compliance initiatives such as the PhRMA Code and Draft Compliance Guidelines by the HHS OIG. The *Key Principles Guide* contains, *inter alia*, acknowledgment of laws prohibiting kickbacks and off-label marketing, and regulating sampling and other actions which may affect government health care drug pricing programs (including the Medicaid rebate program). The CEO promised that more detailed rules and regulations manuals would be coming and that the field sales force, marketing and medical would all be trained in compliance. Relator received these materials and training.

E. Pharma Guidelines Issued in 2003 by the HHS OIG

33. In May 2003, the Inspector General of HHS published final guidance on marketing practices known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers" 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines" or "Pharma Guidelines"). In addition to addressing kickbacks and other illegal activities, the OIG Guidelines address appropriate Compliance Programs that Pharmaceutical Manufacturers are encouraged to maintain. Some of the relevant elements of those Guidelines are the following:

"Compliance Program Elements II A 2:

The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation..

Designation of a Compliance Officer II C 1:

Responsibilities shall include…. Participating with the company's counsel in the appropriate reporting of any self-discovered violations of federal health care program

requirements….

II C 2 – Hotlines and Other Forms of Communication

…. Reported matters that suggest substantial violations of compliance policies or applicable federal health care program requirements should be documented and investigated promptly to determine their veracity and the scope and cause of any underlying problem. **The compliance officer should maintain a detailed log that records such reports, including the nature of any such investigation, its results and any remedial or disciplinary action taken. Such information redacted of individual identifiers, should be summarized and included in all reports to the board of directors, the president or CEO, and the compliance committee."** (emphasis added).

F. Pfizer's 2004 Neurontin Settlement and Second Corporate Integrity Agreement

34. During the time Mr. Collins was complaining internally at Pfizer, the company was involved in an ongoing federal and state investigation and litigation involving the marketing of Neurontin under Pfizer's subsidiary Warner-Lambert (before Pfizer's acquisition of that company), and, on information and belief, was negotiating a possible resolution with the federal and state governments. Subsequently, in May, 2004, Warner-Lambert/Parke Davis/ Pfizer, the United States and the States, resolved the Neurontin investigation by agreeing: (a) that Warner-Lambert would plead guilty in the District of Massachusetts to two counts of violating the Federal Food, Drug and Cosmetic Act and pay a fine of $240 million; (b) that Warner-Lambert would settle federal and State FCA and consumer protection claims by paying the United States and the States a total of $190 million to account for damages caused to federal and state health insurance programs; and (c) that Pfizer, Warner-Lambert's parent company, would enter into a corporate compliance agreement/program to ensure that the changes Pfizer supposedly made

after acquiring Warner-Lambert would be effective in training and supervising its marketing and sales staff and to ensure that any future off-label marketing conduct would be detected and corrected on a timely basis. This Corporate Integrity Agreement ("CIA") incorporated and superceded the CIA entered into by Pfizer as part of the 2002 LIPITOR settlement referenced above.

The CIA contains several relevant provisions, among them the following:

III A - Duties of the Compliance Officer –
The Compliance Officer is responsible for the day-to-day monitoring and reporting of compliance activities.

III B – Written Standards
Pfizer's Code of Conduct manual shall set forth the right of individuals to use the Disclosure Program (III E below) and Pfizer's **commitment to nonretaliation** and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

III E – Disclosure Program –
The Disclosure Program [implemented as the Open Door Policy] shall emphasize a nonretribution and nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained.

The **Compliance Officer is required to maintain a Disclosure Log** which shall contain a summary of each disclosure received the status of the respective internal reviews and any corrective action taken in response. The Log shall be made **available to the OIG upon request**.

V C – Certifications
The Annual Report shall include a **certification by the Compliance Officer** that, to the best of their knowledge, Pfizer is in compliance with the requirements of the CIA.

VIII – Documents and Record Retention
Pfizer shall maintain for inspection documents and records relating to compliance with the CIA for six years. (Emphasis added)

35. In response to the Neurontin settlement, Pfizer issued a statement that: "The underlying allegations and related investigations originated in 1996, well before Pfizer's acquisition of Warner-Lambert in 2000. The allegations and conduct pertain solely to Warner-

Lambert practices. Pfizer has cooperated fully with the government to resolve this matter, which did not involve Pfizer practices or employees. Pfizer is committed to compliance with all healthcare laws and FDA requirements and to high ethical standards in all aspects of its business practices. Indeed, the government has acknowledged the voluntary compliance measures Pfizer has long had in place." (emphasis in original).

G. Plaintiff/Relator's Position With Pfizer U.S. Pharmaceuticals

36. Plaintiff/Relator Blair Collins began working for Pfizer U.S. Pharmaceuticals, in October 1998 in the Fort Worth, Texas district of the then Southwest Region (renamed the Gulf Coast Region in April, 2003 after Pfizer acquired Pharmacia and realigned Pfizer's sales divisions). At the beginning of his employment in 1998, Relator worked in a newly formed division called Division J (renamed the Steere Division in early 1999). Relator's district manager was Dennis Gooch and his Regional Manager was Craig Smith. The Southwest Region at that time included Texas, Louisiana, New Mexico, Arizona, Oklahoma, Utah, Wyoming, Montana and Idaho. The Steere Division was primarily responsible for selling VIAGRA, but the sales representatives also sold other drugs including ZITHROMAX, GLUCOTROL XL, NORVASC (starting late in 1999), and LIPITOR (starting in 2000). They also worked alongside sales reps who were selling ZOLOFT, ZYRTEC, DIFLUCAN, ARICEPT, TROVAN, CELEBREX and BEXTRA, among others. This organizational structure, with multiple reps selling the same product across divisions or groups, was part of Pfizer's copromotion marketing strategy noted above.

37. For the years 1999 and 2000, Relator was his District's recipient of Pfizer's Blue-Vase award given to one individual each year. That person is chosen by their peers as the person who best represents the "Billy Peck" attitude (it shall be done) and the Pfizer core values (among

them are integrity, leadership, performance, teamwork, and loyalty). After his promotion in 2001, Relator was no longer eligible for this award.

38. In about October 2000, Relator's District Manager in Texas recommended Relator be promoted to Institutional Healthcare Representative (IHR) (i.e. selling to institutions such as hospitals, not just to individual physicians or physician practices). The recommendation was based on Mr. Collins' performance matching Pfizer's "core values." Relator was promoted to IHR in July 2001. As an IHR, Relator was responsible for covering four major health systems consisting of many hospitals and about 20 outpatient clinics associated with them.

39. By December 2001, Relator was selected to train as the Assistant to the Southwest Regional Manager. By November 2002, Relator ranked as the seventh best sales representative in the Steere Division among all 84 institutional healthcare sales representatives nationally.

40. In August 2002, the illness of Relator's mother caused him to seek a transfer from Fort Worth, Texas to Provo, Utah. The only opening there was as a sales rep in the Pratt Division (to replace Corbett Carver who had been promoted to IHR in Salt Lake City). Relator changed Divisions and became part of the Pratt Sales Division. He took a demotion in title (to sales rep), but kept the same pay grade. Relator's new division was the leader in LIPITOR sales.

41. By October 1, 2002, Mr. Collins' transfer to Utah was complete and he began working in Utah's "Pilot District" where he was responsible for selling LIPITOR, NORVASC, ZYRTEC, ZITHROMAX and VIAGRA. His new District Manager ("DM") was Scott Latimer, who was the DM for the Labs Division and the "Cluster X" Utah Pilot Program, which included the "Cluster X" representatives and IHR's in the Salt Lake and Provo, Utah Territories. Mr. Latimer had been with Pfizer since February 1990, including over six years as a DM. For the

year ending December 2002, despite Relator's move to Utah and the attendant transitional time, Mr. Collins generated more than $27 million in sales for Pfizer U.S. Pharmaceuticals.

42. Relator's compensation package, like that of other sales representatives, included salary, potential bonus(es), potential rewards trips, tuition reimbursement for anyone seeking advanced degrees, a handsome "ACE" Point Rewards compensation, health insurance for Relator and his family, other insurance benefits, and numerous other fringe benefits.

43. Mr. Collins, like other sales representatives, had a marketing budget. The size of a rep's budget depended on the size of their territory, and the type/level of sales representatives they were. For example, sales representatives had between $28,000-$35,000 per year for meals, travel, expenses, etc., and an additional $8,500-$10,000 per year to pay for speaker honoraria, preceptorships and the like. IHR's and other specialty reps (e.g., CHS reps, RU reps) had between $45,000 and $50,000 with an additional $12,000 to $15,000 or more per year to be used for "developing" residents and fellows to speak, as well as paying honoria to staff and other trusted specialists to speak to residents and fellows to change their prescribing toward Pfizer products, or reinforce their commitment to write Pfizer products. This money was supplemented with additional funds each district manager "held back" at the first of the year and allotted to the reps or specialty reps who used their money in the first 8 or 9 months of the year in order to generate greater returns. Management also had budgets to be used separately, or to supplement, reps' budgets. For example, as illustrated below, District and Regional Managers had *annual* marketing budgets estimated by Relator to be about $80,000 for DMs, $100,000 for RMs, $50,000-$60,000 for RMRs, National Account Managers and National Healthcare Organization Representatives, and $40,000-$50,000 for PharmD Pharmacy Consultants ("CECs"). In addition, the Disease Management Teams had what appeared to be "limitless" budgets (hundreds

of millions of dollars/year). Pfizer expected to get a $10 return on investment (i.e. sale of its drugs) for every $1 spent through marketing budgets.

44. In addition to these cash budgets, Pfizer regularly provided the reps and the managers with very large volumes of drug samples that were to be liberally provided to customers to, *inter alia*, influence prescription writing habits and formulary choices. Described below are the volume of samples Relator had in Texas as a rep and an IHR and in Utah as a rep.

H. Summary of Facts and Allegations

45. As outlined in detail below, Pfizer has engaged in numerous types of illegal activity on a national scale involving the marketing, selling, prescribing, pricing, and billing of LIPITOR, VIAGRA, ZYRTEC, NORVASC, ZITHROMAX, ZOLOFT, GLUCOTROL XL and CADUET, and the pricing and promotion of numerous other drugs including without limitation DIFLUCAN, ARICEPT, TROVAN, CELEBREX, BEXTRA, RELPAX and DETROL LA. Among Pfizer's transgressions are the following:

(a) using unlawful advertising, including, without limitation, unapproved articles, price lists and other materials, including to promote off-label uses of the Drugs;

(b) providing unlawful incentives (i.e. kickbacks) to customers in exchange for patient referrals, prescribing of medications manufactured and/or sold by Defendant, and to facilitate the placement of such drugs on formularies; and

(c) engaging in various activities which affected the pricing of Pfizer's drugs and resulted in Government Health Care Programs overpaying for Pfizer's drugs, including without limitation, by distributing large numbers of drug samples to all clinics, doctors offices and health institutions, that were never reported to Government Health Care Programs; and

(d) Marketing the maximum dosages of the Drug, including in the off-label context and/or when not medically reasonable or necessary, and thereby increasing the risk of serious side effects and otherwise undermining the quality of care afforded to patients.

Moreover, Pfizer made false representations to the government in the context of the investigation and negotiation of the Neurontin settlement and has violated the terms of both Corporate Integrity Agreements ("CIAs") it entered into with the United States Department of Health and Human Services OIG; and Pfizer retaliated against the Relator for his complaints about Pfizer's illegal activity in violation of the federal False Claims Act and the CIAs.

46. Pfizer's illegal activities are each violations of law, but together demonstrate a concerted national corporate strategy to use kickbacks, off-label promotion, pricing "incentives" and other tactics directed from the highest levels of the company to assure that Pfizer's drugs would not only compete, but would receive preferential treatment, thereby putting Pfizer's competitors at an unfair disadvantage, depriving certain providers and consumers of a fair and informed choice, and causing Government Health Care Programs to expend excessive amounts of money to reimburse the cost of Pfizer's drugs. All of this has been done despite two CIAs, the OIG's Pharma Guidelines, and internal complaints from employees such as Relator who instead of being treated with respect, are harassed and harshly retaliated against.

I. Specific Examples of Pfizer's Illegal Activities

1. Pfizer's Use of Illegal Price Lists in Violation of the FFDCA

47. By October 1, 2002, Mr. Collins' transfer to the Utah "Pilot" District was complete. A few months earlier another co-worker, Bryan Osborn, began working at Pfizer in Utah's Parke-Davis III Division within the Utah Pilot managed by District Manager Scott

Latimer. At about the same time Mr. Collins arrived in Utah, Mr. Osborn completed Pfizer training. Around the time of Relator's arrival, September 27, 2002, Mr. Osborn distributed to his co-workers by electronic mail ("e-mail") a price list that contained a direct cost comparison of Pfizer's drug ZYRTEC with its competitors as a way to help his new co-workers increase sales and meet quotas.

48. Every month all sales representatives with responsibility for sales of drugs in the same territory would have a meeting, known as a "LAT" to compare notes and make sure they were calling on all the physicians, and to be sure they were also focused on the most important physicians so their time was used most efficiently. The District Manager would typically attend such meetings.

49. At the Utah District "LAT" meeting on May 9, 2003 attended by his co-workers in the District and his District Manager, Mr. Osborn gave his co-workers handouts and suggestions on the use of homemade local comparative price lists for the drug LIPITOR based solely on prices at a local Wal-Mart ("the Wal-Mart Price List"). His original price list was highlighted (as were the copies) to compare the prices of LIPITOR 10 mg ($66.08) with competing drugs Zocor 20 mg ($127.32) and Pravachol 40 mg ($127.84). He told how he had used such lists to convince physicians to write prescriptions for Pfizer drugs, including LIPITOR. That was when Mr. Collins learned for the first time that Mr. Osborn had been using such price lists in selling to physicians.

50. Relator was very concerned over what he saw as illegal price lists being used to sell to doctors. Immediately following this meeting, Mr. Collins approached his District Manager, Scott Latimer, in the meeting room, alone after everyone else had gone. He told his Manager words to the effect that Pfizer had good products and good sales reps and they could do

really well without doing anything that was wrong. Mr. Latimer spoke to Relator in words to the effect: "Don't worry about it Blair."

51. The next business day, May 12, 2003, DM Latimer traveled to Denver for a Regional Managers and District Managers meeting to be held from May 12-16, 2003. Part of the agenda for this meeting was to discuss Pfizer's 2002 CIA, the Sarbanes-Oxley Act, sexual harassment and wrongful termination, etc., and various other legal developments, as a result of which Pfizer's legal department had issued new training for all U.S. employees. At that meeting the RMs and DMs also planned for an upcoming "Point of Action" ("POA") meeting of all sales representatives to be held in Denver. A POA meeting is a three day meeting held three times a year for the sales force to receive information from management on how to sell the drugs in the field for next four months. In addition, there are three mid-POAs during the year, and a "kickoff" meeting at the beginning of the year.

52. On Wednesday May 21, 2003, the Relator met with his DM at his request to see how RMs and DMs wanted VIAGRA presented at the upcoming POA meeting in Denver. This POA was a meeting for all of Region 8 Cluster X and included Utah, Washington, Oregon, Montana, Idaho, New Mexico, Wyoming, Colorado, Kansas, Oklahoma and part of Arizona. DM Latimer had earlier chosen Relator for leadership of the VIAGRA Team and they were discussing VIAGRA strategy for the POA. Relator had an article he intended to use and wondered if he should just bring the original article or if he should also bring a copy of it with key points highlighted. This query by Relator prompted the DM to say words to the effect that he needed to be sure to send a message out to everyone in the district to make sure their [detailing] books were "cleaned up" for the upcoming POA. He said it would be bad to have unapproved pieces in the books.

53. Unlike a typical POA meeting, all Pfizer DMs, RMs, vice presidents of sales and senior vice presidents for Cluster "X" were expected to be present at the upcoming Denver POA meeting. By voicemail on Friday May 23, 2003, to his sales team, DM Latimer reminded his team: "Hi team, it's Scott, hey, it's 12, about 12:30 on Friday, hey, I just wanted to see if I could get you all to do me a favor. To prepare for this POA meeting next week, uh, if you could do me a favor and just make sure that your detail books are, um, you know, that you have them in one place, you've got the visual aids in place, and, I'm sure there's nothing in there, but if there's anything like, um, price sheets, spreadsheets, you know, unapproved clinicals, uh, make sure that we get those things cleaned up, and uh, get those things out of there. Again, I'm confident that, uh, we've been pretty clear on that in the past, but if there's any question on that, uh, please, uh, make sure that's cleaned up. So if you have any questions, give me a call." (emphasis added).

54. "Detail books," as referred to in DM Latimer's voicemail, are books that each sales representative has in which they keep all the material they use to assist them in selling drugs to customers. "Detailing," as understood by Relator, includes all oral and written material presented by a sales representative to a customer such as a physician or a hospital. Relator's understanding was that in "detailing" a representative was to use only Pfizer approved materials.

55. On May 29, 2003, the third day of the POA meeting in Denver, Relator learned that the ZYRTEC sales representatives were using a homemade list of competing drugs and a comparison of which Health Maintenance Organizations approve which drugs to sell to doctors. DM Latimer had approved use of this list. At that same meeting, sales representative Bryan Osborn redistributed the Wal-Mart Price List for LIPITOR and its competitors that he had handed out at the May 9, 2003 LAT meeting. According to Osborn, DM Latimer had approved the Wal-Mart Price List also, and indeed was present when Osborn used it in selling to Dr.

Badger and other cardiologists. According to Osborn, the DM discussed the Wal-Mart Price List with the doctors, emphasizing the low cost of LIPITOR. Mr. Osborn claimed these discussions were effective in changing doctors' minds. At the same meeting, Renee Christensen also revealed that she had been detailing doctors with certain Intermountain Healthcare ("IHC") newsletters. While Pfizer had sent the reps a United Healthcare pricing comparison as part of the materials for this POA, Christensen, Carver and DM Latimer decided to use the IHC piece instead of the UHC material because IHC was more relevant to the Utah territory.

56. Federal law prohibits using stated prices to be the means of selling medication by pharmaceutical manufacturers except in certain circumstances. Pfizer had distributed price lists that were acceptable, but the homemade price lists of the kind being used in the Utah District are illegal. When price lists are permitted at all they must meet several requirements, including: (a) prices must be verified by independent, objective, "outside" (i.e. not the company) sources for accuracy; (b) the list cannot compare competitor's drugs side by side because this implies that all of the drugs have similar/comparable composition, effectiveness, side-effects and safety; (c) prices presented must be industry-wide, i.e., not based on one pharmacy in one city; and (d) so-called "homemade" price lists (i.e. put together by an employee, not the company) are forbidden under any circumstances.

2. Pfizer's Unlawful Off-label Marketing and Use of Unapproved Articles

57. As noted above, in 2004, Pfizer entered into a global settlement with the government including a criminal plea, a civil settlement and a CIA, involving the off-label marketing of the drug Neurontin which Pfizer had acquired when it purchased Warner Lambert/ Parke-Davis in 2000. While Pfizer implied that this off-label marketing was unique to Neurontin (and a hold over from Warner Lambert), the truth is that *Pfizer* has marketed many

drugs "off-label" over the years as part of a concerted strategy. Pfizer's off-label marketing includes, without limitation, drugs developed and marketed by Pfizer in the 1990's such as ZOLOFT, ZITHROMAX and VIAGRA, as well as other drugs, most notably LIPITOR, which Pfizer was marketing for Warner Lambert from launch in 1997, and was still off-label marketing more than 3-4 years *after* purchasing Warner Lambert. Indeed, the off-label marketing of LIPITOR and other drugs described herein was blatantly occurring during the Neurontin investigation and settlement negotiations, and continued afterwards. As demonstrated below, off-label marketing was/is but one strategy used by Pfizer to undercut competitors and preserve or grow market share and revenues.

a. Off-label Marketing of LIPITOR, NORVASC, and CADUET

58. Pfizer acquired the cholesterol lowering drug LIPITOR when it purchased Warner Lambert in 2000. Before that, Pfizer sold Lipitor with and for Warner/Lambert starting in 1997 when Lipitor was launched. There were various competitors to LIPITOR, including Zocor (Sumvistatin), manufactured by Merck, and Pravachol (Pravastatin), manufactured by Bristol Myers Squibb.

59. Over the years after launch, one of LIPITOR's main drawbacks or weaknesses versus its competitors was that there was no "outcomes data" for LIPITOR , i.e., data that showed that LIPITOR reduced morbidity and mortality. In contrast, by 1997, *both* Zocor and Pravachol had been FDA approved for "outcomes data" for a few years. In addition, Zocor and Pravachol were both approved/indicated to reduce cardiovascular events [i.e. strokes and heart attacks] in diabetic patients (of which there are now some 21 million in the U.S., increasing at about 16%/year since 1995) and in patients with atherosclerosis (i.e. hardening of the artery walls). However, from the time LIPITOR was launched in 1997, it had neither outcomes data

nor approval for use in diabetic or atherosclerotic patients.

60. Relator began selling Lipitor in October of 2000 while in the Southwest Region of Pfizer, and he continued selling Lipitor after he moved to Utah in October 2002. In Lipitor's first years on the market it enjoyed great success, growing at 12%-15%/year. However, in 2000, Merck began to promote Zocor using Merck's "Heart Protection Study", and by September 2001, LIPITOR sales began to go flat. This trend worsened with the FDA approval of Zetia (manufactured by Merck and Schering Plough) in 2002. As a result, during the period October 2001- October 2002, sales of Lipitor were flat and then falling, especially among specialists such as cardiologists and endocrinologists whom Pfizer viewed as critical thought/opinion leaders able to influence the prescription writing habits of primary care physicians. See the *Lipitor Lowdown*, Issue 1 January 2003 (a newsletter distributed to Cluster X employees). Similarly, according to that issue of the *Lipitor Lowdown*, Lipitor monthly detail share [i.e. sales calls by reps] *and* monthly sample share [i.e. number of samples of the drug left with customers such as doctors, etc.] had both declined during the period September 2001- September 2002. In the newsletter, Pfizer headquarters called on reps and managers to increase both details and samples because each is a *"key driver that influence physician prescriptions."* (*Id.* p. 7, emphasis added).

61. In addition to flat or falling LIPITOR revenues, by early 2003 Pfizer was anticipating *three* new competitors to Lipitor. One of them, Zetia, manufactured by Merck/Schering Plough and approved in October 2002 was the first cholesterol lowering drug to work through the small intestine. Zetia is also mentioned in the *Lipitor Lowdown, supra.* The two other looming competitors were Crestor, manufactured by Astra-Zeneca and to be marketed using members of the former Warner Lambert Lipitor Disease Management Team who had launched Lipitor (Crestor was ultimately approved for marketing on or about August 12-13,

2003); and Vytorin (a combination of Zocor and Zetia that would compete with CADUET—also noted in the *Lipitor Lowdown*), ultimately approved in October of 2003.

62. Through the POA meetings in 2003, Pfizer headquarters directed a national strategy to turnaround Lipitor's performance and blunt the competition. For example, as described in detail below, the materials and slides developed by Pfizer for the August 2003 mid POA state Pfizer's clear concern that: "this is the most important time in the [Lipitor] brand's history since it was launched in 1997;" "[in] June 2003, LIPITOR owns its smallest percentage ever of the cholesterol market and is losing market share and this trend must be reversed;" and "the months of August to November 2003 will be 'three critical months' for LIPITOR."

63. Among the company's objectives were to "Take ownership of ***specific patient types***" (emphasis added), namely, diabetics, atherosclerotic, and hypertensive patients. The slides outline the ways to do this, essentially through incentives/kickbacks and through off-label marketing. Key to this strategy is Pfizer's plan to use "Exciting New Data on the Horizon for LIPITOR," i.e. studies that address these targeted "specific patient types," including:

> "ASCOT" which "studies the effect of lipid-lowering in the *hypertensive* patient"
>
> "CARDS" which "studies the effect of lipid-lowering in the *diabetic* patient" and
>
> "REVERSAL" which "studies the effect of lipid-lowering on the progression of *atherosclerosis*." (sic) (emphases added).

However, at that time, none of these studies should have been used in any detailing by the sales force to physicians or other customers. Pfizer didn't receive approval to change the labeling of LIPITOR to include outcomes data or a statistically significant cardiovascular benefit for the *hypertensive* patient until late July-early August 2004, almost one year after this 2003 mid POA. The CARDS trial was not submitted to the FDA until October 2004, and *still has not been approved* by the FDA for a revision in LIPITOR's package labeling for the prevention or

reduction of cardiac events in the diabetic patient. The REVERSAL study, with Pfizer's claim that LIPITOR can reverse the effects of *atherosclerosis,* has to Relator's knowledge, not been submitted to the FDA; and it has never been approved for Lipitor's package labeling. In other words:

- from at least mid-2003-mid 2004, Pfizer used the results of the ASCOT study to engage in unfair competition and misleading and off-label marketing of LIPITOR for the treatment of hypertensive [i.e. high blood pressure] patients who had normal cholesterol levels, *and* to tout "outcomes data" [i.e. mortality and morbidity] for LIPITOR; and
- since at least mid-2003 and continuing at present, Pfizer has used the CARDS and REVERSAL studies to engage in off-label marketing of LIPITOR for treatment of diabetic and atherosclerotic patients, in both cases claiming that LIPITOR reduces the number of cardiovascular events [i.e. heart attacks and strokes] in such patients.

64. Pfizer's 2003 Lipitor marketing strategy (described in detail below, combining off-label marketing with kickbacks and other incentives including heavy sampling), was extremely successful. By the end of 2003, there was an impressive turnaround in LIPITOR revenue: despite the launch of two new competitors (Vytorin and Crestor) into the market and the dismal first 6-8 months of the year, LIPITOR revenue rose by 18% for 2003. The upward trend continued into 2004-2005.

65. In the first quarter of 2004 (compared to the first quarter of 2003), LIPITOR revenues rose by 17% (or $510 million) (see SEC filing April, 2004), with CEO McKinnell declaring that this increase was due to "reinforcing data from the ASCOT, CARDS, REVERSAL

and PROVE-IT studies, *which have all demonstrated early and significant improvement in cardiovascular outcomes*." (emphasis added). By the end of 2004, LIPITOR (and NORVASC and CADUET) were on over 80% of the national formularies. In its January 15, 2005 8-K filing with the SEC for the last quarter of 2004, Pfizer states: "The performance of LIPITOR is driven by the wealth of clinical evidence from such trials as ASCOT-LLA, REVERSAL, CARDS and PROVE-IT which are shaping cholesterol management." Statement of Karen Katen, Executive Vice President of Pfizer Inc. and President of Pfizer Global Pharmaceuticals. *See* January 15, 2005 8-K filing with the SEC for the last quarter of 2004. *See also* Pfizer's 2004 10-K filing in which Ms. Katen and the Pfizer CEO Hank McKinnell both explain the connection between LIPITOR'S impressive revenue growth and these *off-label* studies.

66. LIPITOR revenues continued to rise in 2005, with the first quarter of that year recording revenue of over $3 billion, resulting from another substantial gain (i.e. about 20%) compared to the same period in 2004. During 2005, in addition to ASCOT, CARDS and REVERSAL, Pfizer touted other studies as well including PROVE-IT and Treat to New Targets ("TNT") released in March 2005 (although TNT did not cover diabetic or AT patients either). According to Pfizer's SEC 8-K filing dated April 19, 2005, TNT found that intensive therapy with Lipitor 80 mg can reduce cholesterol and cardiovascular events to among the lowest levels ever achieved in the history of statin trials, *with a safety profile comparable to that of lower-dose LIPITOR therapy*. At least the latter claim in patently false: according to the LIPITOR approved package insert, the incidence of irreversible liver damage jumps from 0.2% with LIPITOR at 10 or 20 mg. to *2.3%* at 80 mg. In other words, with some 65 million people or so taking LIPITOR in the United States, that is a difference of some 130,000 patients (.2%) developing rhabdomyalysis (irreversible liver damage) versus some 1,495,000 patients (2.3%) developing

this condition. Nevertheless, according to CEO McKinnell, "These results take the treatment of cholesterol to new frontiers, while also reinforcing data from the ASCOT, CARDS, PROVE-IT, and REVERSAL studies—which have all demonstrated early and significant improvement in cardiovascular outcomes."

67. Using the TNT trial to sell LIPITOR constituted (and still constitutes in some aspects) illegal off-label marketing. In particular, from 2005 until at least May 2007 when the FDA approved a change in the LIPITOR label for five new indications (listed above in paragraph 22), it was illegal to use TNT to promote those five new indications. Continuing to this day, it is illegal to use TNT to promote the use of LIPITOR for diabetics and/or AT patients. It is also illegal to use it to advocate that 80 mg of LIPITOR provides a greater benefit to the patient than 10 mg of LIPITOR *with the same level of side effects* constitutes off-label marketing. In fact, the results of the study itself did not show that LIPITOR 80 mg had the same level of side effects as LIPITOR 10 mg, and neither does LIPITOR's package labeling, as most recently approved by the FDA in May 2007.

68. The first of the three studies Pfizer used as the foundation for its 2003 off-label marketing campaign to aid Lipitor's spectacular turnaround was The Anglo-Scandinavian Cardiac Outcomes Trial ("ASCOT"). This study consisted of a parent study, and a substudy known as the ASCOT Lipid Lowering Arm ("LLA"), which together studied the effect of lipid lowering in some 22,000 patients with *hypertension (i.e. high blood pressure), but normal cholesterol ranges*. One part of the study consisted of about 8,000 patients and compared those who were treated with an ACE Inhibitor alone with those patients who were treated with an ACE Inhibitor *and* NORVASC. Another part of the study, ASCOT LLA, involved some 12,000 patients whose cholesterol ranges were normal, and compared patients in one group who were

treated with an ACE Inhibitor and no LIPITOR with patients in another group who received LIPITOR *and* NORVASC. ASCOT also studied/contained "outcomes data" for LIPITOR. The study showed that those patients who were treated with LIPITOR had fewer heart attacks and strokes than the control group who was not treated with LIPITOR. The ASCOT study was slated to last five years, but it was ultimately stopped ahead of schedule because the data showed positive effects on hypertension from NORVASC when used in combination with an ACE Inhibitor; and because the ASCOT LLA data showed positive effects of LIPITOR on hypertension. The ASCOT data also purported to show that those patients who were treated with LIPITOR had fewer heart attacks and strokes than the control group who was not treated with LIPITOR (in other words, it provided positive "outcomes data").

69. The second of the three studies Pfizer used in 2003 was the "CARDS" study. This study consisted of only about 2,200 Type 2 *diabetic* patients who had normal cholesterol levels; about 84% of them had high blood pressure. The study compared those being treated with a 10 mg. dose of LIPITOR to those on placebo (i.e. no statin drug at all) to see what, if any, effect there would be on cardiovascular events, i.e. heart attacks and strokes. Of the 2,200 patients, 600 ended up not being evaluated in the study results.

70. Pfizer also stopped the CARDS study early, not because it showed that diabetic patients receiving LIPITOR had fewer cardiac events than those receiving no statin at all, but because Pfizer wanted to use ASCOT to market LIPITOR as a way to eliminate angioplasty procedures in diabetic patients. Consequently, Pfizer claimed that CARDS (even with its small population and lack of data) showed the same benefit for the diabetic patient that ASCOT had shown for the hypertensive patient. Pfizer also fostered the false impression that a 40 or 80 mg. dose of LIPITOR would prevent cardiovascular events in diabetic patients (even though CARDS

patients only received a 10 mg. dose of Lipitor). In fact, diabetic patients are at a much greater risk of heart attack or stroke than a hypertensive patient, and bypass surgery or angioplasty are the traditionally accepted therapy for cardiac patients who suffer from diabetes. Using LIPITOR for the treatment of such at-risk patients effectively leaves these diabetic patients untreated. Moreover, diabetic patients are at higher risk for liver damage from LIPITOR.

71. The third study Pfizer touted was "REVERSAL." This study consisted of only about 502 patients with *atherosclerosis* [hardening of the arteries] who had normal blood pressure (unlike the ASCOT patients) and slightly elevated cholesterol levels (unlike the ASCOT patients). REVERSAL was intended to study the effect of using LIPITOR on the progression of atherosclerosis. The study was completed by September 2003, and Pfizer, again using the momentum from ASCOT, claimed that REVERSAL, despite its small patient population, showed LIPITOR's ability to reduce cardiovascular events in the atherosclerotic patient. In fact, REVERSAL merely showed that in the 136 patients who were treated with LIPITOR vs. the 147 patients who were *not* treated with LIPITOR (17 patients did not continue with the study and were not evaluated), those patients treated with LIPITOR had a *slight* reduction of plaque in the artery wall based on ultra sound evaluation. In other words, REVERSAL did *not* show a reduction in any cardiovascular events for these atherosclerotic patients, but merely a slight reduction of plaque in the artery wall that was evaluated.

72. As noted above, from at least mid-2003 to mid 2004, Pfizer used the results of the ASCOT study to engage in off-label marketing of LIPITOR for the treatment of hypertensive [i.e. high blood pressure] patients who had normal cholesterol levels, and to tout "outcomes data" [i.e. mortality and morbidity] for LIPITOR. In late July-early August 2004, the FDA approved such use of LIPITOR, but in the interim period, Pfizer engaged in unfair competition

and misleading and off-label marketing.

73. In addition, since at least mid-July 2003 and continuing to date, Pfizer has used the CARDS and REVERSAL studies to engage in off-label marketing of LIPITOR for treatment of diabetics and atherosclerotic patients, respectively, in both cases claiming that LIPITOR reduces the number of heart attacks and strokes in such patients. Significantly, the FDA has not approved such additional indication for LIPITOR's package labeling, nor has the FDA approved LIPITOR for the prevention or reduction of cardiac events in the diabetic patient (based on CARDS or any other study), even though Pfizer submitted the CARDS study to the FDA in October 2004. As noted above, using LIPITOR for the treatment of such at risk patients effectively leaves them untreated, and increases their risk of liver damage.

74. At least as of July 2007, Pfizer has not obtained from the FDA a revision in the package labeling for LIPITOR based on the REVERSAL study. Thus, LIPITOR is not indicated for the prevention or reduction of cardiovascular events (i.e. heart attacks or strokes) in atherosclerotic patients. Rather, the FDA approved treatment for an atherosclerotic patient continues to be angioplasty because the arteries are so clogged and the benefit is so urgently needed to allow blood flow back to the heart.

75. It is difficult to imagine the FDA approving such an indication for LIPITOR in the diabetic or atherosclerotic patient at this time given: the severe consequences of failing to appropriately treat diabetic and atherosclerotic patients; the small numbers of patients (2200 and 502, respectively) in the CARDS and REVERSAL studies (vs. 22,000 patients in ASCOT); and the shorter time of the CARDS and REVERSAL studies (2 years and 18 months, respectively vs. 3.3 years with ASCOT).

76. The steps taken by Pfizer to implement its off-label strategy for LIPITOR

beginning in the first quarter of 2003 are detailed below. As described later in this Complaint, Pfizer combined this off-label campaign with kickbacks and various other illegal incentives. These efforts proved extremely effective, successful, and lucrative.

77. Pfizer's off-label marketing strategy for Lipitor came from the highest levels of Pfizer. Relator's exposure to Pfizer's off-label marketing campaign for LIPITOR began in earnest in March 2003. By e-mail on March 26, 2003, John Woychick, the Senior Vice President of Sales for Pfizer Pharmaceutical's Cluster X, informed all of the Regional and District Managers as well as Rick Burch, Senior Vice President over Cluster A, and Mick Mosebrook, Senior VP of Sales of US Pharmaceuticals, about the status of ASCOT, and what use the sales force could (or could not) make of this study. In particular, he informed them that the results of the lipid-lowering arm of the trial (ASCOT LLA involving LIPITOR) would be reported at the upcoming American College of Cardiology ("ACC") meeting on April 2, 2003, and shortly thereafter the full results of ASCOT would be published in a major medical journal. *The antihypertensive arm of ASCOT, which included treatment with Pfizer's NORVASC, was still ongoing, and would not be reported at the ACC.* He noted that ASCOT would show "many benefits of treatment with LIPITOR, the most exciting aspect of ASCOT is that it is expected to provide extremely compelling morbidity and mortality data for LIPITOR." [i.e. outcomes data]. He cautioned, however, that:

> "While ASCOT results will provide important news about LIPITOR, it is critical to remember that you will ***not be allowed to discuss*** the specific results of ASCOT with physicians or customers for two very important reasons: 1. The results are outside the currently approved labeling for LIPITOR. 2. *The results of the trial will potentially be used in an FDA filing that may change the labeling of LIPITOR. Any discussion of the ASCOT results could place the future labeling of LIPITOR in jeopardy.* It is important to remember that Medical Information Services is your best resource for physicians or customers who have specific questions about ASCOT." (italics emphasis added).

78. Despite this caution, the email from Woychick stated that representatives would

be provided with "a number of relevant materials and field resources, which will include:

ASCOT Design/Results Backgrounder (4/23/2003; via email);

ASCOT Results Reprint (to be distributed via Washington Legal Foundation [WLF] Principles) (week of 4/7/2003);

'All about ASCOT' Training Module (mid-end of April)." (emphasis added).

Woychick went on to say that "For your information, attached to this e-mail please find an "ASCOT Study Design Backgrounder" that provides a summary of the overall design and objectives of the trial. Woychick concluded the email by reminding all that it is critical to stay "focused on our POA 1 strategies [from January 2003—see *Lipitor Lowdown, supra*]: delivering a consistent and targeted *Power you can trust* ™ message, increasing our market share with specialists and taking ownership of specific dyslipidemic patient types." In other words, they were going to target patients like those ASCOT patients whose cholesterol levels have been considered normal in the past, and whose blood pressure ranged from elevated to high--meaning a range from 125 over 85: 125/85 to 150 over 100: 150/100. Thus, despite the cautionary email, Pfizer distributed marketing material in breach of 21 U.S.C. section 360aaa.

79. Later that same day, District Manager Latimer forwarded Mr. Woychick's email to the Utah District sales force, including the Relator, with the following message: "Please read John Woychick's message regarding ASCOT. As you can see we will be unable to discuss this study. The best way to get this information to your physicians after its release is Medical Information (solicited by physician) or the WLF [Washington Legal Foundation] that will be available on April 7."

80. On April 5, 2003 The LANCET published the ASCOT study/results. The primary significance of the study for Pfizer was that it finally provided "outcomes data" for LIPITOR, i.e.

data on mortality and morbidity. This had not previously been available for LIPITOR, although competitor reps who sold drugs such as Zocor and Pravachol had approved studies they could present to doctors. ASCOT provided scientific data to support a claim that LIPITOR was an effective treatment for patients whose blood pressure indicated a significant risk factor for a heart attack, but who did not have a cholesterol problem. When the study was published, and at the time that Woychick sent his email providing details of the ASCOT study, the prescription of LIPITOR for those "not conventionally deemed dyslipidemic" (i.e. those without a cholesterol problem) was off-label.

81. Pfizer's reprint of The LANCET article (provided in multiple copies to its sales force) contained a cover sheet put out by Pfizer which specifically noted that LIPITOR was *not* indicated for prevention of cardiovascular events. Nevertheless, as discussed below, Pfizer went on to instruct its sales force to promote Lipitor for these purposes off-label. This followed a standard practice at Pfizer. For example, in April 2003 Pfizer also published and distributed to its sales force a "do not detail" piece regarding a study on C - reactive protein ("CRP") in the New England Journal of Medicine in November 2002 (on whether CRP is an indicator of cardiovascular events). While on its face instructing the sales force not to discuss CRP with doctors, to refer any questions about it from doctors to medical affairs, and that Lipitor is not indicated for reducing CRP, the 8 page glossy handout from Pfizer headquarters provides the sales reps with great detail on the study and how it fits with Lipitor's marketing message and strategy. As with other so-called "do not detail" pieces sales reps like Mr. Collins received in the mail prior to a POA, the reps would use a paper cutter supplied by their DM to cut off the bottom of the glossy handout where it said "do not detail" and then put the copies in their detail binders.

82. Based on his experience at Pfizer, Relator believed he was allowed to discuss the

ASCOT study, just as he had been allowed to detail other studies such as the ALLHAT study with NORVASC earlier that year. In particular, he understood that he was allowed to discuss the parameters of the study with doctors/customers and then point to the general area of the page where the results of ASCOT were with a pen, without discussing them. On May 9, 2003, before a LAT meeting with his sales group, Relator told his DM how he was detailing the ASCOT study; his DM corrected him and told him he was not allowed to point to the results with his pen.

83. However, at the LAT meeting, a senior sales representative, John Dehaas, a then seventeen year Pfizer employee, showed the group how he was detailing the ASCOT study—and it was exactly how Relator had been doing it, and exactly how they had been detailing ALLHAT for NORVASC before. Neither Relator, nor more importantly the DM, corrected Dehaas, nor was Relator or Dehaas told that by presenting the study results *or reprints* to a doctor he was engaging in illegal off-label marketing using a clinical study. On information and belief, other sales representatives were also presenting the study to doctors for the off-label use while not "discuss[ing] the specific results" of the study.

84. Indeed, despite the Relator's May 9 discussion with the DM, at the LAT meeting in Provo, Utah, or again at the POA 2 meeting in Denver, Colorado on May 27-29, 2003, which was attended by Woychick, the sales representatives, including Relator, were presented with a "LIPITOR POA 2 PLAYCARD." A Playcard generally is a laminated Pfizer "cheat sheet" on how to promote a particular drug. A Playcard is developed by RMs and the Vice President of a Sales Division under which the drug is marketed (in this case, Dan Collier, VP of the Pratt Division). This information would then be disseminated to the specialty and field sales representatives at their next POA (identified on the "playcard" as "POA 1 – POA 2 - or POA 3) so that for the upcoming quarter all Pfizer representatives would give a consistent message to all

of the doctors across the country. In the case of the LIPITOR Playcard, the design was to use the favorable results from ASCOT to boost sales of LIPITOR. The card contains quotes on what the representatives should say to doctors, including one that reads:

"*Doctor, as you know competitors have been detailing that we haven't had 'outcomes' data, in the past. We now have a newly published trial, the ASCOT, are you familiar (Detail study and patient type if not familiar).*" (emphasis in original).

85. In other words, the sales representatives were being instructed that they should affirmatively discuss or "detail" this study with the doctors, rather than waiting for a doctor's inquiry and then referring such inquiry to Pfizer's Medical Information Services. In addition to the Playcard, the sales representatives at the POA meeting were trained on ASCOT both at the POA, and leading up to it. They had received training modules on ASCOT for 6 weeks leading up to the POA. Thus, though they supposedly were not supposed to discuss the study results, all the sales representatives were well versed in ASCOT.

86. "Playcards" like the one distributed for LIPITOR, were distributed three times per year at POA meetings; typically there is one Playcard/POA. The normal approval chain before a Playcard would be distributed would be that the Vice President of a Sales Division, in this case, Dan Collier who was Vice President of the Pratt Division under which LIPITOR was marketed, would meet with Regional Managers to decide what information could be used. At a Regional Manager/District Manager meeting, like the one in Denver May 12-16, 2003, there would then be a decision on what material was most effective, i.e. would help the drug sell best. After that, the Playcard would be drawn up and distributed to the sales force at a POA.

87. The sales force began using doctors to speak about ASCOT as early as May 2003. For example, Bryan Osborn arranged a program at which Eliot A. Brinton, M.D. (who was Chief

of the Section of Metabolism, Endocrinology and Nutrition at the Carl T. Hayden VA Medical Center and an Associate Professor at the University College of Medicine) spoke on or about May 20, 2003 to a group of other doctors in Orem, Utah. In emails to Dr. Brinton, Mr. Osborn noted that he would bring copies of ASCOT for the participants and explained the purpose of the program as follows: "I am very grateful that you will be speaking for us on Tuesday. I am presenting this topic to the other physicians as an opportunity to discuss the recent ASCOT lipid lowering arm trial with you and also to give these physicians an opportunity to ask you for some advice on how to effectively treat the metabolic syndrome patient. *The emphasis on this presentation will hopefully benefit Lipitor and its effectiveness.* Please let me know if you need anything from me. Thank you." Relator, his DM, Osborn and Dehaas attended this program. Osborn scheduled the speaker, "prepped" him, and brought all of the ASCOT articles to be handed out. The DM and Dehaas were there to observe, and to evaluate the speaker and Pfizer's relationships with the key physicians.

88. After the May 27-29, 2003 POA meeting, another e-mail was circulated regarding yet another study on LIPITOR, this one known as CARDS. Relator received this e-mail as well. The e-mail was from Dan Collier, Pfizer Vice President of the Pratt Sales Division within Cluster X, and the format is nearly identical to the earlier Woychick e-mail about the ASCOT study. The Collier email describes the status of the study, how helpful the results are for LIPITOR, and warns that the sales force is not allowed to discuss details about the trial with physicians or customers for the same reasons Woychick cited. Again it refers to Pfizer's Medical Information Services as the best resource for doctors or customers who have specific questions about CARDS and says questions should be referred there. Nevertheless, it too attached a "backgrounder," promised to forward additional information, and reminded the sales force to stay focused on the

POA-2 strategies: "consistently deliver a complete *Power you can trust*™ message, increase our market share with specialists …take ownership of specific dyslipidemic patient types." The e-mail is signed "The US LIPITOR Team." It appears that Woychick's email on ASCOT and Collier's email on CARDS are derived from a common template email and indicates a corporate modus operandi regarding new unapproved uses of its drugs.

89. The results of the third LIPITOR study at issue here, REVERSAL, were talked about in Pfizer beginning by at least early summer 2003 (although the study results were not officially released/published until September 2003). Also, by forwarding a voicemail from Bryan Osborn to his sales team, including Relator, on July 9, 2003, District Manager Latimer informed them about a new Newsweek article on cholesterol drugs which mentioned LIPITOR and its potential off-label uses for treating Alzheimer's disease and Multiple Sclerosis.

90. As already noted, the timing of the CARDS, ASCOT and REVERSAL studies/ results was critical to Pfizer and sales of LIPITOR: revenues from Lipitor in April-June 2003 were continuing the flat or downward trend that had started in 2001. Competitors Zetia and Zocor continued to be a challenge for LIPITOR, and two new competitors were on the horizon: a Zetia/Zocor combination (now known as Vytorin which at a lesser dosage lowers LDL as well as 80 mg. of LIPITOR), and, more significantly, Crestor (which could lower LDL—bad cholesterol— and raise HDL—the good cholesterol--almost twice as much as LIPITOR at every dose). Pfizer was especially concerned about Crestor not only because of its efficacy at lower doses, but because (a) the United States launch of Crestor was being done by Astra Zeneca using most of the former Warner Lambert ("WL") LIPITOR Disease Management Team who had

departed WL after it (and LIPITOR) was purchased by Pfizer in April of 2000, and (b) Crestor had done very well head to head with Lipitor outside the U.S. where it had already been released.

91. In July 2003, a cardiologist in Texas passed on to a Pfizer IHR some "competitive information" about the timing and substance of AstraZeneca's plans for launching Crestor, a cholesterol reducing drug that would compete with LIPITOR. The word was that it would be launched right after Labor Day. This information was in turn circulated within Pfizer and reached Relator through a voicemail his DM sent to his district on July 17, 2003 after returning from a Regional meeting in Denver. The following is the text of the voice mail Latimer received from Regional Managers to be passed on to IHRs and all sales reps now that every sales rep was to begin every visit with doctors by talking about LIPITOR (aka "leading with LIPITOR")]:

MESSAGE:

Hi this is Scott, Hey, it's about 7:30, uh, on Thursday evening, just getting back from Denver. I wanted to forward this information to ya regarding some, uh, competitive information on, uh, Crestor [Astra Zeneca's competitor drug to LIPITOR that is about to be released six weeks after this]. Uh, as you can hear from the message, uh, they are ramping up, uh, ***their activity with speaker programs as well*** as, uh, some information on what their message may be focusing on, um, but obviously, uh, ***we want to maintain our share of orders to, uh, speaker programs*** as well, and, uh, try to keep them as jam packed in that same week and in the same time frame their talking about on this message. So, if you have any questions, give me a call. (emphasis added).

Hi, this message is to Dean, with a copy to my IHR LIPITOR counterparts, I wanted to give you guys a little bit of info. that was shared with me by ***one of our very important thought-leaders,*** **Dr. Steve Haffner**. Uh, he let me know, that he was told that those extra Crestor teams are launching their product the week after Labor Day, and that they have been charged to do a speaker program Monday through Friday the week after Labor Day. **So, we want to make sure that our thought-leaders are secured with, um, Pfizer, and are not gonna be doing some of those talks**. Secondly, he was also, um, privy to some marketing information, as far as the marketing message is concerned, and, he was told, that they're going to do a 70-20-30 marketing message. 70% LDL reduction with a start dose of to[sic] of ten and twenties, then 20% on the HDL increase and 10% the metabolism, similar to that of Pravachol, and the safety. So those two things, I think, are important just for us to keep in the back of our mind as we are preparing for the launch of a competitor. You guys take care, and when I find anything else out, I promise to let you know. (emphasis added).

92. The next mid-POA for the Relator's area was held in Salt Lake City on August 21, 2003. Similar mid-POA meetings were held in every Pfizer district across the United States. As usual, Relator was sent the materials for this mid-POA by federal express from Pfizer headquarters in New York City. The package was mailed on August 13, 2003, and received on August 14, 2003. (Crestor was approved by the FDA on about August 12, 2003). However, Relator did not attend the mid-POA because, as described below, he was terminated by Pfizer the day before that meeting.

93. The marketing map laid out in the LIPITOR POA slides dated August 14, 2003 is referenced above and further discussed below. In summary, the slides show Pfizer's intent to buy the reputations of "Super KOL's" or National Key Opinion Leaders and have them promote LIPITOR off-label for the reduction of cardiovascular events in the diabetic and atherosclerotic patient to regional Cardiovascular Key Opinion Leaders who would in turn promote LIPITOR off-label to local cardiologists who would then be paid to promote LIPITOR off-label to local family practice and internal medicine specialists. According to the slides, these local doctors/KOL's would also be paid to give Pfizer's sales representatives the language and training they needed to sell these unapproved treatments of LIPITOR to all of the physicians in every territory. All this was part of Pfizer's strategy, even though Pfizer knew that LIPITOR was not, and would not be, approved by then to reduce cardiovascular events in this very difficult to treat patient population, and even though outcomes data was not yet approved.

94. Pfizer's off-label message to its reps is mentioned again in the August 2003 POA Slides 22-23. Those slides note that Astra Zeneca is being successful with their Crestor message outside the United States and that Crestor is significantly more effective than LIPITOR at corresponding doses. In an attempt to blunt this comparative advantage of Crestor, Pfizer

compares Crestor's product profile to LIPITOR's by claiming that for "Outcomes Data", there is none for Crestor at launch while for LIPITOR there is "ASCOT/CARDS." However, at this time, in August 2003, the only cholesterol lowering medicines which the FDA had approved for "outcomes data" were Zocor (Sumvistatin), manufactured by Merck, and Pravachol (Pravastatin), manufactured by Bristol Myers Squibb. Indeed, as noted above, the absence of this "outcomes data" was the big weakness of LIPITOR in the eyes of most specialists and analytical physicians.

95. The August 2003 Mid POA presentation and call to action also highlight the many efforts the sales reps are to make to detail physicians and customers on LIPITOR through promotional programs, thought/key opinion leaders, specialists and in other ways. On information and belief, Pfizer and its medical specialists and paid speakers used the results of the "new studies", namely, ASCOT, CARDS and REVERSAL, to promote off-label prescribing of LIPITOR over competitors' drugs, including those that were approved for such indications.

96. Pfizer's business plan, as unveiled at the August 2003 Mid POA, was extremely successful, as already discussed in paragraphs 1-95 above. After being flat or falling for between 18-24 months, LIPITOR revenue rose consistently and substantially, with revenue increases of 18% or greater for 2003, 2004 and 2005.

97. It was not until July 30, 2004, the FDA approved a new use of LIPITOR, to reduce the risk of myocardial infarction and to reduce the risk of revascularization procedures and angina in adults who have multiple risk factors without heart disease, based on the ASCOT study. However, between late March 2003 and July 30, 2004, Pfizer was engaged in an illegal off-label marketing scheme using the ASCOT study to increase prescriptions for LIPITOR for this off-label use, and thereby deceived the FDA.

98. The FDA has not, to date, approved a new use based on the CARDs or REVERSAL studies, and as a result, Pfizer has been off-label marketing LIPITOR for diabetic and AT patients since at least mid-2003.

99. In addition, using the TNT trial to sell LIPITOR constituted (and still constitutes in some aspects) illegal off-label marketing. In particular, from 2005 until at least May 2007 when the FDA approved a change in the LIPITOR label for five new indications (listed above in paragraph 22), it was illegal to use TNT to promote those five new indications. Continuing to this day, it is illegal to use TNT to promote the use of LIPITOR for diabetics and/or AT patients. It is also illegal to use it to advocate that 80 mg of LIPITOR provides a greater benefit to the patient than 10 mg of LIPITOR *with the same level of side effects* constitutes off-label marketing. In fact, the results of the study itself did not show that LIPITOR 80 mg had the same level of side effects as LIPITOR 10 mg, and neither does LIPITOR's package labeling, as most recently approved by the FDA in May 2007.

100. The information described above disseminated by Pfizer did not provide a prominently displayed statement, pursuant to 21 U.S.C. §360aaa, that disclosed, *inter alia*: that the information concerned use(s) that had not been approved by the FDA; that the information was being disseminated at the expense of the manufacturer; that there are other drugs which have been approved for such [off-label] uses; nor was there a bibliography of published, scientific articles addressing the off-label uses of LIPITOR.

101. By distributing such information on off-label use, and promoting the benefits of LIPITOR for off-label uses, Pfizer violated the FFDCA. Pfizer's use of studies for off-label marketing of LIPITOR since early 2003 shows a pattern of conduct and behavior on a national scale. Based in part on this unapproved literature, physicians have prescribed LIPITOR for

patients covered by Government Health Care Programs, and in patients (including diabetics and arthesclerotics) for whom LIPITOR is *not proven safe or effective* and indeed may be dangerous. Such off-label promotion in these at risk patients has potentially put patient's health and lives in danger and greatly increased the amount of money that all Government Healthcare Programs have paid for a treatment that is valued by the FDA as no better than placebo. This misconduct gives these severely "at-risk" patients and their doctors false confidence that the patient is better protected from cardiovascular events.

102. Pfizer's practices resulted in the submission of false and fraudulent claims for reimbursement of the cost of LIPITOR. On information and belief, LIPITOR is not a drug for which any State has determined that the drug is essential to the health and welfare of the beneficiaries such that Medicaid will reimburse off-label prescriptions under the exception within 42 USC § 1396r 8(a)(3). Pfizer failed to disclose these violations of the Federal Food, Drug, and Cosmetic Act and, as a result, claims related to LIPITOR filed with the Government Health Care Programs have contained material omissions and defects. PFIZER has thus caused false and fraudulent claims to be filed against the Government Health Care Programs, including the jointly funded Medicaid program.

103. Moreover, use of unapproved studies and other materials for any purpose, whether to promote off-label uses or otherwise, constitutes unlawful advertising and labeling and is illegal. Pfizer has used such studies and materials not only to promote Lipitor, but also to promote NORVASC. For example, in advance of the POA 2 meeting in 2003, the NORVASC Disease Management Team ("DMT") distributed multiple copies of a handout marked "do not detail" to its sales force, including Mr. Collins. The expressed purpose of the handout was to provide:

> "new opportunities to use pieces based on ALLHAT [a recent study]. We have provided you with this not-for-detail sheet to give you some direction while discussing the relevance of this invaluable study. Please add this sheet to your Playbook as you compile your resources for this POA."

As with other such pieces, Relator and others used paper cutters supplied by DMs and others at the POAs to trim the "do not detail" language off of the handouts before putting them in their detail books. In other instances, Pfizer would distribute "do not detail" pieces that were fold outs—on those, the design enabled the sales reps to fold the flaps over and conceal the "do not detail" language, and that is what they would do, before placing the piece in their detail books.

b. Off-label Marketing of ZITHROMAX

104. ZITHROMAX (azithromycin) is indicated and approved by the FDA for acute exacerbations of bronchitis, community acquired pneumonia, tonsillitis, acute otitis media, and uncomplicated skin and skin structure infections. ZITHROMAX is *not* indicated for sinusitis and is *not* effective in treating sinusitis because the drug does not penetrate the sinusoidal cavities like it does the lung tissue. (This is primarily because blood flow is so much weaker and much more limited to the sinuses than it is to the lungs, the tonsils, and the ears). Because of this less intense blood flow to the sinuses, and because ZITHROMAX is picked up and carried by the white blood cells to the site of infection, it needs strong blood flow to and throughout the site of infection to be effective. Furthermore, sinusitis requires 14 days of therapy to kill the bacterial infection in this limited blood flow region and a "Z [Zithromax]-PAK" only provides ten days of therapy. Because of these limitations of Zithromax, the antibiotics Augmentin and Ceftin are the traditionally accepted treatments for sinusitis by allergists and by otolaryngologists (i.e. ear, nose, and throat doctors—"ENT's").

105. Nevertheless, the Relator and the rest of the sales force of the Steere and the Labs divisions of Pfizer, were directed to promote/sell ZITHROMAX off-label for sinusitis,

particularly in the Spring and Summer months in order to make quota and keep sales for ZITHROMAX consistent over the year. (Pneumonia is only a money maker for Zithromax from October to March, and next to pneumonia, sinusitis is the big money maker for antibiotics).

106. The FDA has never approved ZITHROMAX for sinusitis, yet it has approved both Augmentin and Ceftin as treatments for this "hard-to-treat" illness. However, because ZITHROMAX is indicated to treat the bacteria that cause sinusitis (i.e. Streptococcus Pneumoniae, Group A Streptococcus, Streptococcus Pyogenes, Haemophilus Influenzae, and Moraxella Cateralis), Pfizer instructed Relator and others to detail and sell all of their Allergists, ENT's, Internal Medicine Specialists, Family Practice physicians, Pediatricians and Emergency Room physicians on this off-label use of ZITHROMAX. In order to do this, they were instructed by Dennis Gooch, Craig Smith, and all of the District Managers throughout the Southwest Region (and elsewhere) to use their Infectious Disease Specialists to talk about how effective Zithromax was against these various bacteria that cause sinusitis. The strategy assumed, correctly, that if the Infectious Disease Specialists recommended ZITHROMAX, other doctors would prescribe ZITHROMAX for sinusitis with confidence, not realizing that it was not approved to treat sinusitis.

107. Relator and the rest of the sales force were instructed how to market ZITHROMAX off-label, and how to respond to doctors' questions and/or concerns. For example, when asked by a doctor why ZITHROMAX was not indicated for sinusitis, the sales force was instructed to respond that studies are so expensive and difficult (i.e. to get enough subjects for the comparison) that Pfizer would probably not seek the sinusitis indication until ZITHROMAX's patent was close to expiring. When the physicians asked why Zithromax was working for their pneumonia patients and for their otitis media patients, but was *not* effective for

their sinusitis patients, and when they explained that when the patient was switched to some other antibiotic like Augmentin or Ceftin, or Biaxin the patients got well, the Pfizer reps were instructed to tell the doctor that antibiotic resistance must be growing and therefore it wouldn't matter which medicine is used first, because the patient would require *two* antibiotics to get better. The sales rep would add, however, that one of antibiotics should be ZITHROMAX.

108. When Pfizer bought Warner Lambert in April 2000, all of the Parke Davis 1 sales division was instructed to sell ZITHROMAX for sinusitis the same way Relator and others had always done. From then on, Parke Davis 1 sales division was the lead division for selling ZITHROMAX.

109. Off-label detailing and promotion of ZITHROMAX for sinusitis has caused Government Healthcare Programs to overpay for an expensive *and* ineffective treatment for sinusitis. This not only leaves the patient essentially untreated for this hard-to-treat illness, but it contributes to bacterial resistance to this antibiotic over time—i.e. rendering the drug potentially less effective in treating those conditions for which it *has* been approved.

110. About 35 percent of the antibiotic prescriptions written in the United States are for sinusitis. Accordingly, Relator estimates that about 35 percent of the prescriptions of ZITHROMAX, and virtually all of the summertime prescriptions for ZITHROMAX, have been for sinusitis and therefore constitute off-label marketing damages.

c. Off-label Marketing of ZOLOFT

111. ZOLOFT (sertraline hydrochloride) is one of a class of central nervous system drugs known as selective serotonin reuptake inhibitors ("SSRIs"). The first such drug was Prozac, developed by Eli Lilly & Co. in the late 1980's-early 1990's. ZOLOFT was developed by Pfizer at around the same time, and was first approved by the FDA in about 1991 for the

treatment of depression in adults. Since then, the FDA has also approved ZOLOFT for use in treating obsessive compulsive disorder, panic disorder, post traumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder.

112. However, of all these approved indications, the *only one for children and teenagers is obsessive compulsive disorder*; all others apply to *adults only*. Indeed, of the many SSRIs/antidepressants on the market, only Prozac has been FDA approved to treat depression in children and adolescents. Nevertheless, over the years, Pfizer has on a nationwide basis aggressively, systematically, and successfully, marketed and promoted the use of ZOLOFT in children and adolescents, including at the highest "approved" dose, i.e. 100 mg (and has misleadingly suggested--including in its 2006 Annual Report--that the drug is more broadly indicated for children than is true). Pfizer has done so through various means, including marketing "off-label" not just to psychiatrists, but perhaps more importantly, to pediatricians, family physicians, and internal medicine doctors. As of 2003, ZOLOFT was the most widely prescribed antidepressant in the United States, with some 32.7 million prescriptions written.

113. There are serious public health and safety issues involved in the use of antidepressants such as ZOLOFT by children and teenagers (less than 18 years of age). Concerns that "off-label" use of antidepressants causes suicides, suicidal attempts, suicidal ideation, and self-mutilation in children led the FDA to take action in 2004, ordering antidepressant makers such as Defendant Pfizer to put a "black box" warning (the FDA's strongest warning short of a ban) on the drugs to alert doctors, parents and patients that the drugs increase risks of suicidal behavior among children and teens. According to the FDA, such behavior can be expected in about one out of 50 treated pediatric patients. There are other potentially serious side effects from ZOLOFT as well, including a life-threatening condition

known as Serotonin Syndrome that can occur when SSRIs such as ZOLOFT are used with Triptan medicines used to treat migraine headaches. See FDA Alert July 2006.

114. In April 2007, the FDA increased the age under the Black Box warning on these antidepressants to 25 years. Also recently, the Journal of the American Medical Association analyzed some 27 studies in favor of Pfizer, Glaxo SmithKline, Wyeth, and Forest Labs Inc., and Lilly, and concluded that one could not show that any antidepressant but Prozac was even *effective* in treating children (age 12 and under) for major depression.

> "The new analysis, which was funded by the National Institutes of Health and the Robert Wood Johnson Foundation, also looked at the effects of the drugs by age and found that only Prozac was effective at treating children age 12 and younger for major depression compared with placebo. Indeed, Prozac is the only antidepressant that is FDA approved to treat major depression in children."

In other words, not only is ZOLOFT not approved for use in children or adolescents for depression, it has been shown to be potentially dangerous, and not to even be effective. Nevertheless, ZOLOFT effectively took the antidepressant market away from Prozac.

115. Pfizer launched ZOLOFT through Pratt Pharmaceuticals and has marketed ZOLOFT through several sales divisions including: the Central Nervous System (CNS) sales division, for whom ZOLOFT was the primary drug; the Roerig sales division, which also sold ZITHROMAX and other drugs; the Powers Rx sales division (which also sold other drugs); the Vista Rx sales division, created in 1999 to sell ZOLOFT, ZYRTEC and other drugs to pediatricians, allergists and obstetricians/gynecologists; and the Ped/Allergy Specialty sales field force (renamed the Alta sales division in about 1997), created in about the mid 1990's to sell ZOLOFT, ZITHROMAX and ZYRTEC to pediatricians, allergists and ob/gyns (i.e. Zoloft for patients with PMS and Zithromax for patients with chlamydia trachomatis and gonorrhea). Since ZOLOFT was not sold to allergists, the Alta sales reps had to rely on marketing to

pediatricians to make quota on ZOLOFT. Pfizer also marketed ZOLOFT through the Pediatric/Gynecology group and the Urology/Gynecology group. This marketing strategy reflects the copromotion philosophy of Pfizer noted above, i.e., the theory that every doctor should see a Pfizer rep once every day of the month, with the more influential doctors being called on 2-3 times a day.

116. While in Texas beginning in 1998, Relator's Regional Manager was Craig Smith. Prior to becoming the Regional Manager of the Southwest Region of the newly-formed Steere Division, Mr. Smith had been the Vice President of Sales for the CNS sales division since about 1994. Relator's job as a sales representative included selling the drugs ZYRTEC and ZITHROMAX to pediatricians. Between 1998 and 2001 (when Relator was promoted to IHR), he was present at many lunches and other events with pediatricians when various of his counterpart Pfizer sales reps from other sales divisions marketed ZOLOFT "off-label" for pediatric/adolescent depression. Two pediatricians in one practice group explained to Relator that they treated almost as many children for depression as they immunized, so it was a very important part of their practice.

117. Relator went on field rides with Ken Smith, the IHR in his District when Smith was training to be a district manager (Smith was promoted to DM in New Mexico, and Relator was promoted to IHR to replace Smith). Together they called primarily on pediatricians, family practitioners and ob/gyns in South Arlington, Texas, where Smith had made strong friendships selling Zoloft and Zithromax before the STEERE division was created (i.e. while Smith was still in the ALTA sales division). As a "District Manager in training" (IHR) Smith would detail ZOLOFT while Relator detailed ZITHROMAX. It was in this capacity, and on these field rides, that Relator heard Smith say many times that the pediatricians and family practice physicians

should look for and recognize the symptoms of depression in children and adolescents. These symptoms could include the feelings that ensue when a girl tried out for, but did not make cheerleader, or a boy who tried out for but did not make the football or basketball team, and that these physicians should especially watch for elementary school children who may have a hard time making new friends or be frustrated in class with teachers or with peers. Smith said words to the effect that: "these were the children who should be on ZOLOFT. And that ZOLOFT should be tried for two to three weeks at 50 milligrams, but when that did not do it, they should be titrated (dosage increased) to 100 milligrams." Smith knew well, as did all who sold ZOLOFT, that ZOLOFT takes at least six weeks to regulate a person's feelings and moods and to titrate at 2 to 3 weeks was too early. However, they also knew that it would get the patients to Pfizer's desired goal of 100 milligrams and likely keep them there, despite the fact that ZOLOFT was *not* indicated to treat children with depression at *any* dosage.

118. Pfizer's off-label promotion of ZOLOFT continued after Relator was promoted to an IHR in 2001, with sales of ZOLOFT increasing. Relator is aware of various reps continuing their off-label promotion. In addition, Relator worked with two IHRs who sold for the Roerig and Alta divisions who had a display at John Peter Smith Hospital ("JPS") twice each month where reps from all companies would come and set up a display table with give aways, and some type of breakfast, and detail the residents and fellows. JPS is a county health care system for Tarrant County, Texas. When Relator was in Texas, JPS had approximately 9 outlying clinics as well as the main Hospital, which also had an outpatient clinic. At any given time they had about 45 to 50 residents plus faculty. He understood that more than 95% of JPS' payments came from Medicare and Medicaid reimbursement.

119. Relator repeatedly and frequently heard Pfizer IHRs detail Zoloft to the pediatric

and family practice physicians at these JPS events solely for depression *and* at the 100 milligram dose. They urged these doctors to remember how poor many of their patients were and how poverty lends itself to depression in children and adolescents. Then they would remind the residents how important it was for them to identify depression in their child patients and "get them on Zoloft." The gist of the detailing was that the Pfizer IHRs instructed the residents to start the children on 50 milligrams, but if they could handle the 50 milligrams without diarrhea or nausea, then the doctor should titrate the patient up to 100 milligrams on the next visit or so in order to get the maximum protection. When asked about insomnia or somnolence, the IHRs would simply respond to the doctors with words to the effect that if the patient continues to take Zoloft, the insomnia and/or somnolence will eventually subside. This was said despite the fact that diarrhea and the nausea are simply digestive, but the insomnia and somnolence are definite signs of disrupted brain activity. The 100 milligram dose increases the side effects by almost 300 percent vs. 50 milligrams in the *adults*, and perhaps more for children.

120. Pfizer's practices resulted in the submission of false and fraudulent claims for reimbursement of the cost of ZOLOFT. On information and belief, ZOLOFT is not a drug for which any State has determined that the drug is essential to the health and welfare of the beneficiaries such that Medicaid will reimburse off-label prescriptions under the exception within 42 USC § 1396r 8(a)(3). Pfizer failed to disclose these violations of the Federal Food, Drug, and Cosmetic Act and, as a result, claims related to ZOLOFT filed with the Government Health Care Programs have contained material omissions and defects. PFIZER has thus caused false and fraudulent claims to be filed against the Government Health Care Programs, including the jointly funded Medicaid program.

121. Moreover, use of unapproved studies and other materials for any purpose,

whether to promote off-label uses or otherwise, constitutes unlawful advertising and labeling and is illegal.

d. Off-label Marketing of ZYRTEC

122. ZYRTEC (cetrizine hydrochloride) is indicated/approved by the FDA for treatment of seasonal allergic rhinitis, perennial allergic rhinitis, and chronic urticaria (hives and pruritus). When first approved and marketed in 1995 by Pfizer (in conjunction with UCB Pharmacia), ZYRTEC was approved only for use in adults. In 1998, ZYRTEC was approved for use in children 24 months and older (for seasonal allergic rhinitis) and over the age of 6 months for the other two indications.

123. ZYRTEC has become the most widely prescribed antihistamine medication in the United States. Between one quarter and one half of all Zyrtec prescriptions are for pediatric patients. Total prescriptions have grown from some 9.3 million in 1998 to some 25.7 million in 2002, and increases continue to date. For example, Pfizer's April 19, 2005 SEC filing (p. 7, last paragraph) states that: "[for the first quarter of 2005] Zyrtec revenue reached $342 million dollars, ahead 14 percent compared to the same period in 2004, and it continues to be the most prescribed antihistamine agent in the U.S. in a challenging market. Zyrtec has the broadest range of formulations and treats patients as young as six months old. Zyrtec received a warning letter from the FDA on April 13, 2005 addressing three print consumer advertisements. Pfizer will respond to the FDA in the requested timeframe." (SEC 8-K filing dated April 19, 2005).

124. This revenue growth occurred despite the fact that by mid 2004, the FDA required Pfizer to change the label on ZYRTEC to acknowledge some "additional rare, but potentially severe adverse events" that had been reported in the post marketing experience. These events included: "aggressive reaction, anaphlyaxis, cholestasis, convulsions, glomerulonephritis,

hallucinations, hemolytic anemia, hepatitis, orofacial dyskinesia, severe hypotension, stillbirth, *suicidal ideation, suicide* and thrombocytopenia." (emphasis added). Requiring this type of label change/ warning is a serious and infrequent action by the FDA; it is just short of requiring a so-called contraindication or a black box warning (the latter of which was discussed in the ZOLOFT section above). Some or all of these adverse events may result from the fact that ZYRTEC is the active human metabolite of hydroxyzine (an antianxiety and sedative agent) and crosses the human blood brain barrier, i.e., affects the central nervous system. Just as antidepressants have been shown to, in some instances, *increase* depression and cause suicidal thoughts, etc. so too may ZYRTEC increase anxiety and cause suicidal thoughts, etc.

125. On information and belief, Pfizer off-label marketed ZYRTEC by, among other things, detailing doctors with articles that were not approved for detailing and that in some cases provided incomplete and misleading comparisons of ZYRTEC and one or more other drugs. Pfizer also encouraged reps to tout ZYRTEC's safety despite knowing about the post marketing adverse events noted above and that ZYRTEC could cause drowsiness.

126. For example, on May 29, 2003, the third day of the POA in Denver described above, some of Relator's co-workers (Bryan Osborn) showed how they had been using two articles on ZYRTEC (one by Day and one by Pieroit) that were not approved for detailing, as well as an IHC newsletter (Renee Christensen) to detail ZYRTEC to doctors. They said DM Latimer had approved these for detailing. In addition, reps had been sent by Pfizer headquarters as part of the POA materials, a Pfizer "do not detail" reprint of United Healthcare's ("UHC") 2003 preferred drug list. The UHC drug list contained information on reimbursement, compared Zyrtec and Allegra, and contained numerous off-label reviews of Allegra, one of Zyrtec's chief competitors (see below).

127. Then, on June 21, 2003, Relator received by e-mail from co-worker, Bryan Osborn, and two "write-ups" being used by the Parke Davis 3 ("PD3") group out of Milwaukee, Wisconsin, regarding ZYRTEC. These write-ups are illegal homemade detail pieces based on two articles in the Journal of Allergy and Clinical. That email stated:

> "Here are 2 write-ups on those articles that our district is using. If you'd like a copy of the papers just let me know…Use them as your own. Your PD???! Counterparts may find some use in them. (**But they are not for detailing purposes…blah…blah…you know the rest**.)" (emphasis added).

On information and belief, these articles and the derivative "write ups" had not been approved for detailing.

128. This off-label detailing of ZYRTEC was done in conjunction with sales reps use of illegal price lists for ZYRTEC, as described in paragraphs 47-56 and 125 above. Use of unapproved studies and other materials for any purpose, whether to promote off-label uses or otherwise, constitutes unlawful advertising and labeling and is illegal. Together, the unapproved articles and price lists influenced doctors, especially pediatricians, family doctors and internists, to prescribe ZYRTEC over competitor drugs.

129. Indeed, by mid-2003, the ZYRTEC marketing team's goal was to increase Zyrtec prescriptions among primary care physicians (having achieved number one status with allergists and pediatricians) and to blunt competition from Allegra (particularly the tablets) and Clarinex tablets (being launched in June 2003). This strategy is detailed in the materials mailed to Relator from Pfizer headquarters in advance of the mid August 2003 POA. Among these materials are the *ZYRTEC 2003 Fall Rally Playbook & Resource Guide* (which is marked "do not detail", but encourages the reps to order various reprints that are off-label to use in their marketing), reprints of two off-label studies (Ramaekers and Weiler, both of which reps can order more of from Pfizer as reprints), two "backgrounders" apparently prepared by Pfizer's legal department

marked "Privileged and Confidential Attorney Work Product Attorney Client Privilege Do Not Detail," and a one page summary of a "do not detail" study also apparently from the legal department (all of which reps can order extra copies of from Pfizer).

e. Off-label Marketing of VIAGRA

130. When VIAGRA was approved by the FDA and launched by the Labs and Pratt Divisions of Pfizer in 1998, it was indicated only for erectile dysfunction. The same is true today. VIAGRA was incredibly successful in its first year, with profits for the drug exceeding 1000 percent of its estimated first-year financial potential. Such success placed pressure on Pfizer and in turn its sales force to meet higher quota and sales figures. In the last quarter of 1998, Pfizer launched a new division, known as Division J, which sold VIAGRA as its primary medicine. By February 1999, the Division was renamed the Steere Division, after then Pfizer CEO William C. Steere, Jr. As noted above, Relator worked in this division from the time he was when he was hired by Pfizer in October 1998.

131. As early as February, 1999, Pfizer engaged in off-label promotion of VIAGRA by heavily marketing the drug for use in women, selling to physicians such as obstetricians and gynecologists, and using such specialists to sell to other doctors who treat women including ob/gyns, and internal and family medicine doctors. This enabled Pfizer to continue to increase its sales of, and revenues from, VIAGRA. This was done despite the fact that such promotion was off-label, and also despite the fact that VIAGRA had never been appropriately tested in women.

132. For example, starting in early 1999, the Steere Division sales representatives were informed by the Southwest Regional Manager of the Labs Division, Jo-Ann Rolle-Harper, that her brother, Chuck Rolle, M.D., the head of Ob/Gyn studies at the University of Arizona Medical

Center, would be the featured speaker at a series of programs sponsored by the Labs Division. Dr. Rolle would be speaking to Ob/Gyns all over the Southwest Region, about VIAGRA and their female patients' sexual health, about encouraging women to ask their male partners to go to their doctor for a sexual health exam, and about how the doctors should code their medical charts for "proper reimbursement." The Steere Division was encouraged to do the same, since both the Labs and Steere Divisions called on Ob/Gyns (because they both sold ZITHROMAX, an antibiotic which is safer for pregnant women and more easily tolerated generally by women than some other antibiotics).

133. Dr. Rolle, through the Steere Division, spoke to the Ob/Gyn's in Fort Worth, Arlington, Grapevine, Irving, Denton, South Dallas, and Waco, Texas in early 1999. Relator and his colleagues were instructed to have all of their Ob/Gyn's there. Relator went to the talks in Fort Worth and Arlington, because he had doctors who could schedule one or the other. At the programs that Mr. Collins attended, Dr. Rolle would speak and then take questions. When the Ob/Gyn's started asking about VIAGRA for women (and all of them asked about VIAGRA for women, and then took notes), Dr. Rolle would answer and say words to the effect of:

> "VIAGRA has not been approved for treatment in women, *but* we find at the University of Arizona Medical Center, in our patients, that VIAGRA increases the intensity of orgasmic sensation, and it further seems to eliminate anorgasmia, or the inability of women who are either post-menopausal or who are being treated with an SSRI like Prozac or ZOLOFT and do not feel orgasmic sensations as often or as intensely as they once did. In other words, VIAGRA can restore and increase orgasmic sensations, and is doing this for our patients at the University of Arizona Medical Center."

134. All of the reps from Labs, Pratt, and Steere divisions that Relator knew in the Dallas, Houston, San Antonio, Louisiana, Oklahoma, New Mexico, Salt Lake, Phoenix and Fort Worth districts had Dr. Chuck Rolle in to speak several times in each of their territories. Afterwards, at the direction of their District and Regional Managers Craig Smith, Regional

Manager with STEERE, Joanne Rolle-Harper, Regional Manager with LABS, and Ben Parody, Regional Manager for Pratt Southwest, the sales force echoed Dr. Chuck Rolle's message to as many doctors as they came in contact with for the following year. Then, when the VIAGRA for women off-label marketing effect was waning somewhat, after about 18 months, many of the districts had Dr. Rolle back again to rekindle the embers.

135. Sales reps were also trained by management to use off-label, "do not detail" materials to sell VIAGRA. For example, in the Mission 3 Rx files audiotape distributed to sales reps in 2001 in preparation for an upcoming POA, Tom Griffin, Vice President of Steere Pharmaceuticals, can be heard instructing the sales force that:

> "You'll find a 'Do Not Detail' Chains of Conviction pocket card in your Mission 3 Brief for a quick reference in the field. Commit these chains to memory…and incorporate the language into your every day sales call. Your selling survival may depend on it."

136. Efforts such as those by Dr. Rolle and his sister, Jo-Anne Rolle-Harper, the Southwest Regional Manager of Pfizer's Lab Division, and the sales reps in using the off-label detailing pieces referred to by Tom Griffin as Vice President of Steere Pharmaceuticals, were instrumental in enabling Pfizer to continue to increase its sales of, and revenues from, VIAGRA. Pfizer's efforts were very successful. Jo-Ann Rolle-Harper's efforts in the initial and continued success of VIAGRA were rewarded in late 2001, when she was chosen to fill the vacancy for the Vice Presidency of the Steere Sales Division (this opening occurred because Griffin became Senior Vice President over one of the two newly acquired Pharmacia divisions).

137. At the last POA meeting Relator attended in Denver in May 2003, the opening remarks of John Woychick (the Senior Vice President of Sales for Pfizer Pharmaceutical's Cluster X, and JoAnn Rolle-Harper's boss), included a run down of quota attainment for all of

Cluster X medicines During that, he proudly announced that VIAGRA prescriptions had increased with all specialists, and he laughingly said words to the effect of: "but no specialist is writing VIAGRA more often than the Ob/Gyn's".

138. This off-label promotion of VIAGRA for use in women, a patient population in which the drug had never been approved as safe and effective for *any* indication, caused Government Health Care Programs to reimburse false and fraudulent claims for the drug. In addition, it caused doctors to bill for associated office visits which were often billed at an increased or upcoded level as described in the Kickback section below, and resulting in further damage to Government Healthcare Programs..

f. Off-label Marketing of GLUCOTROL XL

139. As with the other Drugs discussed above, Pfizer encouraged its sales force to use unapproved, so called "do not detail" materials to market GLUCOTROL XL, its drug for treatment of Type 2 diabetes. As with other off-label marketing strategies discussed above on other drugs, for GLUCOTROL XL, Pfizer sent sales reps materials in advance of POAs, to be used in preparation for the POA trainings. As with other drugs, the sales reps would use paper cutters to trim any "do not detail" language from materials (with knowledge of and cooperation from their DMs) before placing them in their detail books. At the POA, the reps would be trained in, and practice how to use these materials to effectively sell to their customers.

140. For example, Pfizer distributed at least three pieces in 1999 which discussed studies supposedly showing that GLUCOTROL XL caused no increase in body weight and demonstrated a low incidence of hypoglycemia (in a 22.7 month study of some 564 patients) compared to competitor drugs Amaryl, Glipizide or Glyburide. However, because the only drug in these Pfizer sponsored studies was GLUCOTOL XL, there was no head to head comparison

with these other three drugs. In fact, all these drugs are very similar and all three competitors (Glyburide, Amaryl, and Glipizide) have *at least as low* an incidence of hypoglycemia as GLUCOTROL XL. In addition, Amaryl actually causes less weight gain than GLUCOTROL XL. But, these competitor drugs were not "allowed" in the Pfizer's sponsored study(s).

141. GLUCOTROL XL carries a Black Box warning from the FDA on increased risk of cardiovascular mortality (as do the three competitors noted above—all are in the same class of drugs).

142. As with other off-label marketing strategies discussed above on other drugs, for GLUCOTROL XL, Pfizer sent sales reps materials in advance of POAs, to be used in preparation for the POA trainings. As with other drugs, the sales reps would use paper cutters to trim any "do not detail" language from materials (with knowledge of and cooperation from their DMs) before placing them in their detail books. At the POA, the reps would be trained in, and practice how to use these materials to effectively sell to their customers.

143. Use of unapproved studies and other materials for any purpose, whether to promote off-label uses or otherwise, constitutes unlawful advertising and labeling and is illegal.

3. Pfizer's Use of Kickbacks/Unlawful Incentives in the Marketing of The Drugs

144. During Relator's employment with Pfizer in Texas/the Southwest Region (as a sales representative and then an IHR), and in the Utah Pilot District/Rocky Mountain Region (as a sales rep), he became aware of numerous ways in which Pfizer had its sales force *across* the country and *across* sales divisions, influence or attempt to influence the prescription writing habits, and formulary decisions, of physicians and other customers. These techniques included, without limitation, so-called flooding the market with free samples of the drugs, speaker

programs, entertainment, meals, trips, cash gifts, "educational" grants (restricted and unrestricted), and preceptorships.

145. These inducements were often combined with, and were part and parcel of, Pfizer's off-label marketing strategies (including illegal price lists) alleged above, and other illegal marketing strategies alleged below. Pfizer's co-promotion "way of life" and "way of marketing" ensured that doctors and other customers were besieged with programs and other inducements, all of which increased the writing of prescriptions for Pfizer drugs over competitor drugs.

146. Mr. Collins, like other members of the sales force, had a budget to be used for the marketing of drugs. During the relevant times, Pfizer had about 15,000 reps (including 825-1,000 IHRs and another 3,500-4,000 specialty reps for cardiovascular health, endocrinology/urology, psychiatric and infectious disease) selling the drugs involved in this case. Depending on the size of their territory, the sales representative had between $28,000 to $35,000 per year for meals, travel, expenses, etc. while the IHR's and specialty reps had $45,000 to $50,000 dollars per year to use. These sales forces' budgets were for meals with doctors, nurses, staffs, or any other interaction with the physician and his office. Usually it meant lunches, breakfasts, coffee, afternoon ice cream socials, dinners at fine restaurants, and activities with doctors like dinner and a sports game. The IHRs had higher budgets because they were expected to influence the residents and fellows who would be coming into the local medical community before they graduated from their residency and began practicing in the community. The specialty reps had higher budgets because they used their money primarily for entertaining the Key Opinion Leaders ("KOLs") who recommended treatment courses for the primary care physicians and small community hospitals along with Pharmacy & Therapeutic committees.

147. Sales reps, specialty reps, and IHRs also had an additional budget to pay for "programs." Sales reps had about $8,500-$10,000 per year to pay for "programs", e.g., speaker honoraria, journal clubs, preceptorships and the like. IHRs had about $12,000 to $15,000 dollars per year to "develop" residents and fellows as speakers, pay staff and specialists to speak to and "influence" the prescribing habits of the residents and fellows under them. This additional money was also used for preceptorships, and in some cases to bring other National Key Opinion Leaders in from some other part of the country to speak to the residents, fellows, and staff of a various hospital. Specialty reps used their program budgets primarily to pay specialists and KOLs to speak and to develop (or draft) specialists who particularly liked competitors' drugs to speak for Pfizer's drugs. Through the use of preceptorships and speaker honoraria with this chosen physician they would hope to create an advocate for Pfizer products instead of another drug company's products.

148. District and Regional Managers also had marketing budgets for POAs and for programs and entertainment. Relator estimates their budgets were at least in the range of $80,000-$100,000/year. The RMs and DMs would also supplement sales reps and IHRs budgets with additional funds each district manager "held back" at the first of the year and allotted to the reps or IHR's who used their money in the first 8 or 9 months of the year in order to generate greater returns on investment.

149. In addition, several other groups or individuals had budgets for marketing and promoting the drugs, as described in paragraph 43-44 above. This included, the Disease Management Teams ("DMT") who had budgets to sponsor programs about a particular drug, the Vice Presidents, the National Healthcare Operations ("NHO") (established to contract the drugs with managed care plans and with long-term care organizations in the federal sector), the clinical

education consultants ("CEC") (for entertaining pharmacists at important accounts), and the Regional Medical Representatives ("RMRs") (who had large budgets for the programs and entertaining that they did on the Regional and National level).

150. To keep track of its various programs, Pfizer introduced the Budget and Education Tracking System ("BETSY") accounting software to the Sales Field Force soon after Pfizer bought Warner-Lambert in 2000. Pfizer was very meticulous about keeping track of which representative had which doctor speak. BETSY serves many purposes, including allowing managers to hold their reps, the RMRs, the CECs/Pharm-D's, etc. and even each other accountable for their work and the efficacy of journal clubs, programs, and preceptorships. This accountability encourages managers and their reps to spend their budget "effectively" within a prescribed time with "influential doctors." Reps are mandated to spend their "journal club" or program budget. However, before a doctor can be paid to speak that doctor must be entered into the BETSY database, and management must approve the program. While there are differences between a journal club, a program and a preceptorship, BETSY recorded all such events as "Programs" for its tracking purposes.

151. Pfizer used another software program known as "Sherlock 3" (which consisted of many components including Sherlock Analyzer) to track drug samples left with doctors, and prescriptions and sales data by physician, by group practice, by customer, by product, by time period, by geographical location, by sales rep or IHR, etc. This software enabled Pfizer reps and their managers to "Determine which practices have the greatest impact on your business." In other words, Pfizer could track how effective their various sales and marketing techniques were in influencing prescription writing and formulary decisions. For example, in the month after a

POA, Pfizer could track whether the sales techniques pushed at that POA affected prescription writing and drug sales.

152. When used on its own, Sherlock enabled Pfizer to see how the number of drug samples left with a physician correlated to prescriptions written at a later time. When Sherlock data was used in conjunction with BETSY, Pfizer was able to track the correlation between its "programs" and its sales. In other words, it could see how effective certain of its programs and/or speakers were in influencing doctors and other customers to write prescriptions for Pfizer's drugs. This type of correlation was referred to as "Return on Investment" ("ROI"). Generally, Pfizer wanted to see at least a 10-1 ROI.

153. Generally, Pfizer's mode of operation was to develop relationships with physicians who were seen as "key opinion leaders" (or "thought leaders" or "chief influencers") among their peers and within their specialty/area of practice, and then used those doctors to help sell the drug to other doctors and to train other doctors to sell the drug. These key opinion leaders were recruited through educational grants (restricted and unrestricted) and other incentives, and by the promise of future lucrative speaking engagements around the country. This was done not only at the launch of a new drug, such as when VIAGRA was launched, but it continued after, and often intensified as new competitors to the drug were coming onto the market, as happened, for example, with LIPITOR in 2003.

154. In addition to the "Key Opinion Leaders," Pfizer's reps would enlist and pay doctors in their territories/districts as speakers to conduct programs, journal clubs, lunch 'n learns, etc. in their local area. A "journal club" generally was an event at which a local doctor would address his local peers, for example, a family practice doctor in Provo, Utah speaking to other family practice physicians in Provo, Utah. Often these speakers were influential in their

own community, because of the number of patients they treated, their reputation, and/or their position to influence the formulary decisions of a hospital. These "Journal Clubs" were held throughout Southwest and Rocky Mountain Regions, and throughout the country. The Clubs were intended to "develop" local doctors and allow representatives to win over local doctors and gain their business and influence.

155. Pfizer reps would also pay doctors in their territories/districts for preceptorships. Typically, Pfizer would pay $500.00 for a new non-specialist physician, $750.00 for a new less influential specialist physician or a non-specialist physician who had been used several times, and $1000.00 to $1500.00 for an influential specialist or Key Influencer who treated many patients, or who dominated a Pharmacy & Therapeutics Committee. Then, script writing or recommendations made to the P&T committee for inclusion of a particular drug on a formulary were carefully monitored by the manager to see if the money spent on the preceptorship brought the desired Return on Investment. As described above, this ROI was monitored by Sherlock and BETSY software, showing what was spent on a particular physician and what was received in return (e.g., prescriptions written).

156. A key and integral part of Pfizer's overall marketing strategy was to flood the market with free samples of the drugs. Sampling was recognized by Pfizer as a "key driver that influence physician prescriptions" and, as demonstrated below, it also influenced formulary decisions by P&Ts , in part because free samples could drive down the acquisition cost of the drug. Reps were evaluated in part based on their sampling. As already noted, Pfizer tracked samples for ROI. The importance and scope of Pfizer's sampling strategy is also addressed in other parts of this Complaint.

a. <u>Kickbacks in Texas and the Southwest Region of Pfizer</u>

157. The following are some examples of the kinds of incentives Relator is aware of from his time with Pfizer in Texas from 1998-2002, both as a rep and as an IHR. By way of background, as an IHR, Relator was responsible for covering four major integrated health care systems, including the hospitals and their outpatient clinics. They were: (1) Scott & White Health Plan consisting of one Main Medical Center in Temple, Texas and 19 or more outlying hospitals and outpatient clinics throughout Central Texas (Relator was largely responsible for the formulary because the P & T Committee resided at the Main Medical Center); (2) John Peter Smith ("JPS") Health system (including the hospital and nine outlying outpatient clinics); (3) Darnall Army Hospital in Fort Hood (and its four outlying outpatient clinics); and (4) Baylor Medical Center consisting of the main hospital with four outpatient clinics and about 13 other outlying hospitals and and clinics (as with Scott & White, Relator was responsible for the formulary).

Dinner Programs and Entertainment

158. Del Frisco's restaurant was a popular draw for physicians and because it was, The Labs, Pratt, Steere cluster or Cluster "X" side of Pfizer held a program there every 3 to 4 weeks through the year. A typical program was attended by some 22 to 25 physicians and their spouses or dates. With food and drink, the typical bill was $7,500 to $7,800 dollars. This would be split among six to eight reps including Labs, Pratt, Steere from Arlington and Fort Worth and then the Specialty reps who often participated. Richard Winn, M.D. for Zithromax, and Ken Goldberg, M.D. from Grapevine, Texas for Viagra, are among the doctors who attended.

159. Other fine restaurants where programs were held included: REATA also in Fort Worth, and in Dallas; The Mansion at Turtle Creek, which cost about $175.00 per person with dinner and drinks; Three Forks, which cost about $150.00 per person; Old Warsaw, which cost

about $175.00 per person; and The Silver Fox in Grapevine, Texas which cost about $125.00 per person. All of these restaurants were visited often.

160. Frequently, these Dinner Programs had a speaker during dinner and then the reps and the doctors and their guests would go to a "broadway show" at the Dallas Performing Arts Center or at The Bass Performance Hall, like "Smokey Joe's Café", or "Ragtime", or "Jekyll & Hyde", or "Cabaret" to name a few. These show tickets ran an additional $70.00 to $85.00 per person. Dinner Programs such as these were held to promote VIAGRA, ZITHROMAX, LIPITOR, NORVASC and ZYRTEC, as well as other drugs.

161. Another frequent type of dinner program involved a speaker named Darryl Wilson, who was Chief of Pharmacy at JPS, and influential on the P & T Committee there. Relator had known Darryl Wilson for almost the entire time Relator worked in Texas. Ken Smith, Vaughn Hawkins (he was with Roerig--Zoloft was his main drug) and Woody Goodson (Labs) via Mark Walgren (IHR for the Labs Division), had Darryl Wilson speak often throughout the Fort Worth District. These were not talks to physicians about disease states, but rather "non-medical" talks about getting along with each other and understanding how other co-workers or patients might be feeling. These were very "touchy – feely" kind of talks that always occurred at nice places like country clubs or fine restaurants.

162. One Dr. Wilson event Relator remembers particularly well was a talk the doctor gave to the Arlington Medical Association at the Rolling Hills Country Club in Arlington on Valentine's Day 2000. This talk was given to pharmacists and their spouses, some physicians and their spouses, and some key hospital personnel like Sandy Halliburton, Director of Education and Certified Medical Education at Arlington Memorial Hospital. The thirty minute talk was at the beginning of the evening, and done before the entrée arrived. After dinner,

dessert and coffee, there was dancing with a live band. Wilson was paid $1,000.00 for the talk and the evening. In addition, Pfizer paid $9,500.00 for the use of the country club, the decorations, the meal, the liquor and the band. Relator's Arlington counterparts complained to him that Wilson spoke for such a short time about "nothing" and made $1,000.00. Relator himself was shocked to learn how much made for his "non-medical" talks.

163. Wilson spoke about developing better relationships and he emphasized relationships with medical staff, with pharamacists, with physicians, and with nurses. Then he expanded his talks to relationships to significant others and spouses and asked for interaction from those in attendance.

164. When Relator started as an IHR in July 2001, he called on Darryl Wilson because he did not know anyone else in the JPS hospital yet. Wilson and Relator talked for about 30 minutes, maybe more. Relator tried to build on common ground by telling him how much he enjoyed Wilson's presentations. Wilson told Relator that Vaughn Hawkins and Woody Goodson had put him on a "talking circuit" where he went to different states all over the South presenting his 5 separate presentations to various groups and that he was now making more money from speaking for Pfizer than he made from his salary at JPS. He was friendly to Relator and all of the Pfizer reps for their whole tenure.

165. While Wilson *said* that he would not recommend Pfizer drugs on the P&T Committee for JPS because he felt that that was a conflict of interest, he also always said that he would not block Pfizer products if they won approval from the other members of the P&T. While this was what Wilson said, his actions spoke louder and guaranteed special access and influence for Pfizer. Wilson determined the agenda of each meeting and what things would and would not be discussed. He always gave the Pfizer reps the dates of the P&T meetings, the

agenda that would be discussed, and then after the meeting made the minutes available to the Pfizer reps so that they could know who was championing Pfizer products and who Pfizer needed to "convert." As if this were not enough, he also allowed the Pfizer reps to provide lunch before each P&T Committee meeting so that they could talk to the various members before they went in to vote. Perhaps not surprisingly, despite what Wilson said about his "conflict of interest", ZOLOFT was *always* first line therapy at JPS for the time Relator was there and the SSRI's were never even put on the agenda for possible review.

Texas Rangers Baseball Programs

166. Ken Smith, an IHR in Relator's district, also put together several programs at The Ball Park at Arlington, Texas, home of the Texas Rangers baseball team. He would rent a box and fund a doctor to speak. The doctor would come in and speak to about 20 doctors and their guests for ½ hour or so over dinner before the game and then everyone would watch the baseball game. Smith told Relator that Dennis Gooch, their District Manager, gave him district money which was separate from his IHR budget to do these programs, which he said cost $8,000.00 for each evening. These programs included the Yankees, The Red Sox, The Cardinals, The Diamondbacks, and The Padres, etc. Dr. David Gould, Chief of Urology at JPS Hospital, spoke about VIAGRA at the Yankees game, but the other programs, like the programs listed above, included not only VIAGRA, but also ZITHROMAX, LIPITOR, NORVASC, and ZYRTEC. Needless to say these programs at The Ball Park were very popular.

Dallas Cowboys Football Programs

167. There was a ZITHROMAX evening at Cowboys Stadium in Dallas, Texas, that Vaughn Hawkins, the district manager for Roerig in Fort Worth put together. He had been a district manager for 23 years in Fort Worth and he did this "program" to sell ZITHROMAX to

the most influential doctors in the Fort Worth District. The program was attended by about 30 infectious disease and pulmonolgy specialists and their guests. It was conducted in the same in format as the programs at The Ball Park at Arlington (i.e. a speaker, dinner, the game). Although Hawkins never said exactly how much the program cost, it was more expensive than the ones at The Ball Park had been.

NASCAR Programs

168. Another set of "programs" that were very expensive were the VIAGRA NASCAR "programs" at the Texas Motor Speedway. Like the other programs, the Key Opinion Leaders like Dr. Kenneth Goldberg, and David Gould Chief of Urology at JPS, and 25 other doctors were whisked away with their guests to one of the most exclusive boxes at the Speedway. They were served filet mignon and then instead of a physician speaking, Mark Martin came up to the booth to speak to the doctors about the race and his interest in NASCAR. Then everyone went down to pit row before the race to meet the drivers. There was *no* medical education content to this program; rather it was just a good time to wine and dine the most influential doctors in the District. Relator is not sure how expensive it was to rent the box and feed everyone, get the pit passes and keep the open bar, but he believes that it would have been in excess of $20,000.00 for the afternoon.

169. These same NASCAR/VIAGRA programs went on all over the nation wherever NASCAR raced for as long as Pfizer sponsored NASCAR with VIAGRA. There were/are at least 50 races per year. During a trip to La Jolla, California, Lauren Patani, then director of the VIAGRA Disease Management Team, said that Pfizer spent $10 million per year just to sponsor the VIAGRA car and the Mark Martin racing team. This did not include the money spent at each race for the box programs.

170. Like the LIPITOR marketing directives set forth in the mid POA slides dated August 14, 2003, these NASCAR programs were not initiated or sponsored at the representative level, and they were not paid out of any "meager" district budget; rather these were initiated, sponsored and directed at the highest levels of Pfizer by the respective Disease Management Teams with the sole interest of "influencing prescribers" away from what may be best for individual patients.

Hunting, Fishing and Resort Trips

171. Other favorite activities included fishing, hunting, etc. trips. For example, Greg Bradburn who was Relator's Steere counterpart in Waco, Texas (and started the same time that Relator did), used to share his success stories at the POA's. He said that the way he was so effective (he was the no. 1 sales rep for the Steere Division in 2001) was that he took his Key Opinion Leading physicians on trips. For example, who would arrange hunting trips to the hill country of Texas just west of San Antonio and Austin. He said that he paid a fee for himself and his two or three companions, however many went each time, and then he could hunt on the private reserves. He explained that he expensed these "hunting programs" through Dennis Gooch, the District Manager.

172. Bradburn also took his Key Opinion Leaders and high writers on ocean fishing trips off of Matagorda Island in South Texas/the Gulf of Mexico. He said that he went four or five times per year and chartered a boat out of his budget which he disguised as restaurant receipts that he had managers at various restaurants create for him, so that DM Dennis Gooch (who was aware of the truth) would approve the expenses.

173. Bradburn and his wife also took his chief high writer and his wife to Disney World and expensed the trip the same way – with restaurant receipts. Again the DM was aware

of the truth. Gooch stressed to the other reps that they should have as good relationships with their doctors as Bradburn did with his.

174. Bradburn's actions were not those of a rogue representative. He used to brag about the great relationships that he had with his physicians at the POA's Relator attended. Bradburn would explain that he had taken these doctors fishing, or those doctors hunting or this high writer to Disney World, along with both of their wives, during his presentations at the POA's - in front of everyone including the DM, the IHR, and numerous reps. Again, rather than reprimanding Bradburn, DM Gooch just said that he wished Relator and his co-workers all had great relationships with their physicians like Bradburn had with his. These actions were endorsed by Gooch, but Bradburn made it clear to Relator that Gooch would not approve the expenses unless they came across his desk in the form of "legitimate receipts".

175. These elaborate fishing trips, and hunting expeditions, and vacations to Walt Disney World were used to influence physician prescriptions and eliminate patient choice. Because Bradburn was the number 1 Steere Division rep in the nation in 2001, and his actions were praised by the DM, it encouraged other reps, IHRs, etc. to engage in similar misconduct..

Strip Clubs

176. Another way that non-medical "programs" took place with the knowledge of management and resulted in increased sales is illustrated by Greg Bradburn's LABS counterpart (also in the Waco territory), Gaylen Hench. Because LABS and STEERE sold the exact same drugs (LIPITOR, NORVASC, VIAGRA, and ZITHROMAX), *Hench and Bradburn were the number one sales reps in the nation at the same time.* Hench had been with Pfizer since 1992 and had always worked for Woody Goodson, the LABS district manager for Fort Worth.

177. While the sales force, including the Relator, were in Orlando for the Cluster "X"

launch, Relator congratulated Hench and asked him how he did so well every year and how he had taken the top spot in 2001. Hench explained that he did not waste his time detailing doctors, but instead that he entertained them at strip clubs. He said that he had 25 high writing doctors, who he took to strip clubs regularly. He did not take all 25 at once, but rather 2 or 3 at a time, and he said that he went 2 or 3 times per week. Relator asked him how much he spent and he said that he did not know, but that he just got fake receipts at restaurants and turned them in to his district manager, Woody Goodson. Relator asked him if he was afraid Goodson would learn what he was doing and fire him, to which he laughed and said that Goodson was the one who told him how to falsify the restaurant receipts and that Goodson goes with him whenever he is in Waco. Relator replied words to the effect: so my manager goes around to doctor's offices to evaluate my sales techniques and my relationships with my physicians (evidenced by how much time they give me while I detail them) while yours goes to the strip clubs with you? Hench replied with words to the effect of "when you're on top of the sales world, nobody scolds you for how you got there."

178. Hench further explained that he broke down how many prescriptions of each drug these top 25 physicians would have to write to put him at the number one spot in the nation based on the Goal Attainment Report (GAR) and then he would ask them to write that many additional prescriptions per month on top of what they were already writing. He said that it worked every year for him, and he always ranked at the top of the GAR.

Casino Night for Lipitor

179. In March or April of 1999, Relator went to his first Casino night. It was held at the Renaissance Worthington Hotel, in Fort Worth. He was a new rep who had been out of training for a only a few weeks and this was his first big program. All of the other reps wanted

Relator to go to this program so that they could use some of his budget. Relator was concerned about getting reimbursed so he did not want to go. He expressed his concern to his district manager, Dennis Gooch, and he reassured Relator that he would be reimbursed, saying words to the effect that it would be a good way for Relator to associate with his doctors in a relaxed atmosphere and that this is how reps become good friends with their doctors.

180. The ballroom was laid out just like a Las Vegas, or Atlantic City Casino: 3 Roulette tables, 2 Craps tables, and several tables for Black Jack and Poker. It started at about 6:30 pm and about 45 or 50 doctors and their guests showed up. It was an open bar and a fine dinner. The speaker spoke for about 30 minutes while the guests, reps, etc. ate. The senior reps made a big deal that the speaker needed to be done by the time people finished their main course to get the maximum amount of time with the casino people. The speaker began at about 7:00 and he was done by 7:30.

181. Once the speaker was finished, everyone was given a notional "10,000 dollars" worth of chips and they could play until all of their chips were gone, or until they could win everyone else's chips, if that were possible. Then they could "cash in their chips" and trade their winnings for Home Depot gift cards, Cole-Haan Shoes gift certificates, Brooks Brothers gift certificates, Barnes & Noble gift certificates, Blockbuster gift certificates, On The Border (a restaurant) gift certificates or medical textbooks.

182. This Casino evening cost just over $26,500 for the meal, the use of the ballroom and the open bar. Relator paid $1,500.00 on his American Express Card, and his payment went to the hotel that had booked the Casino Night people. The speaker was paid for by Jay Reynolds: a Pfizer Labs rep in Fort Worth. The speaker was not part of the $26,500.

183. There were 3 reps in Fort Worth, 3 in Arlington, 3 in South Fort Worth, 3 in

Denton, 3 in South Dallas, and the 12 reps from Parke-Davis to share this bill and the reps in Irving, Texas covered the gift certificates.

184. Relator's DM was right; even though Relator did not sell Lipitor at that time, it was a very successful night for building friendships with doctors like Dr. Michael Jutras, Dr. Barry Aldridge, Dr. David Kaner, and Dr. Gilbert Ledesma that he kept until he moved to Utah. These were all high-prescribing doctors and they always gave Relator extra time after that and were very warm and friendly to him, but not to reps from other companies. In fact, reps from other companies like SmithKline and Abbot would talk about how these doctors were indifferent toward the information they presented.

Horse Racing Programs at Lone Star Park

185. Pfizer had four or five of these programs that Relator attended at Lone Star Park, an upscale horse racing facility. One program took place on September 30, 2002; it was devoted to ZITHROMAX and Dr. Toshio Yamauchi spoke. Misty Rohne, a fellow rep in the Fort Worth district who called on doctors in Denton, TX, and Relator rented a box at Lone Star Park and hosted about 25 pediatricians and their guests.

186. Dr. Yamauchi spoke for about 30 minutes on the disease state Acute Otitis Media (children's ear aches) and how to determine when pediatric patients need an antibiotic. Then he talked about the value of using Zithromax to treat Acute Otitis Media. The whole talk lasted about 30 minutes while the audience ate appetizers. After the talk guests ate dinner and bet on the races. The night began at about 6:30 and ended between 9:30 and 10:00 pm.

Casino Night at the Forth Worth Club (Lipitor and Norvasc)

187. The purchase of Warner-Lambert created many openings for IHRs to become District Managers. As a result, by September, 2001, almost all of the IHRs in Fort Worth were

new and had to build strong relationships with John Peter Smith Hospital ("JPS") for Lipitor, Norvasc, and Zoloft (at least), since JPS provided around 50 new physicians into the Fort Worth District each year. Pfizer managers decided at their local Target Area Customer Unit ("TACU") meeting (TACUs were local groups whose meetings were attended by regional account managers, district managers, and local market managers, among others) meeting that a Casino Night would be a quick way to open doors for the new IHRs at JPS. Consequently, in about September of 2001, JPS Staff physicians, Fellows, Residents, and Pharmacy enjoyed another Casino Night. This event was held at The Fort Worth Club, a beautiful private club on three floors of one of the skyscrapers in Fort Worth. Woody Goodson, District Manager, Pfizer Labs, was a member and that enabled Pfizer to rent and use the venue.

188. Dr. Richard Fulkerson spoke about using LIPITOR over Zocor and NORVASC over Plendil. Dr. Matt Rios spoke about using ZOLOFT over Prozac to reduce insomnia in geriatric patients. This program was for all of the IHR's to build better relationships with the residents and Faculty at JPS as well as ultimately increase the use of all of Pfizer's products. Cluster X had its greatest quota with Lipitor and Norvasc, so they wanted a faculty speaker to speak and recommend Lipitor and Norvasc. Cluster A had their greatest quota with Zoloft, so if they were going to use their money to sponsor a casino night for JPS faculty and residents then they wanted a second talk where a faculty member would recommend Zoloft over Prozac. The compromise was to have each physician speak for twenty minutes before the Casino Night (party) began.

189. The faculty and the first residents arrived at about 6:00 pm and the talks went from about 6:15 pm until about 7:00 pm. Like the other Casino Nights, the speakers spoke while the guests ate. The timing was important for this program, because the residents were going to

stagger their shifts so that they could all enjoy the Casino Night. In other words, some would stay until 8:30 pm and then go back and cover for the other residents so that they could go over to the Fort Worth Club. The second group of residents who had to work for the first part of the program, came at about 8:30 and the Casino Night lasted until about 10:30 pm. In total, Relator estimates that about 40 physicians and 4 or 5 pharmacists attended, along with their guests.

190. There were 3 Roulette tables, 2 Craps tables, and several tables for Black Jack and Poker. This casino night did not have an open bar, but simply a choice of red and white wine and beer. Like the other Casino Nights, no money was exchanged, but everyone was given a notional "10,000 dollars" worth of chips and they could play until all of their chips were gone, or until they could win everyone else's chips, if that were possible. Then they could "cash in their chips" and trade their winnings for gift cards (see paragraph #181).

191. The night in total cost just over $20,000 dollars for the meal, the use of the ballroom and the wine and beer. Relator paid about $2,500.00 on his American Express Card (to the Fort Worth Club who had booked the Casino Night people). The gift certificates were paid for by: Vaughn Hawkins, Woody Goodson, Dennis Gooch, Mitch Alberto (Pratt DM), Mike Maddox (Parke-Davis 1 DM) and the Parke-Davis 3, Parke-Davis 2, Powers and Alta District Managers. Relator cannot recall who paid for the speakers. Like the other Casino night, this event really opened doors for all of the Pfizer IHRs at JPS with the faculty and the residents. In addition, there were other programs for JPS, including the ski trip to Breckenridge, Colorado described below.

The Scott & White Golf Invitational For NORVASC

192. In late January or early February of 2002, NORVASC was taken off of Scott & White's formulary and replaced by Plendil. This was shortly after Pfizer had hired away 3 of the

voting members of Scott & White's P&T committee to be Pfizer RMRs. Hence, they were not at Scott & White to vote for NORVASC. When Pfizer got word that NORVASC had been replaced on the formulary, every rep in the Waco, Texas LATU, all of the Fort Worth IHR's, all of the Fort Worth District Managers, Chad Walker, Pfizer's Regional Account Manager, Donna Jermain and Annie Harrington (PharmDs and Pfizer RMR who had just been hired from Scott & White), cleared their schedules and met together at the Quality Inn restaurant in Waco, Texas.

193. They discussed the situation for most of the day, with Donna and Annie directing the discussion. All of the Pfizer reps and managers pushed to just flood Scott & White with Norvasc samples and eliminate the discount they would receive from using Plendil. Donna and Annie were convinced that strategy would not work; they were concerned that the Scott & White pharmacists were so upset with Pfizer (presumably because some of their peers had been hired by Pfizer to receive triple the salary of the Scott & White pharmacists), that they would operate a budget in the red just to spite Pfizer.

194. Nevertheless, it was decided that the reps needed to flood the Scott & White healthplan with samples of Norvasc and all of Pfizer's other drugs (this meant samples to all of the doctors that contract with the Scott & White healthplan), and the IHR's would keep the outpatient clinics well stocked with samples of Norvasc and Pfizer's other drugs. They also needed to strengthen relationships with the various members of Scott & White's P&T committee, both new members and old members. To do this, all reps and IHR's would sponsor every lunch, dinner, breakfast, and physician or pharmacy event that they learned of, and Donna and Annie would run models with the Scott & White pharmacists to show how much money they would lose by replacing Norvasc with the *less expensive* Plendil.

195. Additionally, some of the pharmacists were very good golfers, so it was

determined that Pfizer would sponsor a tournament. To this end, Mark Walgren, Woody Goodson, Dennis Gooch and Relator sponsored the Scott & White Invitational Golf Tournament. This Pfizer / Scott & White Invitational had been done a few times over the years that Goodson had been a district manager, but this time it was seen as critical, to get Norvasc back on formulary. This tournament was to be especially elaborate.

196. Because the formulary decision makers were primarily in the main hospital in Temple, Texas, and this account belonged to Walgren and Relator, they really promoted the tournament and encouraged department rivalries.

197. The DMs ordered $30.00 Pfizer logo golf shirts for all participants. They also ordered $15.00 hats, $45.00 jackets, and golf bags estimated to have cost $85.00 to $150.00 each. They ordered all of the above and $10.00 golf gloves, $10.00 golf towels, $10.00 pin markers and divet repairers, and 12 golf balls for everyone. Each item had a Pfizer logo on it.

198. Goodson told Relator that prior Scott & White golf tournaments had been like this one, except they had never ordered shirts, hats, jackets, golf bags, and golf gloves for everyone before. (They had only ordered Pfizer golf balls, golf towels and pin markers in the past).

199. The tournament took place on a Saturday in one of the first weekends in March 2002. Breakfast was served at 7:30 am then one of the cardiologists from Scott & White spoke about Norvasc and hypertension for about 40 minutes. Then Pfizer reps distributed the shirts, hats, jackets, golf bags, gloves, pin markers, towels and golf balls. Tee time was at 9:00 am.

200. In all there were about 42 physicians divided into several teams: Pharmacy A and B teams, Cardiology A and B teams, Pulmonology team, Urology team, Infectious disease team, Microbiology team, Emergency A team and Emergency B team, and an ICU team. As hoped by Pfizer, Pharmacy won everything.

201. This tournament had the desired effect of "making a lot of friends" with these various departments. The pharmacy welcomed Pfizer in after this tournament. The RMRs showed Pharmacy how much would be lost with the Plendil decision, and the reps and IHRs flooded the offices, outpatient clinics, etc. with samples, as planned.

202. Four months later, in July, just six months after Norvasc had been taken off of Scott & White's formulary, Norvasc replaced Plendil. Normally these contracts last at least a year and typically three. To save face, Pharmacy said that reviews of Plendil had shown that they were not getting the reduction with Plendil that they had with Norvasc and patients' health was at risk.

The ParView VIAGRA Golf Programs

203. Pfizer sponsored a ParView Viagra Golf Program held at the Tour 18 Golf and Country Club in Flower Mound, Texas in October 2001. This program was so successful that it was then replicated around the country.

204. The Tour 18 golf program was an all day event on Saturday October 20, 2001. Pfizer, in conjunction with PSP Sports, hosted 75 doctors, thirteen of their guests, and eight Pfizer representatives, including the Relator (who was an IHR by then), and a number of RMRs. Among the Pfizer RMRs in attendance was John Lloyd, PhD, head RMR for the Southwest Region who had just returned from a program that Dr. Mobley and several other urologists of national import had attended in New York. The doctors and their guests were treated to 18 holes of golf at one of the three most exclusive country clubs in the Metroplex (there are some 40 golf courses in the Metroplex), a golf shirt, free golf balls, a breakfast buffet, lunch, dinner, refreshments on the course, and the awards presentation including a free putter and a driver.

205. In the morning program, Dr. Mobley spoke about the importance of physicians

taking an active and aggressive role in diagnosing and treating erectile dysfunction as part of evaluating the overall health of patients. After Dr. Mobley's talk, Pfizer's RMRs under the direction of RMR Lloyd led break-out sessions of about 30 minutes in which the physicians were able to interact and give their evaluation of the presentation and the slides. After that, there was lunch, golf on the acclaimed Tour 18 course, and an awards dinner.

206. The physicians who attended this program were also paid a $750.00 honorarium for agreeing to return to their offices and present to repeat to their colleagues at office lunch programs the same information that had been presented to them by Dr. Mobley. These were usually 15 or 20 minute presentations over lunch. This way, the doctors were paid for their attendance, but in BETSY it would show up as a speaker honorarium for a talk, and the honoraria would be paid on separate days, instead of all of the attendees receiving their checks on October 20, 2001.

207. Relator evaluated this golf event as highly successful: "In light of the impact from this first event, I believe it would be a valuable ROI [return on investment] to hold again." Pfizer agreed and it held 7 of these golf programs (one in each region) at very expensive Country Clubs between October of 2001 and April of 2002.

The Four Seasons Hotel (Dallas) Weekend Dinner and Golf Program (Viagra)

208. In late August - early September 2002, Pfizer (VIAGRA) was expecting imminent launches from competitor drugs Cialis and Levitra. In an effort to blunt these launches, Pfizer held 4 Disease Management Team ("DMT") sponsored programs in each of the then seven (7) regions for a total of 28 DMT sponsored programs. (These VIAGRA DMT sponsored programs were much like the LIPITOR DMT sponsored programs that were held in 2003 that are discussed in the POA slides from August 2003).

209. An incredible amount of money goes into a DMT sponsored program (money that is not a part of the representative budgets, the District Manager's budgets, the Regional Manager's budgets, or the Vice President's budgets). In addition to DMT budget money, these programs are paid for by the NHO teams (including National Account Managers and counterparts with the TACU's and the RAM Councils), the CECs, and the RMRs .

210. This program; along with *28 others* throughout the United States, was sponsored by the VIAGRA DMT. It was held at the Four Seasons Hotel, Dallas and the reps, IHRs, etc. were instructed to bring their top writers from the surrounding area. Relator was an IHR by then, but he was going to be moving back to Utah in just a few weeks. Nevertheless, his DM Dennis Gooch, asked Relator to bring Dr. Michael Hermans, Dr. King Coffield, and Dr. Patel, Urologists from Scott & White Medical Center, Dr. David Gould from JPS, and Dr. Wade Lowry, a KOL urologist from Bedford, Texas. Relator did so. Several other reps and IHR's were also asked to bring their KOLs. Relator estimates that there were 45 to 50 physicians along with their guests.

211. The wine reception began in the art gallery, at about 7:00 pm. Some physicians traveled in from Oklahoma, Shreveport Louisiana, and North and east of Dallas. Each physician brought at least one guest and some more than one guest.

212. The dinner was served along with the presentation in the auditorium. The speakers were Louis Ignarro, and Ferid Murad, the two men who received the Nobel Prize for Medicine in 1998. They spoke from about 8:00 pm until about 9:30 pm. Then the doctors and their guests were excused.

213. The next morning breakfast began about 7:00 am and tee times began at 8:00 on the Four Seasons Golf Course at Las Colinas. [This is the same course where the PGA plays the

Byron Nelson]. Las Colinas is the finest in the Dallas Metroplex. Those who wanted to golf did, mostly the doctors, and their guests had unlimited use of the hotels amenities including the spa, the tennis courts, the swimming pool, etc.

214. Lunch was served between play on the front and back nine (deli sandwiches and chips) and then play continued until about 4:30 or 5:00 pm. Then there was an awards ceremony during another very nice dinner.

215. Putters, and drivers, sweatshirts, and hats were given away for longest drive, closest to the pin, etc. Everyone went home after dinner on Saturday night and Relator recalls that the doctors seemed resolved to continue to prescribe, and recommend, VIAGRA over competitors Cialis and Levitra.

216. Relator conservatively estimates the price tag for the event as follows: The rooms cost about $500.00 each, the dinner and the wine for the first night would be another $200.00 per person, the golf or the amenities would be another $200.00 per person, free beer and snacks totaling another $50.00); then the second dinner, the accompanying drinks and the awards ceremony would be another $200.00 per person. The resulting estimated cost is about $1,150.00 per person. There were about 100 people there, not including the reps, for a total of at least *$110,500.00* for this one program, of which 28 were scheduled throughout the United States (4 for each of 7 regions).

Skiing: the John Peter Smith (JPS) Grand Rounds Get-Away Breckenridge/Vail (Glucotrol and Lipitor)

217. The John Peter Smith (JPS) Grand Rounds Get-Away was held for several winters at Breckenridge/Vail, Colorado. Pfizer sponsored this ski trip for the teaching physicians and some 45 residents at JPS Memorial Hospital and clinics. This ski program illustrates the influence Pfizer had with doctors through trips and speaking engagements. In 2002 alone, the

trip paid off handsomely for Pfizer, with JPS agreeing to have GLUCOTROL XL replace generic glipizide on the JPS formulary (on or about the first of March 2002), and to have LIPITOR replace Zocor on that formulary by the end of the year (it happened around the first of November 2002).

218. A flyer for the 2002 JPS Get-Away program was distributed to all of the Pfizer representatives in Fort Worth, Texas in about November 2001 (about four months after Relator became an IHR). Relator was approached by Dr. Bart Pate, M.D., the chair of the residency program at JPS, and asked if Pfizer would be sponsoring the JPS Grand Rounds Get-Away in February of 2002. Relator was told that his predecessor Ken Smith (whom Relator had replaced upon his promotion to IHR in July 2001) and Mark Walgren, IHR for the Labs Division, under Woody Goodson (Fort Worth DM for about twenty years), had been the benefactors for this get-away in the past. Dr. Pate explained that the DM had obtained an "unrestricted educational grant" for the event in the amount of about $5,000.00, each year, for the last several years.

219. Relator raised the sponsorship issue at the next IHR meeting and one of his counterparts, Eric Knamm, who sold GLUCOTROL XL, Accupril and LIPITOR, explained that he would contact DM Goodson and make sure that the JPS Residency program received their money. Mr. Knamm also told Relator that he was going to attend, just as Mark Walgren and Ken Smith had for the preceding several years. The attendees were to have dinner every night with the sales reps, and Mr. Knamm said that someone would have to pay for "their" dinners and "remind them about our products."

220. Relator was told that the $5,000.00 was to be used for ski lift tickets, and "incidentals" which the 45 residents of JPS and their accompanying teaching physicians would use during the weekend. As Relator understood it, Roerig, Powers, Alta and Parke Davis 2 also

submitted applications for $5,000 from each of their district managers (the physicians would off-set what was not covered by the grants). Relator believes that the Powers and the Parke Davis 2 reps also went with Eric Knam on the trip to Breckenridge for this "educational" outing.

221. The doctors paid for whatever part of the trip costs could not be raised from the "unrestricted educational grants." On information and belief, the residents, fellows and staff, also received assistance from Breckenridge to reduce the normal cost of all of the amenities at the Lodge because these were staff and residents at a county hospital in Fort Worth, Texas.

222. Relator asked Mr. Knamm and Relator's DM Dennis Gooch, about this "unorthodox" use of funds and they explained that DM Goodson and Pfizer did not care what the "educational grant" was used for, because once the money was in the hands of another institution, that institution was responsible for how that money was spent.

223. Under the JPS Get-Away Program, third-year residents (who would soon be practicing out in the Fort Worth community) were also paid by Pfizer to make presentations at Breckenridge. Relator believes that the payment was $250.00 for residents to make their presentations and $500.00 for the Chief Resident to make his presentation. Relator believes that Pfizer provided the slides that the speakers presented. Typically, a new speaker who has not spoken before would be paid around $250.00 and an experienced presenter, which could be a third-year resident and Chief Resident, may get $500.00 to speak, mostly because of their experience and the influence they wield. Furthermore, an entire year's worth of required Continuing Medical Education ("CME") credit could be obtained at this one weekend event. CME credits are sometimes expensive to obtain. Here, they would receive the credits in addition to the other benefits.

224. Relator did not attend the trip, but when Eric Knamm came back from the trip to

Breckenridge, he told Relator that the trip was spectacular and that Relator should have come along. He explained that because of some great relationships he had developed there, GLUCOTROL XL was about to replace *generic* glipizide on the JPS formulary (and it did on or about the first of March 2002). This was a very important switch; Relator had been told by his DM Dennis Gooch (former Roerig sales rep – which division launched Glucotrol--in 1984--and Glucotrol XL--in 1990), that since 1994, the profits from GLUCOTROL XL, had been enough to pay the *entire salaries for the* Pfizer sales force including managers, Vice Presidents, and Senior Vice Presidents of all of the separate sales divisions. This was always reiterated when the sales force would complain that GLUCOTROL XL was an old "dog" drug with very little new information they could give to the doctors. GLUCOTROL XL revenues amounted to between $500 million and $530 million dollars per year.

225. Mr. Knamm also told Relator that he was sure he could get LIPITOR to replace Zocor by the end of the year on the JPS formulary. As Relator remembers, LIPITOR did replace Zocor as first-line therapy around the first of November 2002, after he had moved to Utah. Shortly thereafter, in about April of 2003, Eric Knamm was promoted to District Manager in Oklahoma City, Oklahoma.

Marketing the Upcoding for Office Visits for VIAGRA

226. Pfizer used its VIAGRA KOLs and other speakers to teach doctors how to "correctly code their charts," in other words, conduct their office visits so they could "upcode" those office visits for male *and* female patients. This message was part of Pfizer's Process of Care Model for marketing Viagra, which was supposed to answer what Pfizer called the physician's greatest question: "What's In It For Me?" By "upcoding", a doctor could realize reimbursement of about $40-$100 more for the office visit depending on whether the doctor was

a primary care doctor or a specialist and whether the upcoding was from a Level 2 or from a Level 3. This could be done regardless of whether the doctor had any real basis for believing the male patient had erectile dysfunction and despite the fact that use of Viagra in women was "off-label." Marketing the "upcoding" in these circumstances is similar to "marketing the spread" between a drug's price and its reimbursement as a incentive.

Purchasing Advertisements in Doctors' Favorite Journals

227. Pfizer also used paid advertisements in medical journals to garner influence. For example, at least two editions of the Baylor University Medical Center Proceedings contained both an advertisement for Pfizer *and* an article endorsing the effectiveness of VIAGRA. In about May or June of 2002, Relator who was then a new IHR, was making his routine calls on Baylor Medical Center ("the Flagship of the Baylor Healthcare System"), and made a call on Dr. William C. ("Bill") Roberts, an internal medicine specialist who was the editor-in-chief of the American Journal of Cardiology. Dr. Roberts took Relator into his office and showed Relator The Baylor University Medical Center Proceedings, Volume 13, number 4. It contained an advertisement for Pfizer (page 326) and on page 356, which had been *marked* with a flyer, there was an article on erectile dysfunction which endorsed the effectiveness of VIAGRA, one of Pfizer's "blockbusters." While Dr. Roberts did not tell Relator that advertising in The Baylor Proceedings would be rewarded with Pfizer-friendly articles, Relator understood this act to carry that message.

228. Dr. Roberts then asked Relator if Pfizer would be advertising again, and gave Relator a form letter explaining whom to contact and how to place an advertisement, along with the price sheet showing how much it would cost to have a full page, ½ page, or ¼ page

advertisement. The form letter was actually one that had been written to an executive of Burroughs-Welcome Company, listing Dr. Roberts' titles at the bottom of the letter. These titles impressed upon Relator how much influence Dr. Roberts wielded in the medical community. Relator told Dr. Roberts that he did not know if Pfizer would be advertising, but that Relator would talk to his Manager Dennis Gooch. Relator then presented his article to Dr. Roberts and left.

229. At the next opportunity Relator had, he asked his DM Dennis Gooch what to do. Gooch he said that he would take care of this with the local TACU. Gooch explained to Relator that Dr. Roberts was too important to Pfizer to let down (i.e. because of his status as editor of all material selected for inclusion in The American Journal of Cardiology).

230. On information and belief, Pfizer did take care of everything and continued to sponsor the advertisements. In return, Pfizer continued to receive articles published, which were favorable to VIAGRA.

Sampling

231. Management's directive to flood offices with samples meant not only keeping the sample closets full with Norvasc, Lipitor, Viagra, Zyrtec, Zithromax, Zoloft, Celebrex, etc.; it also meant that when the sample closet was filled to capacity, the reps would ask the nurses and the medical assistants which drawers they were not using and they would fill those drawers with samples. In addition, they would remove paper towels and ancillary items from cabinets over the counters and fill those with samples, so that there were samples in every vacant drawer, every partially used cabinet, and on every counter in each medical office.

232. The nurses, medical assistants and physicians are not allowed to throw samples away. Rather, FDA regulations require that if the samples expire they must be returned to the representatives (and in the case of Pfizer returned to Brooklyn for destruction). Most of the medical staff and nurses did not want to offend the Pfizer reps by returning the samples (i.e. they didn't want the nice lunches, dinners, breakfasts, ice cream socials and the like to slow down).

233. The result was that most patients who needed a blood pressure lowering agent got Norvasc, even if they got another agent too. Most patients who needed lower cholesterol got Lipitor, most who complained of depression, soft erections, or severe pain, got Zoloft, Viagra and Celebrex samples put aside for them before they even arrived at the office for their appointment.

234. Samples were replaced within one to two days, as there were never more than three days that went by that a doctor did not see a Lipitor, Norvasc, Viagra, Zithromax, Zyrtec, Zoloft, or Celebrex, etc. representative.

Preceptorships

235. Preceptorships were another important incentive. An illustrative example of the importance of preceptorship relationships is shown in Trenton Olson's "Good Example of a Weekly Report" which was circulated by Craig Smith, Relator's Regional Manager, to all of the Pfizer reps in the Southwest Region. It shows the kind of activities that were expected of all of the reps in his region. In this report, Olson, a newly promoted IHR servicing the University of Utah (after years as a veteran sales representative), states his understanding that:

> "the majority of our business will come from the MICU [a Medical Intensive Care Unit where infectious disease patients are separated out from the regular ICU patients in large

Medical Centers] with only a handful of doctors. For them it is important for me to live with them to increase sales [of ZITHROMAX IV]."

236. "Live with them" means paying them for preceptorships, bringing breakfast, lunch, dinner and midnight snacks, and making sure that the nurses and the medical staff are also given premium items and give-aways along with the meals. Olson continues:

"Still setting up preceptorships and will be setting up a date this week with the IHC microbiology lab at Primary Children's [Medical Center] with Dr. Daly who is over susceptibility testing for the system."

237. This preceptorship paid off for Trent Olsen and Pfizer: his report says that the "outcome was positive;" ZITHROMAX IV replaced Rocephin on the University of Utah formulary as the first line therapy. Congratulating Olsen on this success, the RM wrote him a note to "please accept ACE Points." He also suggested Olsen do a newsletter, by which he meant for Olsen to pay for the University of Utah to print and distribute a newsletter to all of its physicians and outlying medical facilities stating why ZITHROMAX IV was chosen over Rocephin. The University of Utah was very influential on this point, because of its Chief of Infectious Disease, Dr. Merle A. Sande. Pfizer then reproduced that newsletter and distributed it to its reps at the next POA for them to use with their accounts.

238. Olsen was promoted to be the Assistant to the Steere Southwest Regional Manager after only having been an IHR for four months; and then just two months later, he was promoted to be DM in Louisiana. Preceptorships are valuable for ownership of territory and earning tremendous credibility with other doctors who refer to that doctor. Pfizer referred to it as

"selling physicians and healthplans with "The Bandwagon' mentality," and it was a very successful strategy. The LIPITOR slides from the August 2003 mid-POA described above further illustrate the value or ROI from a preceptorship.

Grants, Visiting Professorships, Etc.

239. Pfizer also provided research grants, educational grants, monies for visiting professorships, and grants for mini-medical schools to doctors and institutions, including federal hospitals. Examples of some of these are contained in materials disclosed to the Government.

240. One example is that for at least three years, Pfizer gave the University of Texas Medical Branch ("UTMB") a $10,000 grant to run two-hour mini-medical school at UTMB. UTMB is the largest hospital with the largest patient load in n the U.S. They service a very large indigent population and most of the medical care is paid for by Medicaid and Medicare. Pfizer viewed its leadership and partnership with UTMB and the key opinion leaders as critical to Pfizer's continued success there.

Contests Utilizing Various Incentives

241. Pfizer ran various contests or competitions among its reps and regions to increase sales. Among two of these competitions was the "Cut the Sugar Bowl" designed to increase GLUCOTROL XL prescriptions, and for ZITHROMAX "The NZAA Road to the Final Four 'Hot Shot' Contest" also designed to increase prescriptions. These contests were carried out by all 650 reps and 75 IHRs in the Steere Division across the U.S.

242. Materials from these competitions are being provided to the Government; they provide a roadmap for how the reps are to use their selling tools learned at POA and otherwise. For example, the Cut the Sugar Bowl starts with identifying target doctors (who use competing drugs) and then lists how to employ detailing, preceptorships, lunches and/or other meals and snacks, dinner programs, education meetings, and telenets [pre-recorded CME programs that a doctor and rep call into together and discuss]. *The winners are determined by the largest percentage increase in GLUCOTOL XL prescriptions*. The winners earn ACE points.

243. The NZAA [National Zithromax Attitude Adjustment] contest was similar to the Cut the Sugar Bowl, but it had more activities to complete and more emphasis on free samples, preceptorships, and developing new speakers. The winner had to be a great rebounder (calls) and a great passer (assists=sample drops). Awards were based on activities, calls and sampling, with the Season MVP award going to "the player who creates the greatest market share percentage movement from a baseline…combined with the greatest percentage of quota change on the GAR (Zithromax only)".

b. Kickbacks/Other Illegal Incentives in the Utah/Rocky Mountain Region of Pfizer

244. In order to move to Utah, Relator went from working in the Steere Division to working in the Pratt Division as a rep (that position had recently opened up with the promotion of Corbett Carver to IHR in Salt Lake City). It was in this capacity that Carver gave Relator a copy of his Phase 6 presentation (discussed below) because Carver believed that it would help Relator familiarize himself with his new and Carver's former territory.

245. During Relator's employment in the Utah Pilot District and the Rocky Mountain Region, he encountered the same kinds of marketing techniques and incentives that he had seen

in Texas and the Southwest Region of Pfizer. He learned of various kinds of illegal incentives being provided to doctors in the Utah Pilot District and the Rocky Mountain Region to influence them to write prescriptions for Pfizer drugs instead of a competitor's drug, including, without limitation, trips, cash, speaker programs, meals, gifts, preceptorships, educational grants, and drug product samples. For example, he learned of the following illegal conduct by Pfizer sales representatives and the District Manager.

246. James L. Clark, M.D., is a family practice physician and is the only family practice physician who sits on the Pharmacy & Therapeutics ("P & T") committee for all of Intermountain Health Care ("IHC"). He was also the only physician from Pfizer's Provo Territory--all other members of IHC's P&T committee are in the Salt Lake and Ogden Territories. Dr. Clark was also the sole P&T voting physician from the Provo, Utah territory on the Formulary Committee for IHC. IHC is one of the nation's top integrated health systems. Integration means that doctors, hospitals, and health plans work together in a coordinated manner for the benefit of the patient. The IHC is the leading health plan in Utah with 250,000 employees and approximately two million patients.

247. Generally, if a drug is placed on a leading formulary, then the chances of that drug being placed on a government health insurance program formulary increase. More importantly, it greatly increases the rate at which doctors writing under that formulary/insurer (in this case IHC), will prescribe that drug not only for those patients, *but for all their patients*, including, e.g., those covered by Medicare and Medicaid. For example, once LIPITOR, ZYRTEC, ZITHROMAX and/or NORVASC are on the IHC formulary, the doctors who are prescribing for IHC patients are in the habit of writing the same drug for Medicare and Medicaid patients.

248. Because of Dr. Clark's value to Pfizer as a member of IHC's Formulary Committee, he received over the years from the Utah Pfizer sales force many gifts, including professional basketball tickets, fine dinners with his wife, and out-of-office activities. On information and belief, Dr. Clark voted for ZITHROMAX and ZYRTEC to be put on IHC's formulary in January (2002) and February (2002) respectively. Relator's colleague, Corbett Carver, was promoted from sales rep to IHR based at least in part on his success in courting Dr. Clark.

249. When Carver was still a Pfizer pharmaceutical sales representative, he outlined his success in courting Dr. James Clark with "dinner and a Jazz (basketball) game" in a Phase 6 presentation to his peers, his Regional Manager, and a visiting DM(s). A Phase 6 presentation is a presentation an employee makes after he finishes his 18 months of training; at that point his supervisor determines whether he should be promoted, stay where he is, or be fired. Carver's Regional Manager cited the presentation as an example of how to excel. Carver was promoted to IHR shortly after the presentation, making room for Relator to be hired as a sales rep. Moreover, his success was reported in the Publication of the Southwest Region of the Pratt Division entitled Stars Illustrated (August 2001 edition).

250. Carver's stated purpose for the Phase 6 Presentation is to provide his regional manager and "the phase 6 attendees with an excellent insight into the Utah Territory." He also states that a main purpose of his presentation is to "Identify the Players, Opportunities, and Business Plan to Achieve Success." According to the presentation, the Provo Utah Territory consists of "72,000 square miles, 29 Counties, 421 Doctors 15 Hospitals, and 47 Zip Codes." Among "The Players" of the Provo Utah Territory, are the following:

"Top Accounts	Pharmacy Benefits Manager	Patient Lives
Blue Cross/Blue Shield of Utah	*Contracts Directly with Pfizer*	565,000
IHC Health Plans	*Contracts Directly with Pfizer*	470,000
Altius	Express Scripts	150,000
Cigna	*National Contract with Pfizer*	60,000
United Health Care	Merck/ Medco	140,000

(emphasis added).

251. Under the "Greatest Challenge and the Greatest Opportunity, which the Provo Utah Territory faces in 2001", Carver lists he greatest challenge as being that "Lipitor is Not Preferred on the IHC Formulary" and he lists the greatest opportunity as the "Opportunity to Work With P&T (Committee) and Advocates." Under his heading "The Plan for Lipitor," Carver notes that he intends to "Work with Key Physicians and P&T Members to Obtain Formulary Status for Lipitor by 1st Quarter."

252. As Carver has been trained to do, he intends to "Target Top Clinics to do Chart Pulls" in order to see if there are missed opportunities for Lipitor prescriptions. In fact, he knows from the Pfizer reports he receives that, based on specific clinics and their patient populations, there are missed opportunities for Lipitor prescriptions. But doing chart pulls will show the physicians and their staff, without revealing the information Carver has access to, that there are *many other* potential candidates for Lipitor.

253. He also intends to "Target Dr. (James) Clark (P&T Member) and other influential doctors to show support for review on Lipitor Formulary." He has "Spent 4 Social Evenings with Dr. James Clark," the only IHC P&T Formulary Committee member he has any influence on because all other IHC P&T Formulary Committee members live in Salt Lake City and Ogden,

Utah. These evenings consisted of dinner and a Utah Jazz basketball game.

254. At another point in his presentation, under the Title "Customer Goal," Carver lists as "Goal #4" that he intends to "Increase Quality of Relationships with Pharmacy, and P&T Members." His strategy to meet this goal is to "Identify Key Members of P&T and Turn Them Into Advocates." He also states under line item # 3 that he will "Identify Key Members of Pharmacy and turn them into advocates," including to "Take Dr. James Clark out on 2 more Social Evenings (P&T)."

255. When Carver summarizes the most important aspects of his presentation, he again re-emphasizes that the "Keys to Success in 2001" are to:

> *"Identify Important Players" and to*
> *"Utilize opportunities to Influence the Players" Including, but not limited to:*
> *"Programs, Hospital Grand Rounds, Speaker Development" etc.*

In January 2003, Dr. Clark informed Relator that he was voting for ZITHROMAX and ZYRTEC to go on the IHC formulary. LIPITOR had not yet come up for P & T review in February 2003, which is the reason Pfizer reps were trying to use stock bottles and samples to "convert" the IHC physicians, including Dr. Clark.

256. After the HHS OIG Pharma Guidelines were published in April 2003, Dr. Clark became upset that these gifts stopped. Subsequently, at District Manager Scott Latimer's direction, sales representatives Bryan Osborn and John Dehaas gave free "stock bottles" of LIPITOR to Dr. Clark to offset the cost for patients to switch from Merck's Zocor to Pfizer's LIPITOR. This practice, known as "conversion" is directly contrary to the 2002 LIPITOR CIA. Because LIPITOR is more expensive on private formulary, i.e., IHC (where LIPITOR is listed as a "preferred" drug, but is down the list as a "third tier" drug), LIPITOR samples are given to the doctor to offset the lower cost of Zocor. In other words, with the free pills, the doctor doesn't

need to write such a large prescription; the patient's health plan will cover it, and the patient will pay a co-pay. Once the prescription writing habits of the doctor are "converted", his prescription habit will spill over into his other patients, e.g., including those on government health care programs. Plaintiff reported this misconduct to Pfizer on July 10, 2003 in Denver, Colorado.

257. Clark Staheli, M.D., headed a twelve physician practice that served as yet another example where stock bottle conversion was successfully instituted. Dr. Staheli was the senior partner with twelve other physicians in his medical office, which was a separate medical office in Southern Utah, in St. George. This office was the most influential internal medical and family practice clinic in Southern Utah, and Dr. Staheli was the head of this clinic. In April and May of 2003, as Pfizer was ramping up its off-label marketing strategy for LIPITOR discussed above, Dr. Staheli received four honoraria for $750.00 dollars each for the same talk, given on the same LIPITOR article, to the same doctors each time. Indeed, those physicians who practiced under him at his clinic in St. George were at 4 separate lunches in 7 weeks. The goal was to buy Dr. Staheli's influence where LIPITOR, VIAGRA, ZITHROMAX and ZYRTEC were concerned .

258. John Frischnickt, M.D., a cardiologist practicing through the Central Utah Medical Clinic ("CUMC") Cardiology Group in Provo, Utah, was another important physician customer. Dr. Frischnickt is the most influential cardiologist in all of Utah, known in the industry as a "Chief Influencer"; in other words, he establishes the standard of care for physicians treating cardiovascular disease, and whatever prescriptions he writes, just about every other doctor from Lehi South to St. George, Utah will follow in the treatment of their patients. In addition, a doctor such as Dr. Frischnickt is also influential in what drugs end up on a formulary: while he was not a voting member of the IHC Formulary Committee, his opinion

was very influential with the voting members. As with Dr. James Clark, Pfizer attempted to "convert" Dr. Frischnickt by giving him free "stock bottles" of LIPITOR so that he would replace his Zocor and Pravachol prescriptions with LIPITOR prescriptions. To successfully influence Dr. Frischnickt in this regard, is to effectively switch *many* Medicare/Medicaid patients throughout Utah from less expensive Zocor and Pravachol prescriptions to more expensive LIPITOR prescriptions. Dr. Frishnickt has a similar influence in the prescription of NORVASC and VIAGRA.

259. Similarly, another office within the same cardiology practice, that of Rodney Badger, M.D., was encouraged by Pfizer with free "stock bottle" samples of LIPITOR to switch their patients from Zocor and Pravachol to LIPITOR. This had the same successful effect with Dr. Badger's practice that it had with the practices of Dr. Clark and Dr. Frischnickt. In addition, Dr. Badger was shown the illegal price list referred to above for LIPITOR by Bryan Osborn and District Manager Scott Latimer, and the doctor apparently couldn't believe the price differential, i.e., how much cheaper LIPITOR *appeared to be* than competitor drugs. Sales representative Bryan Osborn took Dr. Badger and Brian Adams, a nurse practitioner in Dr. Badger's office, mountain biking in Moab, Utah in July 2003; this was a violation of Pharma Guidelines. Dr. Badger was also paid for two talks he was supposed to give in Price, Utah in June of 2003 at the Price Continuing Medical Education Conference. However, he did not give these talks because the person in charge of the symposium was a better friend of the Merck rep and she replaced Dr. Badger with the Merck speaker a few days before the conference. To avoid embarrassment with his manager and Dr. Badger, Brian Osborn paid Dr. Badger for the talks even though Dr. Badger never gave the talks at all.

260. In June-July 2003, DM Scott Latimer and Senior Sales Representative John

Dehaas (who like DM Latimer had been with Pfizer for over ten years), gave checks of $500 and $700 to Andrea LNU (last name unknown), the Office Manager, of the Urology Clinic of Utah Valley, in Provo, Utah, to keep VIAGRA prescriptions flowing out of the office. Andrea was the self-appointed gatekeeper and had indicated that, without payment, she would bar Pfizer reps from visiting the office. This office, headed by Stewart Landeau, M.D., was the top VIAGRA prescribing office in Pfizer's Provo Territory. As discussed below, Relator reported this to Pfizer on July 10, 2003 in Denver.

261. A fourth influential doctor/practice in the Utah District was Susan Maturlo, M.D., of Provo, Utah, the sole endocrinologist for Lehi South for all of Utah. Like Dr. Frischnickt, her value to Pfizer was as a "Chief Influencer" among her peers. Dr. Maturlo also benefited from the LIPITOR "conversion" process, receiving free stock bottles to off set the cost of LIPITOR. Dr. Maturlo exercised considerable influence over primary care physicians ("PCP"s) and when she sent a *diabetic* patient back to their PCP with a prescription for LIPITOR it sent a message to those doctors, i.e. that LIPITOR was appropriate in the diabetic population. Osborn used her as a speaker, and she pushed LIPITOR off-label (using the ASCOT and CARDS studies) during at least two programs at the Utah Valley Regional Medical Center in the spring and summer of 2003.

262. Yet another influential doctor in Utah was Dr. Robert Fowles, a cardiologist at Latter Day Saints (LDS) Hospital, IHC's flagship medical center. On information and belief, Dr. Fowles was a main voting member of the IHC P&T Committee since he was in the Salt Lake City territory which comprised almost all of the voting members of the IHC P&T Committee. The reps had been instructed by DM Latimer to have Dr. Fowles speak as much as his schedule would allow. Relator remembers, for example, one time when Dr. Fowles received $1,500.00 to

speak to only two nephrologists in Provo, Utah at a lunchtime program coordinated by Relator, at DM Latimer's direction. The subject of the program was the ALLHAT study, a blood pressure study involving NORVASC, which like the ASCOT study had more than 20,000 patients and was released in the early part of 2003.

263. Other very well paid speakers Relator is aware of from his time in Utah include: Dr. Jeffrey Fowler, a cardiology fellow from the University of Utah, who also received $1,500.00 per talk and spoke at a lunchtime program at Spanish Fork Medical clinic attended by some 10 doctors in that practice; the topic was the drugs NORVASC and LIPITOR and the ALLHAT and ASCOT studies. He talked about the value of treating hypertensive patients aggressively with NORVASC, and included LIPITOR with ASCOT. At DM Latimer's request, Relator had Dr. Fowler back a few weeks later to speak to the Pleasant Grove Medical Clinic (another office of about 10 physicians and 3 Nurse Practitioners) with the same ALLHAT and ASCOT presentation. DM Latimer was very focused on getting Dr. Fowler on board with Norvasc and Lipitor as he completed his Cardiology Fellowship at the University of Utah Medical Center and DM Latimer wanted to get as much mileage out of each honorarium as they could where Lipitor and Norvasc were concerned. During this time, ASCOT was *not* approved for detailing.

264. There were also "lunch 'n learn" programs at the American Fork Medical Clinic, including one at which Dr. Brian Whisenant, Chief of Cardiology at the University of Utah, spoke about NORVASC and LIPITOR, and ALLHAT and ASCOT for the same reasons stated above. Dr. Whisenant also charged $1,500.00 per talk.

265. On information and belief, "Journal Clubs" were also held throughout Salt Lake City, the Region, and throughout the country. The Clubs were intended to "develop" local

doctors and allow representatives to win over local doctors and gain their business and influence.

266. Scott Barton, M.D., was a physician at Dr. Staheli's practice in St. George. He was the top prescriber for VIAGRA of all *non*-urologist physicians in Utah. As such, he received several honoraria from Melissa Stratton, Rod Williard, Brian Osborn and Relator to speak to other physicians in the St. George area about how to ask patients about erectile dysfunction.

267. On information and belief, during this time, Pfizer was also providing "honoraria" and speaker fees to cardiologists at the Cleveland Clinic, the Mayo Clinic, and other renowned Cardiovascular Care Clinics to speak about NORVASC and LIPITOR On information and belief, some of these cardiologists were booked as speakers far in advance, often to do six or seven talks in a two-three day period, at about $2,500-$3,000 per talk, for a total of about $15,000-$20,000 in a less than one week period.

268. Pfizer did the same with Key Opinion Leaders and specialists in all different territories in the United States. On information and belief, one of these doctors was Dr. Steven Haffner in Texas referred to above. In July 2003 when he "tipped off" Pfizer about the Crestor release date and strategy, he was a cardiology professor of medicine at Baylor College of Medicine who was, in the words of Pfizer "one of our very important thought-leaders." As of the spring of 2004, Dr. Haffner became a professor of medicine at the University of Texas Health Science Center in San Antonio.

269. Yet another physician who spoke on this same type of circuit for Pfizer was Domick Carbone, M.D., a urologist from the Wake Forest School of Medicine. He received $7,500.00 for spending three days in any territory or group of territories to explain to physicians how to upcode their medical charts for maximum reimbursement from Medicaid, Medicare, and their separate insurance plans for VIAGRA.

270. As discussed under the "Off-label Marketing" section above, there was a concerted push to market LIPITOR aggressively at Pfizer's Mid POA meetings in August 2003. This strategy depended not only on off-label promotion as discussed above, but also on the sales force aggressively using incentives to keep doctors from switching patients to new competitors of LIPITOR and from starting new patients on one of these competitor drugs. The use of kickbacks and the detailing of off-label uses and information are intertwined in Pfizer's strategy.

271. The Pfizer Mid POA "Call to Action" included the goals of (a) increasing detailing and sample volumes with all physician types, (b) marketing the maximum and full dose range of LIPITOR (even though the lowest dosage, 10 mg, lowers cholesterol 39% and has the lowest side effects), (c) using increased samples to "create[d] comfort in prescribing higher doses", (d) taking back Pfizer's "leadership position" with specialists [i.e. cardiologists and endocrinologists] who influence local thought leaders and P&T Committee members, and (e) selling to specific patient types [i.e. off-label].

272. Key to the strategy were several speaker and training programs. At the Regional Speaker Training Programs, important specialists and Key Opinion leaders were paid to speak to other doctors and train them to be speakers when they returned to their local areas. There were to be two training programs per region with 60 speakers to be trained per meeting. The Program had already started in June/July 2003 with 8 Regional Programs and 340 speakers trained. The next scheduled ones were to begin in September 2003, with 8 Fall programs and a goal of 480 speakers trained. Speakers who were trained were then required to give one local "promotional" talk.

273. There was also a program in which KOLs would be used to educate cardiologists in local markets ("Winning With Specialists") and another program designed to increase Pfizer's

reps comfort level calling on cardiologists entitled "Meet The Expert Training Program." These programs and their full explanations are featured on page 10 of the Lipitor slides dated August 14, 2003.

274. Yet another program was the "Regional Medical Resources Advisory Programs" in which Pfizer's RMRs would hold two meetings per Region (in May/June 2003 and again in Sept/Oct. 2003), each with 20 "super" KOLs or National KOLs. These were critical because the RMRs focus on the top accounts within a given region, often a hospital or health care system, and the RMRs would try to influence the formulary decision of various P&T committees.

275. On information and belief, each of these programs and trainings included detailing and information about the recent clinical studies regarding LIPITOR and promoted off-label uses of LIPITOR.

276. Pfizer's emphasis on heavy sampling of all physician types is very important. Pfizer planned to track the effect of the sampling through a "Team Recognition Initiative to Accelerate Demand" ("TRIAD") report. Management wanted to determine the answer to this question: if each rep tripled his/her sampling count to each physician he/she calls on, would it eliminate the writing of prescriptions for Zocor, Zetia, Crestor and Vytorin? Additionally, management wanted to know if there were reps who are not significantly increasing the number of samples dropped off. If so, their manager needed to alter their behavior immediately.

277. The theory behind the heavy sampling was that doctors would just keep giving samples out instead of writing prescriptions for *any* statin. With this increase in sampling, one should see a short term marked decrease in all new prescriptions, but Pfizer would benefit in the long run because once the doctor needed to write a prescription or refill, he or she would most likely stick with LIPITOR rather than change the patient over to another statin. Moreover, as

alleged below, these samples would not be figured into discounts offered to Medicaid and other Government Healthcare Programs.

278. The heavy sampling strategy also fit into Pfizer's direct to consumer advertising in which Pfizer by at least 2005 was able to tout that "More Physicians Recommend Lipitor *for their own family members* than any other cholesterol lowering medicine."

279. As already noted, Pfizer's overall strategy of off-label marketing and kickbacks obviously paid off, as LIPITOR U.S. revenue increased from $7.6 billion in 2003, to $8.6 billion in 2004, to $9.2 billion in 2005, to $10.3 billion in 2006. This is tremendous growth, especially in the face of such stellar competitors as Crestor and Vytorin.

280. The August 2003 Mid POA also focused attention on Levitra and Cialis, the new competitors to VIAGRA. Levitra in particular had done well against VIAGRA in Europe where it was launched before it entered the U.S. market. Pfizer's "Call to Action" on VIAGRA included sales divisions "Using all available resources, [to] execute a full-frontal assault on your target list of key doctors to prevent switching!" They were to "Protect high writers of VIAGRA" from switching by identifying the target list of key doctors in their territory, planning to do high detail activity with these doctors during the Levitra launch, utilizing all their Pfizer resources with this critical customer group, including "district programs, lunch 'n learns, etc.", setting market share goals with these doctors, and "appropriately" sampling the doctors. All these steps were to be taken to prevent doctors *who were already* high writers of VIAGRA prescriptions from switching patients (or starting new patients) on a competitor drug like Levitra.

4. <u>Discouraging Generic Competition and/or Substitution of Cheaper Competitor Drugs</u>

281. To conserve program dollars, Medicaid requires adherence to generic preference rules. Pursuant to 42 CFR § 447.331(a), pharmacies must dispense generic drug products unless

a physician specifies that the brand name drug product is necessary for the health of the Medicaid recipient. Despite the generic preference rules under Medicaid, the "least costly alternative" provisions of certain laws and health programs, and the higher cost to Government Health Insurance Programs of branded vs. generic drugs, Pfizer encouraged its sales force to take steps that would ensure that a Pfizer drug such as GLUCOTROL XL, which had a generic competitor, would replace that generic competitor on a formulary. For example, as noted above, the JPS Grand Rounds Get-Away had the effect of GLUCOTROL XL replacing a generic drug on the JPS formulary.

282. In addition, despite these rules, Pfizer routinely trained, expected, and encouraged their sales force to ask doctors to sign on the "dispense as written" line of the prescription form rather than the "substitution permitted" line. This had the effect of undermining the generic preference, least costly alternative, etc. rules. All of the prescription pads that Relator ever saw in his time with Pfizer had two lines at the bottom, one with dispense as written, and one with substitution permitted. That "substitution permitted" line did not just refer to generic substitution, it also referred to and was used by pharmacists to switch from LIPITOR to Zocor, for example, if Zocor was preferred on a specific health plan at a lower tier/lower cost to Medicaid (i.e. tier 2) instead of LIPITOR which might be a tier 3 drug and cost more to Medicaid. In a case such as that, the patient and the health plan would pay a lower fee if the pharmacist switched the patient from LIPITOR to Zocor, or from NORVASC to Plendil, or from VIAGRA to Levitra or Cialis, or from ZITHROMAX to Biaxin, or from ZYRTEC to Allegra or Claritin, or from ZOLOFT to Prozac or Paxil.

283. Failure to substitute the least costly alternative adversely affects state Medicaid programs in at least two ways. First, if for example, California, Texas, Massachusetts or New

York Medicaid has a preferred drug on their formulary like Zocor, they will pay less money to Merck to acquire x number of Zocor pills than they will pay to Pfizer to acquire the same number of LIPITOR pills. However, that deal only exists with Merck as long as more than 60 percent of the statins written on that State's Medicaid Plan are Zocor. If LIPITOR overrides Zocor enough times and exceeds 40 percent of the prescriptions, then that State will not receive the same discount. In other words, the State will not only pay more for Lipitor initially, but if enough Lipitor prescriptions are written, the State will also be damaged because it will pay more for Zocor.

5. Marketing Maximum Dosages and Undermining Quality of Care

284. Pfizer's sales force was consistently instructed to sell the highest dosage of the drugs, including VIAGRA, ZOLOFT, and LIPITOR. On information and belief, this was done for several reasons: in the case of LIPITOR, to blunt competition from drugs that could lower cholesterol as effectively at lower doses as LIPITOR could at maximum dosage (see discussion above); and in the case of all the Drugs at issue in this case, to avoid "pill splitting." Craig Smith and Dennis Gooch tirelessly emphasized Pfizer's strategy to avoid pill splitting. Relator heard Smith propound the message at the launch of the Steere division and all subsequent Fort Worth POA's. Gooch, likewise, used the POA's and "ride alongs" to spread the word, commenting that this policy came from the Pfizer Vice Presidents. Maximum dosing increases the risk to patients of serious adverse side effects, the risks are even more acute in the many patients for whom the drug is being prescribed off-label.

285. The effect of "pill splitting" on Pfizer's profits is as follows. On information and belief, a pharmacist can and will recommend filling, e.g., a LIPITOR prescription for thirty 20

milligram pills with fifteen 40 milligram pills. This would save the patient and their health plan money: a one month's supply of the 20 milligram dose would change from $121.80 per month to half of the cost of the monthly 40 milligram dose [$132.40] because they would sell fifteen 40 mg pills for $66.20 and the customer would only have to pay $66.20 and then cut the 40 mg pills in half. Pharmacists suggest *and* expect this change of all of the milligram strengths of a drug *until* the maximum dose is reached. One of the major reasons Pfizer sold the maximum doses of LIPITOR, ZOLOFT and VIAGRA was to eliminate this pill cutting and consequent price reduction for the patients. By selling the maximum doses the sales force could achieve their quotas without having to sell twice as many pills.

286. But, maximum dosing across the board as a sales strategy raises serious quality of care issues, especially since side effects generally increase significantly with the increase in dose. Examples are provided below for several of the Drugs.

287. **VIAGRA.** With VIAGRA, all of the side effects listed in the package insert are from the fixed dose studies where 50 milligrams was the dose administered, yet Pfizer routinely promoted and sold a dosage of 100 mg Side effects listed with occurrence at 50 mgs. are Headache (16%), Flushing (10%) and Dyspepsia (7%), but other side effects listed under the "Cardiovascular" section are: Cardiac Arrest, Heart Failure, Sudden Cardiac Death, angina pectoris (chest pain), AV block, migraine, syncope, tachycardia (rapid heart beat), postural hypotension (blood pressure drops when lying on your back), and cerebral thrombosis (a blood clot hits the brain). Under the post marketing section it states again that sudden cardiac death, heart failure, and cerebral thromboses have increased since VIAGRA has been on the market.

288. **ZOLOFT**. Zoloft was marketed off-label for children and adolescents as discussed above, and regardless of whether the use was to be on label or off-label, Pfizer reps sold the higher and/or maximum dosages, e.g., 50 or 100 mg. Under the "System Bioavailability" section of the Zoloft package insert, it says that "there is an approximately two-fold accumulation, compared to a single dose of sertraline (Zoloft) with repeated dosing over a 50 to 100 mg dose range." In addition, doses build upon each other and almost one-half of one administered dose may be found in the urine nine days later.

289. As noted above, ZOLOFT is not indicated for major depression in children, but only for obsessive compulsive disorder, and in this capacity, the package insert lists the difference in child absorption rates of ZOLOFT vs. adult absorption rates. Under "Pediatric Pharmacokinetics," the package insert says that: "61 pediatric patients (29 children age 6-12 and 32 children age 13-17 years) were diagnosed with Obsessive Compulsive Disorder. Patients included both males and females. During 42 days of chronic (or daily) sertraline (ZOLOFT) dosing, sertraline was titrated up to 200 mg per day and maintained at that dose for a minimum of eleven days. On the final day, of sertraline 200 mg/day, the 6-12 year old group exhibited a mean sertraline AUC (area under the curve from 0 to 24 hours) of 3107 nanograms per hour per millileter. And a mean Cmax of 165 nanograms per millileter." (Cmax means the maximum tissue concentration). "By comparison, a group of 22 separately studied adults between 18 and 45 years of age (11 male and 11 female) received 30 days of 200 mg per day sertraline and exhibited a mean sertraline AUC [serum/blood concentration] (0-24 hrs) of 2570 nanograms per hour per milliliter and a mean Cmax" or maximum tissue concentration "of 142 nanograms per milliliter." This AUC is almost one-third less for the adults than for the children. This means that the children are effectively being given much higher doses than the adults. The package insert

concludes under this "Pediatric Pharmacokinetics" section that "lower doses may be advisable for pediatric patients given their lower body weights, especially in very young patients (6-12 years old), in order to avoid excessive plasma levels."

290. In other words, the FDA not only failed to approve using ZOLOFT to treat depression in children and adolescents, but, according to the package insert, if children are treated with ZOLOFT for OCD, *those doses need to be the smallest doses that can be administered and still achieve the desired effect.*

291. Nevertheless, as outline above, Pfizer's reps promoted and sold ZOLOFT at its maximum recommended dose of 100 mg per day for *children* to treat *depression.* Because these doses build on each other *daily* and the *adult male* body needs at least 9 days to clear almost one-half of the medicine in one dose, the impact of eliminating serotonin reception at this rate could effectively eliminate the body's ability to benefit from any "good feelings" which the hormone serotonin produces. ZOLOFT calms people down by eliminating the brain's ability to receive serotonin, but when that reception is eliminated altogether there can be "Suicide Tuesday" or extreme rage. This clearing may have to do with body weight, and children and adolescents are certainly more susceptible than adults.

292. **LIPITOR.** With LIPITOR, liver damage side effects increase with each dosage increase. The LIPITOR Package Insert under the "Warnings" section reads "LIPITOR has been associated with biochemical abnormalities of liver function. Persistent elevations (>3 times the Upper Limit of Normal [ULN] occurring on 2 or more occasions) in serum transaminases." In other words, liver damage has occurred as recognized by the medical community. "The incidence of these abnormalities was 0.2%, 0.2%, 0.6% and 2.3% for 10, 20, 40, and 80mg

[dosages], respectively." In other words, when you increase to 40 and 80 milligram doses, you increase the potential liver damage *tenfold* (0.2 % - 2.3%). As discussed above, Pfizer encouraged maximum [i.e. 80 mg.] dosing of LIPITOR, in part to compete with other cholesterol lowering drugs that were as (or more) effective at lower doses than LIPITOR.

293. Pfizer's practice of encouraging and selling drugs at the maximum dosages undermined patient safety and quality of care and resulted in higher reimbursements and profits for Pfizer.

6. Prescription Drug Pricing Fraud

294. Pfizer's illegal actions enumerated above, including kickbacks, off-label and other illegal promotions, and heavy sampling to doctors and other customers (including Pfizer's "conversion" strategy), are relevant to price calculations, reimbursements and rebates for LIPITOR, NORVASC, ZYRTEC, ZITHROMAX, GLUCOTROL XL, ZOLOFT and VIAGRA under Government Health Insurance Programs. Similarly, Pfizer's illegal sampling of these and other drugs including without limitation, CELEBREX, BEXTRA, ARICEPT, DIFLUCAN, VIRACEPT, RELPAX and DETROL LA, are relevant to price calculations, reimbursements and rebates for those drugs under Government Health Insurance Programs.

295. By its own admission, Pfizer was a leader in sampling, and its sales reps received multiple shipments of samples per year, including on drugs that were very well-known and well-established. Pfizer was also very successful at getting its drugs placed on formularies. For example, by the end of 2004, LIPITOR and NORVASC had achieved formulary success on "over 80% of the national formularies." Pfizer's failure to accurately report and fully account for these kickbacks, samples, etc., or *de facto* discounts, to the Department of Health and Human

Services, would cause these programs to pay higher prices for Pfizer's drugs than they should have paid.

296. In order to participate in the Medicaid Program and other Government Health Insurance Programs, pharmaceutical manufacturers such as Pfizer are generally required by law to charge the United States and the States the lowest price the manufacturer sells a covered outpatient drug to any purchaser in the United States. This could be, for example, the "best price" or the "average wholesale price" or the "average manufacturer's price." That lowest price is to be calculated taking into account cash discounts, free goods, volume discounts, coupons, goods in kind, free or reduced price services, grants, or other price concessions or similar benefits, and rebates; and kickbacks may be considered a form of cash discount or other pricing data. *See generally* 42 U.S.C. §1396r-8.1

297. Pfizer is undoubtedly aware of its obligations to accurately and completely report its pricing data including its "best price" and average manufacturer's price for its drugs. As noted above, in late 2002, Pfizer entered into a settlement with the government involving its failure to accurately report "best price" in a federal case in Texas involving LIPITOR. As a result, Pfizer entered into a CIA with the OIG HHS. On information and belief, at issue in that case, was Pfizer's failure to include unrestricted grants in its calculation of best price for LIPITOR. Concern over calculation of best price and Medicaid Rebates is also reflected in Pfizer's CIA (including Appendices) entered into with HHS OIG in May 2004 in connection with the Neurontin settlement discussed above.

298. Pfizer's knowledge of the scope of its price reporting obligations is further illustrated in Pfizer's own Rules and Regulations Field Guide under "Government Contracts and Price Reporting" at p. 11. There, Pfizer acknowledges that "prices [being reported] may be

required to reflect any price reductions, rebates, up-front payments, coupons, and/or goods in kind. In addition, free or reduced price services, price concessions or benefits offered *to induce a sale* are also considered pricing terms and must be taken into account when calculating prices to be reported to government agencies." (emphasis in original). In other parts of this Field Guide (and in the Mid-POA 2003 slides and other materials discussed above), Pfizer freely notes that sampling is considered a promotional activity, *see, e.g.*, pp. B2, B6, and sampling certainly appears to have been a "benefit offered to induce a sale."

299. Additionally, sampling is further acknowledged as a "benefit offered to induce a sale" on page 7 of the LIPITOR LOWDOWN dated January 1, 2003. The LIPITOR LOWDOWN is a LIPITOR in-house newspaper written and distributed under the direction of Dan Collier, Vice President of Sales for Pratt Pharmaceuticals, the Lead Division for Marketing Lipitor, and Walt Johnston, Director, U.S. Team Leader, LIPITOR Marketing Team. On page 7 under a graph which illustrates that samples have fallen compared to samples for Zocor from September 2001, to September 2002, it says: "Recent data show a decline in LIPITOR sample share, a trend we need to change. SAMPLES ARE ALSO A KEY DRIVER THAT INFLUENCE PHYSICIAN PRESCRIPTIONS" (emphasis added).

300. In Pfizer headquarter's materials used in their August 21, 2003 POA Training Meeting for the Sales Field Force, directives were given from the top of Pfizer concerning actually *increasing* drug sample volumes for LIPITOR and VIAGRA distributed to *all* physician types. Pfizer reps already had many more samples of all of their drugs than any of their competitors, and this POA directive would actually increase the already very large quantities of drug sample volumes being distributed to physicians, managed care facilities, etc. This included even drugs that are very well known and well established. Sampling was so important to sales

that Pfizer's Sherlock system tracked samples and the increase in prescriptions or "return on investment" from sampling.

301. Even prior to the August 2003 Mid-POA, Pfizer representatives had been directed by Pfizer management to flood physicians' offices and managed care facilities, etc. with stock bottles of LIPITOR and other drug samples as a means of influencing the prescription writing habits of specialists and physician offices with large patient populations. Pfizer had conducted such specific marketing research as to identify not only how to most effectively get access to physicians' drug sample closets, but how to get access to storage on the shelves at eye-level (because, all factors being relatively equal, physicians will give out what's found at eye-level first).

302. Reps (and IHRs etc) received six shipments per year of samples, or one about every two months. Once received, they kept the samples in a locker and did periodic inventories using multi-copy forms provided by Pfizer, and by doing daily or weekly sampling reports on their computers (for Sherlock—see above). A locker inventory with the DM present had to be done at least yearly or upon promotion or termination of employment. Typically, however, it was done monthly or quarterly. Pfizer headquarters received copies of the forms, and of the computer input. The multi-copy form had a white copy for Pfizer, a yellow copy for the doctor who received the sample(s), and a blue copy for the employee. The DMs did not receive sample shipments, but they had sample forms for inventorying a rep or IHRs samples; the DM's form had a fourth copy (colored pink). By law, the forms had to be kept on file by Pfizer for three years, and the employee had to keep his blue copies for three years. For each of Cluster A and Cluster X, there were 2 people per region whose job it was to keep track of the forms/samples.

a. <u>Sampling by Reps</u>

303. The importance and scope of the sampling expected by reps is illustrated by the approximate numbers and dollar values of the drug samples Relator had in his locker upon his termination from Pfizer in August 2003 *before* the POA. This count was done using a standard sample inventory sheet Pfizer reps used every quarter or month to report samples. It reflects only his samples of LIPITOR, VIAGRA and NORVASC, and does not include the other drugs, including ZYRTEC and ZITHROMAX, for which he (and other reps) would have had at least as many samples.

304. The following sets forth the various drugs from the sample inventory sheet according to the product number from the final count Relator and Pfizer did at Relator's locker/storage unit in August 2003 multiplied by the current (April 2007) cost of the drug to arrive at a total dollar value for the drug samples. The cheapest price per month supply of each product and milligram strength was used.

LIPITOR:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
3703	10 mg	25,592	$2.82 per pill	$72,169.44
3718	10 mg	9,000	$2.82 per pill	$25,380.00
3719	20 mg	34,104	$4.06 per pill	$138,462.24
3721	10 mg	37,440	$2.82 per pill	$105,580.80

LIPITOR continued:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
3722	20 mg	15,300	$4.06 per pill	$62,118.00
3724	80 mg	7,020	$4.07 per pill	$28,571.00
3726	40 mg	4,312	$4.41 per pill	$19,015.92

3727	80 mg	1,792	$4.07 per pill	$7,293.44

NORVASC:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
5803	5 mg	34,560	$2.03 per pill	$70,156.80
5818	2.5 mg	5,760	$2.18 per pill	$12,556.80
5816	10 mg	7,200	$2.59 per pill	$18,648.00
5814	5 mg	23,100	$2.03 per pill	$46,893.00
5828	10 mg	23,856	$2.59 per pill	$61,787.04

VIAGRA:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
4049	50 mg	5,856	$12.79 per pill	$74,371.20

305. The number of samples Relator had in August 2003 are representative of the samples sales reps around the country would have had then (as noted, sampling even increased after the late August POA). Like other Cluster X reps, Mr. Collins received 6 shipments per year of samples (January, March, May, July, September, and November). In Cluster X, there were 5 reps per primary territory in 600 territories or about 3,000 reps like Relator. (In addition, there were IHRs, specialty reps, etc.—the samples they had are described below). The following calculation shows the approximate total value of samples the 3,000 reps would have had *just for* LIPITOR, NORVASC and VIAGRA.

LIPITOR: Relator's Total Dollar Values above added together = $458,590.84.

$458,590.84 x 5 reps = $2,292,954.24 x 6 shipments/year = $13,757,725.00

$13,757,725.00 x 600 territories = **$8,254,635,000** of LIPITOR samples/year.

NORVASC: Relator's Total Dollar Values above added together = $210,041.64

$210,041.64 x 5 reps = $1,050,208.20 x 6 shipments/year = $6,301,249.20

$6,301,249.20 x 600 territories = **$3,780,749,500** of NORVASC samples/year.

VIAGRA: Relator's Total Dollar Values above added together = $74,371.20

$74,371.20 x 5 reps = $371,856.00 x 6 shipments/year = $2,231,136.00

$2,231,136.00 x 600 territories = **$1,338,681,600** of VIAGRA samples/year.

306. As staggering as these numbers are, they actually *understate* the number and retail dollar value of total samples because: they do not include the institutional and specialty reps with all of their samples (i.e. some 375 IHRs who typically had fewer samples than reps, and some 400 specialty reps who typically had as many samples as the sales reps—see below); and the illustration is only for *three* drugs when in fact reps throughout Cluster X *and* Cluster A had large numbers of samples for virtually all of the drugs sold, including those that were well-established and well-accepted.

307. Because Cluster X and Cluster A reps often sold side by side, Relator is aware of heavy sampling of CELEBREX, ZOLOFT, BEXTRA, ARICEPT, DIFLUCAN, RELPAX and DETROL LA by Cluster A reps. For example, their sampling of CELEBREX and ZOLOFT was *higher* than Relator's with LIPITOR.

b. <u>Sampling by IHRs</u>

308. The scope of sampling by IHRs, while less than that of reps, was still high. The following illustrates the number and (current) dollar value of the drug samples Relator had as an IHR in Texas. The following lists the various drugs from the sample inventory sheet according to the product number from the final count relator and District Manager Dennis Gooch

conducted at Relator's storage unit in Fort Worth, Texas on September, 25, 2002; Relator was an IHR at this time, and this IHR sample count is indicative of an IHR's sample count. (This IHR count was taken approximately one year before the sample count conducted with Relator's DM Scott Latimer and Pfizer's Lou Bertram when Relator was terminated).

309. As already noted, IHRs receive far *fewer* samples than the reps. The reason for this is because, except for a few outpatient clinics, the institutions that IHRs call on don't receive or use samples. While one way reps are evaluated is by how many doctors or practitioners they sample per week, per month, per quarter and per year, the way an IHR is evaluated is by how many of his or her drugs each institution has on their formulary and if the faculty and staff are convinced of the efficacy and safety of the drug to the point that they recommend it to the community. While a Pfizer representative samples between 50 and 60 physicians per week, an IHR samples 12 to 15 physicians per week.

310. Relator sampled some 20 outpatient clinics in Texas as an IHR. The numbers of samples he had are enormous compared to the numbers of samples he knew his competing Hospital Representatives from e.g., Merck (Zocor), BMS (Pravachol), Abbott (Biaxin), GlaxoSmithKline (Augmentin), Eli Lilly (Ceftin), Ortho-MacNiel (Levoquin), or Bayer (Cipro) or Roche (Rocephin), or where Norvasc was concerned Plendil, the Ace Inhibitors, or the ARB's. As a rule, Pfizer had *many* more samples for their IHR's than the competitors which was consistent with Pfizer's strategy to "flood the market with samples."

311. The following illustrates the number and current (April 2007) dollar value of the drug samples Relator had as an IHR in Texas in late September 2002:

LIPITOR:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
3703	10 mg	23,744	$2.82 per pill	$66,958.08
3718	10 mg	18,000	$2.82 per pill	$50,760.00
3719	20 mg	8,512	$4.06 per pill	$34,558.72
3721	10 mg	14,760	$2.82 per pill	$41,623.20
3722	20 mg	6,840	$4.06 per pill	$27,770.40
3723	40 mg	6,060	$4.41 per pill	$24,603.60
3724	80 mg	5,550	$4.07 per pill	$22,588.50
3726	40 mg	3,136	$4.41 per pill	$13,829.76

NORVASC:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
5803	5 mg	40,470	$2.03 per pill	$82,154.10
5817	5 mg	24,624	$2.18 per pill	$53,680.32
5816	10 mg	17,700	$2.59 per pill	$45,843.00

VIAGRA:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
4049	50 mg	5,184	$12.79 per pill	$65,836.80

ZITHROMAX:

Product code	Milligram	# of pills	Price Per Pill	Total Dollar Value
6458	500 mg	216	$20.83 per pill	$ 4,499.28

6430	1000 mg	36	$71.97 per dose	$ 2,590.92
6434	600 mg	192	$34.48 per box	$ 6,620.16
6435	250 mg	2,112	$10.41 per pill	$21,985.92
6437	250 mg	432	$10.41 per pill	$ 4,497.12
6470	500 mg	200	$36.22 per vial	$14,856.00
6439	600 mg	192	$46.84 per pill	$ 8,993.28

312. These numbers can be extrapolated (as was done above with reps) to give an estimate of how many samples are shipped and given away by Pfizer Cluster X IHRs per year. If one adds all of the dollar values above together, then multiplies that by 375 IHRs and then multiplies that product by 6 shipments per year, the resulting calculation is as follows:

LIPITOR: Total Dollar Values above added together = $282,692.26

$282,692 x 375 IHRs = $106,009,597.50

$106,009,597.50 x 6 shipments per year = **$ 636,057,585**

worth of LIPITOR Samples Per Year for the Cluster X IHRs.

NORVASC: Total Dollar Values added together = $181,677.42

$181,677.42 x 375 IHRs = $68,129,032.50

$68,129,032.50 x 6 shipments per year = **$ 408,774,195**

worth of NORVASC Samples Per Year for the Cluster X IHRs.

VIAGRA: Total Dollar Values above added together = $65,836.80

$65,836.80 x 375 IHRs = $24,688,800.00

$24,688,800.00 x 6 shipments per year = **$ 148,132,800** worth of VIAGRA Samples Per Year for the Cluster X IHRs.

ZITHROMAX: Total Dollar Values above added together = $64,042.68

$64,042.68 x 375 IHRs = $24,016,005.00

$24,016,005.00 x 6 shipments per year = **$ 144,096,030** worth of ZITHROMAX Samples Per Year for the Cluster X IHRs.

Reps and others working Cluster A drugs also distributed large numbers of samples. Relator estimates that their sample shipments were at least as large as his.

c. Sampling by Specialty Reps

313. In addition to some 3,000 sales reps and some 375 IHRs, Pfizer at all relevant times also had about 200 Endocrinology/Urology healthcare territories and 200 Cardiovascular healthcare territories, for a total of about another 400 reps. The specialty reps called on specialists in their field which often included the key opinion leaders or thought leaders who were the first line of attack in getting a drug accepted and prescribed. The specialty reps sampled at the same rate as the field force reps, i.e. had more samples than the IHRs. The CHRs and EHRs would typically sell and sample NORVASC, LIPITOR and VIAGRA, in addition to other drugs.

d. Damage to Government Health Care Programs

314. For purposes of these illustrations, the samples are valued at recent retail prices, however, each pill costs Pfizer *far less* to manufacture. In other words, Pfizer can give away such staggering numbers of samples because they are in fact giving away pennies in return for lucrative long term prescriptions at full price every month. Even these "pennies" add up to significant damage to Government Health Care Programs if these samples are not reported as discounts or otherwise part of "best price" to Medicaid and the other Government Health Care Programs. Those programs are being cheated because they are not receiving the, e.g., best price actually being received by Scott & White Health Plans or IHC Health Plans.

315. One example illustrate how the liberal use of free samples of just one drug, LIPITOR, can affect a "discount" or benefit to a customer. Pfizer would typically sell the drug to a Health Maintenance Organization ("HMO") or private insurance group such as IHC referred to above, at a discount the entity had negotiated with Pfizer because the entity is a gross purchaser of the drug (and having put the drug on its formulary). For example, it may have negotiated a price of $4.00 for a pill usually selling at $8.00. If, in addition, the entity were to receive 9,000 free samples for every 3,000 pills it paid for at the already discounted price, the price per pill drops *below* $4.00 (i.e. they paid $12,000 not for just 3,000 pills but in effect for 12,000 pills so the price per pill is *greatly reduced, to $1.00/pill*). However, if that additional discount is not reported to the Government Healthcare Programs, or not otherwise also offered to them, those programs are damaged and Pfizer has violated the law.

316. Even if the discount amounts to only 10 cents per pill for LIPITOR, the total discount would be in the tens of millions of dollars (e.g. some one billion LIPITOR pills were sold in the U.S. in 2004).

J. Relator's Internal Complaints and Pfizer's Cover-Up of Its Illegal Activity

317. On May 28, 2003, at the POA meeting in Denver, Relator and the rest of the sales force were given training similar to what the RMs and DMs were given at their May 12-16, 2003 meeting regarding various legal issues. In particular, oral training was given, and manuals and written materials were distributed. Pfizer's legal department had issued new training for all US employees in response to several legal battles in which the Company had been embroiled regarding illegal drug marketing practices, the Sarbanes-Oxley Act, sexual harassment and wrongful termination, etc. Accordingly, the POA training meeting held that day by District Manager, Scott Latimer, spent a great deal of time going over Pfizer's "Open Door" Policy, the

letters sent in August 2002 and January 2003 from Pfizer Chief Executive Officer ("CEO"), Hank McKinnell, and General Counsel, Jeff Kindler, regarding each employee's obligation to report inappropriate or unlawful conduct immediately to the company, procedures to follow in reporting, and the new testing that would begin immediately to ensure each employee's knowledge of the company's policies regarding "open door" reporting, etc.

318. After the POA Meeting, Relator became increasingly concerned that his complaint to his DM on May 9, 2003 was being ignored, and that his co-workers were using illegal price lists and unapproved articles with the complicity of the DM and perhaps others. Mindful of the Pfizer Health Care Compliance Program and communications from Pfizer corporate, including the Chief Executive Officer and the Chief Compliance Officer and General Counsel, beginning in August 2002, Relator reluctantly concluded he was obligated to report his concerns to Pfizer Corporate Compliance through an "open door complaint". In a telephone call to that office in New York, New York on June 2, 2003, Relator lodged a complaint with the operator regarding the May 9, 2003 LAT meeting, the May 27-29, 2003 POA meeting, and other information. The operator indicated that he would prepare a report that would go to Pfizer's Corporate Compliance Office which would then decide about a response or taking any action. He gave Relator a report number to document the call.

319. Around this time, the Pfizer CEO and General Counsel/Compliance Officer/Director, issued yet another letter to all employees (and received by Relator) directing them to report any wrongdoing they witnessed within the Company and began a series of training for exams to take place in the Fall (of 2003) on all Company compliance guidelines and procedures.

320. On June 5, 2003, Relator called Pfizer Corporate Compliance again to see if his

earlier message was received by anyone other than the service representative, and to find out what to expect on timing as he was leaving on vacation in a few days. He was told that they would get back to him when they acted on the report but that it likely wouldn't be for a few more days. On June 20th a call came from Tonya Jaeger, followed by an e-mail, in which she proposed a conference call to take place on the 24th of June 2003. Relator responded affirmatively and the call took place on the morning of June 24th.

321. On the June 24 call, Respondent spoke with two attorneys, Tonya Jaeger and Robert Ladd, of corporate compliance, in a conference call joined in by Rocky Mountain Region Human Resources ("HR") Manager, Julie Jennings. Jaeger explained that compliance routinely involved HR whenever dealing with a "hotline" call. Jaeger immediately suggested a face-to-face meeting on July 10, 2003 and then invited Relator to repeat what he had said on his earlier hotline call of June 5th. Relator repeated substantially all the allegations in this complaint: the questionable detailing of ASCOT and other unapproved articles on ZYRTEC; the Wal-Mart Price List; and Latimer's voicemail directing field staff to "clean up their books" before the May 22-23 POA in Denver. Jaeger and Jennings were silent through most of the call, but expressed particular interest in those complaints which involved a fraud on Pfizer, for example the falsification of gas receipts and Bryan Osborne's practice of expensing his second home, as well as the Wal-Mart price list.

322. Tonja Jaeger asked Relator to send her the price lists at issue, the unapproved clinical article, and tape cassette of the May 23, 2003 voicemail from DM Latimer to the sales force about cleaning up their detail books before the Denver POA. Near the end of the conversation, Relator was told that the two attorneys and Ms. Jennings would meet with him on July 10, 2003 in Denver in an "off-site" location. By USPS Overnight Mail on June 30, 2003,

Relator sent attorney Jaeger the materials she has requested, keeping copies for himself.

323. On July 10, 2003, Relator flew to Denver for the pre-arranged meeting at the Marriott Hotel. While waiting in the lobby about two and one-half hours before the meeting time, Relator saw his DM Scott Latimer (who appeared not to notice Relator). To his surprise, shortly thereafter, the DM was greeted by Regional HR Manager Julie Jennings who escorted him from the lobby. Over two hours passed before she returned for the Relator and he was escorted to a room in which they met with Tonya Jaeger, Assistant Corporate Counsel, Pfizer, Inc. Legal Division. During the ensuing 1 hour, 45 minute meeting, Relator realized they were not interested in investigating his complaints, but rather were looking for grounds to harass, silence and terminate him. Rather than further investigating his report of the illegal conduct of his co-workers, or having any interest in the information Plaintiff/Relator disclosed what he had learned in just the last two weeks about kickbacks and bribes that were going on in his District in order to get more Pfizer prescriptions written and even placed on formulary with the major insurers in Utah. Jaeger was there only to confiscate the documents and evidence Relator had for reporting the illegal conduct and, it seemed, to build a case *against* Relator. Ironically, Relator again met his DM at the Denver airport, waiting to take the same plane home that night. DM Latimer told Relator that HR Manager Jennings had told him a week earlier (on July 3) "not to bother riding with Blair anymore". Since part of a DM's job is to do monthly "field- rides" or "ride alongs" with each district member, to travel their territory, meet with the doctors the members are calling on and evaluate district members' performance, this news clearly signaled to Relator that the Company intended to terminate him, constructively or formally.

324. Later that evening (around 10:17 p.m.), after returning from Denver, DM Latimer sent an email to his Utah district sales force labeled "High Importance". The Subject was

"Unapproved Clinicals & Materials". The e-mail read:

> "Team, I wanted to review Pfizer's policy on unapproved materials and clinicals from promotional purposes with each of you. The following are the policies regarding the use of unapproved materials. It is extremely important that your review these policies and adhere to each of them. Any violation of these policies will result in disciplinary action. If you currently have any unapproved materials in your possession (altered visual aid pages, comparative price lists, unapproved clinicals, etc) it is important that you destroy them. We will continue to stay informed with information from recent published clinicals as we have in the past, although it is extremely important that you not discuss the unapproved information with physicians. Please read the information below and reply to this email that you have read and understand these policies that we recently reviewed during our Healthcare Compliance training. You also can refer to this information in the Healthcare Law Compliance Orange Guide… ." (emphasis added).

Attached were what he said was Pfizer's policy on the subject. This email was received by Relator who responded that he had read and understood the policies.

325. The next day, July 11, 2003, Relator learned from co-worker Bryan Osborn that DM Latimer had called him that morning and told him that he and representative John Dehaas could no longer put expenses on their second homes through on their Pfizer expense accounts by disguising them as hotel receipts/expenses. (This was also an issue Relator complained to Pfizer Corporate Compliance about). DM Latimer told Osborn that it "looks fishy to Pfizer".

326. That afternoon, DM Latimer sent a voicemail to his group, this time telling them that they had to change how they do so-called "Journal Clubs". These were talks at which a doctor could be paid $500-$750 for presenting an article at an office meeting. He told them they could no longer pay a doctor money for presenting an article because that would not qualify as a medical education program. He told them it needed to be "legitimate" medical education. This voicemail was received by Relator.

327. That same night, July 11, 2003, NBC's Dateline aired a story on the civil and criminal investigation of corrupt and illegal drug marketing practices used by Warner-Lambert's Parke-Davis division in the mid to late '90s—a division that was absorbed into Pfizer in 2000.

With this take-over, Pfizer's Pratt Division, the division in which Relator worked in Utah, became the lead division for selling LIPITOR.. The story was about the Neurontin case (another False Claims Act *qui tam* case brought by a former employee, David Franklin) mentioned above. According to the Dateline transcript,

> ". . . the Justice Department said that Franklin's [the Relator's] case 'has presented evidence of an illegal off-label marketing scheme that is rife with false statements and fraudulent conduct all of which had one intended purpose and result, increasing sales'...Three years ago, Pfizer bought Warner-Lambert and Parke-Davis, so now the biggest drug company in the world is the defendant in one of the highest-profile cases in the history of the industry. Pfizer officials would not speak on camera but did provide this statement: 'the events to which you referred are alleged to have occurred well before, in some cases years before, Pfizer acquired Warner-Lambert. Pfizer completed the acquisition of Warner-Lambert in June 2000. It is long-standing policy that Pfizer has not and does not promote its products outside their FDA-approved labeling. We are unable to comment further because of the pending litigation....'" (emphasis added).

328. In other words, despite what Pfizer then knew from Relator Collins about Pfizer's illegal conduct, Pfizer officials specifically denied, to prosecutors, to reporters, and to the public, that Pfizer illegally markets its drugs. Rather, like the press releases issued after the 2002 LIPITOR settlement, and to be issued in May 2004 after the Neurontin case settled, Pfizer represented that the illegal conduct was limited to Warner-Lambert before it was acquired by Pfizer.

329. As detailed further below, from May 9-August 20, 2003, Pfizer harassed, intimidated, threatened, and ultimately fired Relator. They did this despite his stellar performance and his following the Company compliance program, and without putting him on any probationary plan or giving him a termination letter with grounds for his dismissal, all contrary to Pfizer's written policies, their 2002 CIA, and the False Claims Act.

330. On August 21, 2003, the very next day after Relator's termination, DM Latimer ordered his sales group to resume using articles specifically labeled "do not detail". These illegal

detail pieces were to be used for the next several weeks at least, until his district was restructured. When questioned by one of the members (not Relator) about this, DM Latimer made it clear he "didn't want to hear about it," he just wanted them "to do it."

331. The next day, August 22, 2003, the federal district court in Boston, Massachusetts denied Pfizer's motion for summary judgment in the Neurontin civil case. That case, and the related criminal investigation, had been the subject of the NBC Dateline story. In May 2004, Pfizer resolved that case and the related criminal investigation as described above.

332. Pfizer's treatment of Relator's open door complaint mirrors many other examples Relator is aware of where Pfizer did nothing to resolve the issue reported, no action was taken against the person(s) in violation of law or policies, each report was made to "vanish", and the reporter of the wrong-doing was retaliated against, all contrary to Pfizer's 2002 CIA, its Corporate Compliance Program, and the HHS OIG Pharma Guidelines.

333. Relator has served a Disclosure Statement (and supplemental disclosures) upon the government. These Statements and documents provide additional information and evidence concerning the Defendant's conduct and Relator's basis of knowledge.

K. Pfizer's Unlawful Retaliation Against Plaintiff/Relator

334. Before complaining to his DM on May 9, 2003, Relator had a stellar record with Pfizer, rising through the ranks, excelling as a sales representative, and earning sizeable bonuses and positive recommendations as recently as January-late April 2003. Immediately after complaining, he was retaliated against, threatened, harassed and finally fired without cause. In addition to the allegations above, the particulars of the retaliation include the following.

335. On May 21, 2003, in the lobby of the Marriott Courtyard in Sandy, Utah, DM Latimer loudly and falsely accused Relator of dishonesty and poor work performance in the

presence and within "ear-shot" of his fellow district members. He told Relator he was going to launch an FDA investigation of Relator. Prior to May 9, 2003, DM Latimer had nothing but high praise for Relator.

336. From June 30, 2003 on (just shortly after his conversation with corporate compliance and HR), Relator was beset with complaints from his superiors critical of his work performance and his observation of routine paperwork and the submission of expense reports.

337. In an email to the entire district on July 18, 2003, the day Pfizer had told Relator in the July 10 meeting they would let him know about his future with Pfizer, DM Latimer falsely ranked Relator as having the fewest calls on doctors of anyone in the District in the first six months of the year. In fact, Relator had had 1265 visits, but was listed at about 700 visits. The two representatives who were falsely listed as ranking first and second were Messrs. Osborn and Dehaas about whom Relator had complained. Osborn and Dehaas as a result won a trip for themselves and their wives each to Park City, Utah (valued at roughly $675).

338. That evening, July 18, 2003, HR Manager Jennings called Relator to tell him that no decision had been made yet regarding his continuing employment at Pfizer, that the "investigation" was ongoing, and they were hoping to take care of it sooner rather than later.

339. On July 21, 2003, DM Latimer called Relator and angrily told him that he needed Relator's travel and expense reports turned in immediately. Pfizer had asked him to do this at the July 10 meeting, and he believed he had submitted them electronically on July 12, 2003. As was discovered later, due to a computer glitch, the reports had not transmitted properly.

340. Pfizer's harassment and misconduct caused Relator to seek medical attention on July 25, 2003. He remained under a doctor's care and treatment for several weeks and on doctor's orders did not go to work. He instead took vacation and applied for leave under the

Family and Medical Leave Act. He kept his managers and the appropriate HR personnel at Pfizer informed of his situation and followed Pfizer policy. While Corporate HR in New York had approved medical leave, HR Manager Jennings and other Pfizer managers made repeated and numerous harassing phone calls to Relator's home and sent him letters threatening that if he did not return to work, they would consider him to have abandoned his employment and his job with Pfizer would be terminated. This letter was copied to District Manager Scott Latimer, Regional Manager, Randy Looper, and to Vice President of Sales, Larry Smith, and was also copied to all regional managers and vice presidents.

341. On August 15, 2003 HR Manager Jennings sent Relator a second letter by Federal Express, demanding that Relator meet with his DM on August 20, 2003, a drive of some sixty miles (see description below). This letter was also copied to *all* regional managers and vice presidents. Unbeknownst to Relator when he received this letter, there was also an August 18, 2003, letter in which HR *New York approved* Relator's extension of short-term disability and FMLA which retroactively effectively cleared him from returning to work until only August 3, 2003. This letter/approval packet was copied *electronically* to HR Manager Jennings in Denver, so she knew his status, but it was *post* mailed to Relator who did not receive it until *after* he returned home August 20, from what turned out to be his termination meeting with his DM some sixty miles away. The letter from HR NY *also* declared that Relator could not return back to work until his physician cleared him to do so and that Jenny Mark, R.N. would aid Relator and his physician, if need be, with any additional paper work while the FMLA approved leave continued. It was further explained that when the additional paperwork was received, this leave would continue for up to three months with Relator receiving 80% percent of his salary and if he needed additional time off beyond that, as determined by his physician, he would be reimbursed

at 50 percent of his salary for up to an additional 3 months. Relator met with his physician on the 21st of August only to terminate care (because he would no longer have health insurance). The physician recorded in his notes, which were sent to Nurse Mark, that in his medical opinion the stress Relator was feeling was due to his supervisor, Scott Latimer

342. Despite his condition, and his doctor's advice not to drive, Relator traveled the sixty miles to the August 20, 2003 meeting because the Federal Express letter he had received made it clear that if he did not attend this meeting with his District Manager, Scott Latimer, his employment would be terminated. When Relator arrived at the hotel room, in addition to his DM, however, he met HR Manager Julie Jennings, and a non-employee represented by Julie Jennings and Scott Latimer as "Lou from Corporate." During a very lengthy meeting, Relator was fired, even though he had complied with every demand made of him by Pfizer, its legal Corporate Compliance Division, its management and its Human Resource representatives. The termination was explained to him as follows:

> "... *we've actually looked at this not only from local HR, but myself, the HR director, from, uh, attorneys in Corporate Compliance, Tonya Jaeger one of them, for, uh, sales attorney T.R. Kelly with Pfizer um, both Regional Managers, not only has Randy Looper been involved, but also Mike Kraft has been involved who is the Pratt Regional Manager. Both Vice Presidents of Pratt and Labs, Dan Collier and um, Larry Smith and Christy Kinsley in New York* have all looked at the documentation, uh, from really about January on. Um, with it pulled all together obviously by the investigation that Tonya Jaeger and I did, and also from the claims that you brought up as well as Pfizer wants to make sure that we're looking at, at things from every angle. And I think Tonya did a very good job of explaining some of the things she had, had found out in terms of, um, your call to Compliance, and thoroughly investigated those, as would be reckless for her not to do before making a decision, *and it has been the decision, unanimously, of everyone up the chain that at this time we've lost faith in your ability to uphold the value which is most important and that's integrity.*" (emphasis added)

343. Relator was stunned by this news. Pfizer then took numerous immediate steps to obtain any documents and records Relator had, as well as the numerous drug samples in his

locker/storage unit, as discussed in the Sampling section above. When Relator asked for a copy of his personnel file, along with the letters of recommendation it contained, he was told that it had been lost. Relator never received his file, being told later that they couldn't find it. Relator asked to have the grounds for his termination put in writing for him; they refused, telling him that the only reason they could think he would make that request, would be to pursue some sort of legal action. They then threatened him with what would happen if he did so.

344. On August 21, 2003, Relator received a letter dated August 20 from Carol Crane in HR:

> "Dear Mr. Collins, The following is an explanation of the arrangements that have been established with respect to your separation from Pfizer.
> The effective date of your termination will be August 21, 2003. The impact of your termination upon your benefits is set forth in the attached Benefits Summary. If your address had recently changed, please notify HRconnect."

345. On August 20-21, 2003, Relator's family home was called several more times by Pfizer managers between 8:00 p.m. and midnight, and again early the next morning despite the fact that they had already fired him.

346. Ironically, on August 22, 2003, despite Plaintiff's termination two days earlier, the financial department sent him a bonus check for $4,900+ for his continuing great work at Pfizer. He received the check on August 25, 2003.

347. Despite Utah Law requiring the payment of all wages being due within twenty-four hours of employee's termination, Plaintiff's final paycheck did not come until September, and when it came it omitted payment for employee's last five days of work. This check for $1,002.75 was not received until June 2004 after it was pursued on plaintiff's behalf by the Utah Labor Commission via the standard Wage Claim Form. The equivalent of four days' wages ($820.44) was finally sent from Pfizer on July 27th, 2004 and received on July 29th. Curiously,

when Pfizer finally sent it to him, they also sent him an additional $4,030.29 even though he hadn't worked for Pfizer for eleven months.

348. Pfizer was similarly lax in paying American Express for Relator's travel and expense account. Consequently, on September 12, 2003, Plaintiff/Relator's family received several hostile phone calls from American Express over the Travel and Expense Account that Pfizer still hadn't paid three weeks after Relator's termination.

349. In September 2003, Plaintiff also received a periodic notice of requirement to verify the "when, where, and with whom" of randomly selected drug samples and their related starter activity reports (FDA Pedigree tracking forms) subject to the periodic audit being conducted. Plaintiff was also notified that failure to comply or provide adequate verification could lead to an FDA investigation and potentially criminal proceedings. He received this despite the fact that when he was terminated, Pfizer managers insisted on confiscating plaintiff's Pedigree tracking forms and told plaintiff that he would no longer be required to account for samples. Fortunately, Plaintiff was able to fill in the required information because his wife had independently made copies of some of his pedigree forms before turning originals over to Pfizer at their insistence at the termination meeting on August 20, 2003.

350. In October 2003, Plaintiff received a $200 set of knives to celebrate his "fifth year with Pfizer." In December 2003, he received a "skill saw" (and a form regarding its value for tax purposes).

351. Because Pfizer refused to give Relator a termination letter with grounds, he had great difficulty obtaining unemployment compensation. Finally, in November 2003, the Department of Workforce Services granted plaintiff/relator six months' of "unemployment compensation."

352. Since being terminated, Relator has unsuccessfully attempted to find a job in the drug industry. He has suffered great financial loss as well as emotional distress and other damage.

VII. CLAIMS FOR RELIEF

353. The Federal FCA, 31 U.S.C. § 3729(a), makes certain actions a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999). Unlawful actions include: "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment; "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government; conspiring to defraud the United States by getting a false or fraudulent claim allowed or paid; and "knowingly" making, using or causing to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government.

354. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

355. The Federal FCA, 31 U.S.C. § 3729(b), defines "knowing" or "knowingly" to mean that a person, with respect to relevant information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (c) acts

in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

356. As outlined in the Counts below, several states have passed similar False Claims Act legislation, which in most instances closely tracks the Federal FCA. In this case, these State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of these State statutes contains *qui tam* provisions which, like the Federal FCA, govern, *inter alia*, a relator's right to claim a share of the State's recovery.

357. Other relevant laws, as discussed in the earlier portions of this Complaint, include the Federal Food, Drug and Cosmetic Act, and the federal Medicare Medicaid Anti-Kickback Act and its State counterparts. Violation of one of these laws may form the basis for a violation of the federal and/or state FCAs. Pfizer's actions and omissions, including without limitation, its use of illegal price lists, unapproved articles and other promotional pieces, and the paying of kickbacks, have caused physicians to prescribe and administer such drugs to their patients over competitor's drugs, have caused Pfizer's drugs to be listed on formularies over competitor's drugs, have caused physicians to prescribe its drugs for unapproved "off-label" uses and at dosages that are unnecessary and affect quality of care, and have caused Government Health Care Programs as a result to receive and pay false or fraudulent bills submitted to such programs, and to pay higher prices and/or receive lower rebates for such drugs. Moreover, Pfizer has violated the terms of a Corporate Integrity Agreement entered into with the United States Department of Health and Human Services Office of Inspector General; such violations may form the basis for liability under the federal and State FCAs.

COUNT ONE

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(a)(1), (2), and (7)

358. Relator restates and realleges the allegations contained in Paragraphs 1-357 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

359. The Defendant knowingly presented or caused to be presented false or fraudulent claims to Government Health Care Programs and knowingly made, used or caused to be made or used, false statements to get said claims paid by Government Health Care Programs. The Drugs' prescriptions for off-label purposes would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. Moreover, The Drugs' prescriptions resulting from illegal detailing would not have been presented but for the illegal detailing through price lists, unapproved clinicals and the like. As a result of these illegal schemes, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)-(2).

360. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive, in violation of 31 U.S.C. § 3729(a)(1)-(2). The Drugs prescriptions for off-label purposes cost more than comparative drugs with the same or superior efficacy.

361. In particular, these claims were also false or fraudulent and statements and records were false because the cost of The Drugs was inflated due to the Defendant having to cover its illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

362. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Government Health Care Program and it is also illegal to falsely report the

true cost of a drug. In addition to violating 31 U.S.C. § 3729(a)(1)-(2), Defendant's conduct violated 31 U.S.C. § 3729(a)(7).

COUNT TWO

CONSPIRACY TO DEFRAUD: FEDERAL FCA, 31 U.S.C. § 3729(a)(3)

363. Relator restates and realleges the allegations contained in Paragraphs 1-362 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

364. Defendant knowingly conspired to defraud the United States causing increased sales of The Drugs through unlawful promotion in violation of law. Defendant conspired to violate the AKA by unlawfully offering incentives to physicians or other customers who were in a position to prescribe The Drugs and who were often times also in a position of authority to cause others to prescribe The Drugs including through formularies. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

365. Defendant knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Government Health Care Programs. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives which caused the prescriptions of The Drugs to be made. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendant. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

366. The Defendant knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of The Drugs. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to

any Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

COUNT THREE

VIOLATIONS OF THE ANTI-KICKBACK ACT ("AKA")

367. Relator restates and realleges the allegations contained in Paragraphs 1-366 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

368. The Defendant has offered and paid unlawful incentives or kickbacks in violation of the AKA. In order to sell its drugs, Defendant authorized and directed its employees and agents to offer and award unlawful incentives. These expenditures were made to doctors to influence the doctors to write prescriptions for The Drugs.

369. The goal of the AKA in these circumstances is to prevent the prescription of a drug based not on whether or not it is necessary and appropriate, but on whether it is financially beneficial to the doctor prescribing the drug. Because of the Defendant's illegal actions, The Drugs have in fact been prescribed in violation of the AKA and the FCA.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(1)

370. Relator restates and realleges the allegations contained in Paragraphs 1-369 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

371. The California False Claims Act, Cal. Gov't Code § 12651(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
> (1) Knowingly presents or causes to be presented to an officer or employee of the state . . a false claim for payment or approval.

372. Defendant knowingly presented or caused to be presented to the California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Cal. Gov't Code § 12651(a)(1).

373. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT FIVE

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(2)

374. Relator restates and realleges the allegations contained in Paragraphs 1-373 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

375. The California False Claims Act, Cal. Gov't Code § 12651(a)(2), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state... for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . . .

376. Defendant knowingly made, used and/or caused to be made or used false records and statements to get false and fraudulent claims paid and approved by the California Medicaid program, in violation of Cal. Gov't Code § 12651(a)(2).

377. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT SIX

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(3)

378. Relator restates and realleges the allegations contained in Paragraphs 1-377 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

379. The California False Claims Act, Cal. Gov't Code § 12651(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
> (3) Conspires to defraud the state . . . by getting a false claim allowed or paid by the state . .

380. Defendant conspired to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov't Code § 12651(a)(3).

381. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT SEVEN

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(7)

382. Relator restates and realleges the allegations contained in Paragraphs 1-381 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

383. The California False Claims Act, Cal. Gov't Code § 12651(a)(7), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state . . . .

384. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Cal. Gov't Code § 12651(a)(7).

385. The State of California paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in California, because of these acts by the Defendant.

COUNT EIGHT

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(1)

386. Relator restates and realleges the allegations contained in Paragraphs 1-385 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

387. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), specifically provides, in part, that any person who:

> (a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

388. Defendant knowingly presented or caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

389. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT NINE

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(2)

390. Relator restates and realleges the allegations contained in Paragraphs 1-389 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

391. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), specifically provides, in part, that any person who:

> (a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

392. Defendant knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the State of Delaware, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

393. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT TEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(3)

394. Relator restates and realleges the allegations contained in Paragraphs 1-393 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

395. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §

1201(a)(3), specifically provides, in part, that any person who:

> (a)(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

396. Defendant conspired to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

397. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT ELEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(7)

398. Relator restates and realleges the allegations contained in Paragraphs 1-397 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

399. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(7), specifically provides, in part, that any person who:

> (a)(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

400. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay

the correct rebate amounts to Medicaid, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

401. The State of Delaware paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Delaware, because of these acts by the Defendant.

COUNT TWELVE

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(1)

402. Relator restates and realleges the allegations contained in Paragraphs 1-401 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

403. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

151. Defendant knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of D.C. Code § 2-308.14(a)(1).

404. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT THIRTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(2)

405. Relator restates and realleges the allegations contained in Paragraphs 1-404 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

406. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

407. Defendant knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

408. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT FOURTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(3)

409. Relator restates and realleges the allegations contained in Paragraphs 1-408 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

410. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
> (3) Conspires to defraud the District by getting a false claim allowed or paid by the District;

411. Defendant conspired to defraud the District of Columbia by getting false and fraudulent claims allowed and paid, in violation of D.C. Code § 2-308.14(a)(3).

412. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT FIFTEEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(7)

413. Relator restates and realleges the allegations contained in Paragraphs 1-412 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

414. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
> (7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government;

415. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of D.C. Code § 2-308.14(a)(7).

416. The District of Columbia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in the District of Columbia, because of these acts by the Defendant.

COUNT SIXTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(a)

417. Relator restates and realleges the allegations contained in Paragraphs 1-416 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

418. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a), specifically provides, in part, that any person who:

> (a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval; …is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

419. Defendant knowingly presented or caused to be presented to the Florida Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Fla. Stat. § 68.082(2)(a).

420. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the Defendant.

COUNT SEVENTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 60.082(2)(b)

421. Relator restates and realleges the allegations contained in Paragraphs 1-420 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

422. The Florida False Claims Act, Fla. Stat. § 68.082(2)(b), specifically provides, in part, that any person who:

> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to

> get a false or fraudulent claim paid or approved by an agency; …
> is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

423. Defendant knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Florida, in violation of Fla. Stat. § 68.082(2)(b).

424. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the Defendant.

COUNT EIGHTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(c)

425. Relator restates and realleges the allegations contained in Paragraphs 1-424 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

426. The Florida False Claims Act, Fla. Stat. § 68.082(2)(c), specifically provides, in part, that any person who:

> (c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

427. Defendant conspired to submit a false claim to Government Health Care Programs and to deceive Federal/Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Fla. Stat. § 680.82(2)(c).

428. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the

Defendant.

COUNT NINETEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(g)

429. Relator restates and realleges the allegations contained in Paragraphs 1-428 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

430. The Florida False Claims Act, Fla. Stat. § 68.082(2)(g), specifically provides, in part, that any person who:

> (g) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

431. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Fla. Stat. § 680.82(2)(g).

432. The State of Florida paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Florida, because of these acts by the Defendant.

COUNT TWENTY

VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

Article 7B, Chapter 4, Title 49 of the Official Code of Georgia Annotated

433. Relator restates and realleges the allegations contained in Paragraphs 1-432 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

434. The Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq*., specifically provides, in part at 49-4-168.1, that:

> (a) Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
> (4) Has possession, custody, or control of property or money used, or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt…or
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia,
> shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

435. Defendant knowingly presented or caused to be presented to the Georgia Medicaid program false and fraudulent claims for payment and approval, made, used or caused to be used false statements to get such claims allowed, and conspired to defraud the government through such statements and claims which failed to disclose the material violations of the AKA and other laws, all in violation of Ga. Code Ann., 49-4-168.1(a)(1)-(3). Defendant knowingly made, used or caused to be made or used a false record or

statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Ga. Code Ann., 49-4-168.1(a)(1)-(4) and (7).

436. The State of Georgia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Georgia, because of these acts by the Defendant.

COUNT TWENTY-ONE

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(1)

437. Relator restates and realleges the allegations contained in Paragraphs 1-436 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

438. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1), specifically provides, in part, that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
> . . .
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

439. Defendant knowingly presented or caused to be presented to the Hawaii Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Haw. Rev. Stat. § 661-21(a)(1).

440. The State of Hawaii paid said claims and has sustained damages, to the extent of

its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT TWENTY-TWO

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(2)

441. Relator restates and realleges the allegations contained in Paragraphs 1-440 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

442. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(2), specifically provides, in part, that any person who:

> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> . . .
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

443. Defendant knowingly made, used and caused to be made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

444. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT TWENTY-THREE

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(3)

445. Relator restates and realleges the allegations contained in Paragraphs 1-444 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

446. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(3), specifically provides, in part, that any person who:

> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
> . . .
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

447. Defendant conspired to defraud the State of Hawaii by getting false and fraudulent claims allowed and paid, in violation of Haw. Rev. Stat. § 661-21(a)(3).

448. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT TWENTY-FOUR

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(7)

449. Relator restates and realleges the allegations contained in Paragraphs 1-448 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

450. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(7), specifically provides, in part, that any person who:

> (3) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

451. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Haw. Rev. Stat. § 661-21(a)(7).

452. The State of Hawaii paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Hawaii, because of these acts by the Defendant.

COUNT TWENTY-FIVE

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWERREWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3 (a)(1)

453. Relator restates and realleges the allegations contained in Paragraphs 1-452 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

454. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

455. Defendant knowingly caused to be presented to the Illinois Medicaid program

false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

456. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY-SIX

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(2)

457. Relator restates and realleges the allegations contained in Paragraphs 1-456 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

458. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> . . .
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

459. Defendant knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

460. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY-SEVEN

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(3)

461. Relator restates and realleges the allegations contained in Paragraphs 1-460 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

462. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(3), specifically provides, in part, that any person who:

> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;
> . . .
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

463. Defendant conspired to defraud the State of Illinois by getting false and fraudulent claims allowed and paid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(3).

464. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY-EIGHT

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(7)

465. Relator restates and realleges the allegations contained in Paragraphs 1-464 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

466. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §

175/3(a)(7), specifically provides, in part, that any person who:

> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State . . .
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

467. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(7).

468. The State of Illinois paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Illinois, because of these acts by the Defendant.

COUNT TWENTY-NINE

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5

469. Relator restates and realleges the allegations contained in Paragraphs 1- 468 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

470. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount of damages that the state sustains because of the act of that person [including]:

(1) presents a false claim to the state for payment or approval;
(2) makes or uses a false record or statement to obtain payment or approval of a false claims from the state;…
(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
(7) conspires with another person to perform an act described above; or
(8) causes or induces another person to perform an act described above.

471. Defendant knowingly violated these provisions of law by presenting or causing to be presented to the Indiana Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired to defraud the state Medicaid program, and caused others to violate the Indiana Act, all in violation of IC 5-11-5.5-2.

472. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendant.

COUNT THIRTY

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3A

473. Relator restates and realleges the allegations contained in Paragraphs 1-472 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

474. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law ("Louisiana FCA"), 46 La. Rev. Stat. c. 3 § 438.3A, specifically provides, in part, that: "No person shall knowingly present or cause to be presented a false or fraudulent claim".

475. Defendant knowingly presented or caused to be presented to the Louisiana

Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 46 La. Rev. Stat. c. 3 § 438.3A.

476. The State of Louisiana paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Louisiana, because of these acts by the Defendant.

COUNT THIRTY-ONE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3B

477. Relator restates and realleges the allegations contained in Paragraphs 1-476 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

478. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3B, specifically provides, in part, that:

> No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

479. Defendant knowingly engaged in misrepresentation and made, used and caused to be made and used, false records and statements to obtain or attempt to obtain payment from or get false and fraudulent claims paid and approved by the State of Illinois, in violation of 46 La. Rev. Stat. c. 3 § 438.3B.

480. The State of Louisiana paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Louisiana, because of these acts by the Defendant.

COUNT THIRTY-TWO

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3C

481. Relator restates and realleges the allegations contained in Paragraphs 1-480 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

482. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3C, specifically provides, in part, that:

> No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

483. Defendant conspired to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid, in violation of 46 La. Rev. Stat. c. 3 § 438.3C.

484. The State of Louisiana paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Louisiana, because of these acts by the Defendant.

COUNT THIRTY-THREE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.2A(1)

485. Relator restates and realleges the allegations contained in Paragraphs 1-484 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

486. Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.2A(1), specifically provides that:

> No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or … payments, directly or indirectly, overtly or covertly, in

cash or in kind, for the following . ..
(1) In return for referring an individual to a health care provider, ...for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

487. In addition, the Louisiana FCA, supra, section 438.3 provides that:

"No person shall knowingly present of cause to be presented a false or fraudulent claim...shall knowingly engage in misrepresentation to obtain, or attempt to obtain payment from medical assistance program funds...shall conspire to defraud, or attempt to defraud, the medical assistance programs... ."

488. Furthermore, the Louisiana FCA, supra, section 438.4 provides that:

"No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement on any form used for the purpose of certifying or qualifying any person for eligibility ... to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive."

489. Defendant solicited, received, offered and/or paid remuneration, including but not limited to kickbacks, bribes, and gifts, directly or indirectly, overtly or covertly, in cash or in kind, in return for prescribing or arranging the prescribing of drugs which are paid for by the Louisiana Medicaid program, in violation of 46 La. Rev. Stat. c. 3 § 438.2A(1).

490. The State of Louisiana paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Louisiana, because of these acts by the Defendant.

COUNT THIRTY-FOUR

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(1)

491. Relator restates and realleges the allegations contained in Paragraphs 1- 490 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

492. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> . . .
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

493. Defendant knowingly presented or caused to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Mass. Gen. Laws Ch. 12, § 5B(1).

494. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT THIRTY-FIVE

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(2)

495. Relator restates and realleges the allegations contained in Paragraphs 1-494 above as if each were stated herein in their entirety and said allegations are incorporated herein by

reference.

496. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;
> . . .
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

497. Defendant knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of claim by the Commonwealth of Massachusetts, in violation of Mass. Gen. Laws Ch. 12, § 5B(2).

498. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT THIRTY-SIX

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(3)

499. Relator restates and realleges the allegations contained in Paragraphs 1-498 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

500. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(3), specifically provides, in part, that any person who:

> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> . . .
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less

> than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

501. Defendant conspired to defraud the Commonwealth of Massachusetts through the allowance and payment of fraudulent claims in violation of Mass. Gen. Laws Ch. 12, § 5B(3).

502. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT THIRTY-SEVEN

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(8)

503. Relator restates and realleges the allegations contained in Paragraphs 1-502 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

504. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(8), specifically provides, in part, that any person who:

> (8) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth;
> . . .
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

505. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Mass. Gen. Laws Ch. 12, § 5B(8).

506. The Commonwealth of Massachusetts paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Massachusetts, because of these acts by the Defendant.

COUNT THIRTY-EIGHT

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT, MI ST Ch. 400

507. Relator restates and realleges the allegations contained in Paragraphs 1-506 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

508. The Michigan Medicaid False Claims Act, MI ST Ch. 400, provides, *inter alia*: as follows:

(1) In section 400.603, that "A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits… [or] for use in determining rights to a Medicaid benefit." It further provides that "A person, having knowledge of the occurrence of an event affecting …[the] initial or continued right of any other person on whose behalf he has applied…shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled."

(2) In section 400.606, that "A person shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim… ."

(3) In section 400.607, that "A person shall not make or present or cause to be made or presented to an employee or officer [of the state] a claim…upon or against the state, knowing the claim to be false… ." and that " A person shall not make or present or cause to be

made or presented a claim …which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary … ."

(4) In section 400.604, that a person is prohibited from soliciting, offering, making or receiving a kickback or bribe or rebate of any kind.

509. Under section 400.612, "A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the state a civil penalty equal to the full amount received plus triple the amount of damages suffered by the state as a result of the conduct by the person".

510. Defendant knowingly violated these provisions of law by presenting or causing to be presented to the Michigan Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of the Michigan FCA, and thereby caused damage to the State of Michigan.

COUNT THIRTY-NINE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(a)

511. Relator restates and realleges the allegations contained in Paragraphs 1-510 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

512. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(a), specifically provides, in part, that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to

> the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
> (a) Knowingly presents or causes to be presented a false claim for payment or approval.

513. Defendant knowingly presented or caused to be presented to the Nevada Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Nev. Rev. Stat. § 357.040(1)(a).

514. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT FORTY

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(b)

515. Relator restates and realleges the allegations contained in Paragraphs 1-514 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

516. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(b), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
> . . .
> (b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.

517. Defendant knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of false claims, in violation of Nev. Rev. Stat. §

357.040(1)(b).

518. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT FORTY-ONE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(c)

519. Relator restates and realleges the allegations contained in Paragraphs 1-518 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

520. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(c), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
> . . .
> (c) Conspires to defraud by obtaining allowance or payment of a false claim.

521. Defendant conspired to defraud the State of Nevada by obtaining allowance and payment of false claims, in violation of Nev. Rev. Stat. 357.040(1)(c).

522. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT FORTY-TWO

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(g)

523. Relator restates and realleges the allegations contained in Paragraphs 1-522 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

524. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(g), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
> . . .
> (g) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state....

525. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Nev. Rev. Stat. 357.040(1)(g).

526. The State of Nevada paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Nevada, because of these acts by the Defendant.

COUNT FORTY-THREE

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b *et seq.*

527. Relator restates and realleges the allegations contained in Paragraphs 1- 526

above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

528. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq.* (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty and three times the amount of damages that the state sustains because of the act if that person:

> (a) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent claim;
>
> (b) makes, uses or causes to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> (c) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]
>
> (e) makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…."

529. Defendant knowingly violated these provisions of law by presenting or causing to be presented to the New Hampshire Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of N.H. RSA § 167:61-b I. (a)-(c) and (e).

530. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendant.

COUNT FORTY-FOUR

VIOLATIONS OF THE NEW MEXICO FCA N.M. LEGIS 49 (2004) CHAPTER 49

531. Relator restates and realleges the allegations contained in Paragraphs 1- 530 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

532. The New Mexico Medicaid False Claims Act, N.M. Legis 49 (2004) Chapter 4, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

> 4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claims is false or fraudulent claim;
> 4B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;
> 4C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> 4D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]
> 4E. makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…."

533. Defendant knowingly violated these provisions of law by presenting or causing to be presented to the New Mexico Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws; it knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid; and it conspired to defraud the state Medicaid program,

all in violation of N.M. Legis 49 (2004) Chapter 4A-E.

534. The State of New Mexico paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in New Mexico, because of these acts by the Defendant.

COUNT FORTY-FIVE

VIOLATIONS OF THE NEW YORK STATE FCA: 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII, §189

535. Relator restates and realleges the allegations contained in Paragraphs 1 - 534 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

The New York FCA, provides in relevant part as follows:

§ 189. Liability for certain acts. 1. Subject to the provisions of subdivision two of this section, any person who:
(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;
(c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid;
(d) has possession, custody, or control of property or money used, or to be used, by the state or a local government and, intending to defraud the state or a local government or willfully to conceal the property or money, delivers, or causes to be delivered, less property or money than the amount for which the person receives a certificate or receipt;
(e) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state or a local government and, intending to defraud the state or a local government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
(f) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a local government knowing that the officer or employee lawfully may not sell or pledge the property; or
(g) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay

> or transmit money or property to the state or a local government; shall be liable: (i) to the state for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person… .

536. Defendant knowingly violated these provisions of law by presenting or causing to be presented to the New York Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws; it knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, and it conspired to defraud the state Medicaid program. The Defendant knowingly presented or caused to be presented false or fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Programs.

537. Defendant knowingly conspired to defraud the State of New York causing increased sales of the Drugs through unlawful promotion in violation of law. Defendant conspired to violate the AKA and the FCA by unlawfully offering incentives to physicians that were in a position of authority to cause other physicians to prescribe the Drugs.

538. Defendant knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives which caused the prescriptions of the Drugs to be made. Said claims were also monetarily excessive in cost due to the illegal kickbacks and

unlawful promotional activities of the Defendant. Said actions constitute violations of Art. XIII, Section 189,

539. The Defendant knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of the Drugs. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of Art XIII, Section 189.

COUNT FORTY-SIX

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(A)

540. Relator restates and realleges the allegations contained in Paragraphs 1-539 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

541. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A), specifically provides, in part, that any person who:

> (A) Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> . . .
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

542. Defendant knowingly presented or caused to be presented to the Tennessee Medicaid program claims for payment under the Medicaid program knowing such claims were false and fraudulent, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

543. The State of Tennessee paid said claims and has sustained damages, to the extent

of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT FORTY-SEVEN

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(B)

544. Relator restates and realleges the allegations contained in Paragraphs 1-543 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

545. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B), specifically provides, in part, that any person who:

> (B) Makes, uses, or causes to made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> . . .
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

546. Defendant made, used and caused to be made and used, records and statements to get false and fraudulent claims under the Medicaid program paid and approved by the State of Tennessee knowing such records and statements were false, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

547. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT FORTY-EIGHT

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(C)

548. Relator restates and realleges the allegations contained in Paragraphs 1-547 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

549. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(C), specifically provides, in part, that any person who:

> (C) Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;
> . . .
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

550. Defendant conspired to defraud the State of Tennessee by getting claims allowed and paid under the Medicaid program knowing such claims were false and fraudulent, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(C).

551. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT FORTY-NINE

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(D)

552. Relator restates and realleges the allegations contained in Paragraphs 1-551 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

553. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-

182(a)(1)(D), specifically provides, in part, that any person who:

> (D) Makes, uses, or causes to be made or sued, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program knowing such record or statement is false;
> . . .
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

554. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

555. The State of Tennessee paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Tennessee, because of these acts by the Defendant.

COUNT FIFTY

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(1)-(2)

556. Relator restates and realleges the allegations contained in Paragraphs 1-555 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

557. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1), specifically provides, in part, that a person commits an unlawful act if the person:

> (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
> (A) on an application for a contract, benefit, or payment under the Medicaid program; or
> (B) that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program.

558. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §

36.001(2)(B), specifically provides, in part, that a person commits an unlawful act if the person:

> (2) knowingly or intentionally conceals or fails to disclose an event: (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized… ."

559. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid program, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tex. Hum. Res. Code § 36.002 (1)-(2).

560. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT FIFTY-ONE

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(4)(B)

561. Relator restates and realleges the allegations contained in Paragraphs 1-560 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

562. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B), specifically provides, in part, that a person commits an unlawful act if the person:

> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
> . . .
> (B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

563. Defendant by knowingly and intentionally causing to be made, inducing, and seeking to induce the making of false statements and misrepresentations of material facts concerning information required to be provided by state and federal law, rule, regulation and

provider agreements pertaining to the Medicaid program, are in violation of Tex. Hum. Res. Code § 36.002(4)(B).

564. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT FIFTY-TWO

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(5)

565. Relator restates and realleges the allegations contained in Paragraphs 1-564 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

566. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(5), specifically provides, in part, that a person commits an unlawful act if the person:

> (5) except as authorized under the Medicaid program, knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program . . . .

567. Defendant knowingly and intentionally paid and received kickbacks, gifts, money, or other consideration as a condition of service to a Medicaid recipient, in violation of Tex. Hum. Res. Code §.36.002(5).

568. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT FIFTY-THREE

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(9)

569. Relator restates and realleges the allegations contained in Paragraphs 1-568 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

570. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(9), specifically provides, in part, that a person commits an unlawful act if the person:

> (8) knowingly or intentionally enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program . . . .

571. Defendant knowingly and intentionally conspired to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code §.36.002(9).

572. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendant.

COUNT FIFTY-FOUR

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(1)

573. Relator restates and realleges the allegations contained in Paragraphs 1-572 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

574. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1), specifically provides, in part, that any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
> . . .
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

575. Defendant knowingly presented or caused to be presented, to the Virginia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

576. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

COUNT FIFTY-FIVE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(2)

577. Relator restates and realleges the allegations contained in Paragraphs 1-576 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

578. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2), specifically provides, in part, that any person who:

> 2. Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
> . . .
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

579. Defendant knowingly made, used and caused to made and used, false records and statements to get false and fraudulent claims paid and approved by the Commonwealth of

Virginia, in violation of Va. Code Ann. §.8.01-216.3(A)(2).

580. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

COUNT FIFTY-SIX

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(3)

581. Relator restates and realleges the allegations contained in Paragraphs 1-580 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

582. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(3), specifically provides, in part, that any person who:

> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;
> . . .
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

583. Defendant conspired to defraud the Commonwealth of Virginia by getting false and fraudulent claims allowed and paid, in violation of Va. Code Ann.§ 8.01-216.3(A)(3).

584. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

COUNT FIFTY-SEVEN

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(7)

585. Relator restates and realleges the allegations contained in Paragraphs 1-584 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

586. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(7), specifically provides, in part, that any person who:

> 3. knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth;
> . . .
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

587. Defendant knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, including without limitation, by failing to alert the state government or to pay the correct rebate amounts to Medicaid, in violation of Va. Code Ann.§ 8.01-216.3(A)(7).

588. The Commonwealth of Virginia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Virginia, because of these acts by the Defendant.

COUNT FIFTY-EIGHT

False Claims Act Violation by Defendant: Retaliation Against Plaintiff/Relator

(31 U.S.C. section 3730(h))

589. Plaintiff/Relator restates and realleges the allegations contained in Paragraphs 1-588 above as if each were stated herein in their entirety and said allegations are incorporated

herein by reference.

590. PFIZER discharged, threatened, harassed and otherwise discriminated against Plaintiff/Relator Collins because of his lawful acts involving a potential violation(s) of the False Claims Act by his then employer, PFIZER. By these actions PFIZER violated the False Claims Act, 31 U.S.C. section 3730(h).

591. Plaintiff/Relator has been damaged as a direct result of these illegal actions. He has suffered great economic harm, loss of income, and emotional injury.

VIII. PRAYERS FOR RELIEF

WHEREFORE, Relator Blair Collins, acting on behalf of and in the name of the United States of America and the State Plaintiffs, and on his own behalf, demands and prays that judgment be entered as follows against the Defendant under the Federal FCA Counts and under pendent State FCA Counts as follows:

(a) In favor of the United States against the Defendant for treble the amount of damages to Government Health Care Programs from the marketing, selling, prescribing, pricing and billing of The Drugs, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the United States against the Defendant for disgorgement of the profits earned by Defendant as a result of its illegal scheme;

(c) In favor of the Relator for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relator;

(d) For all costs of the Federal FCA civil action;

(e) In favor of the Relator and the United States for such other and further relief as this Court deems to be just and equitable;

(f) In favor of the Relator and the named State Plaintiffs against Defendant in an amount equal to three times the amount of damages that California, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, New York, Tennessee, and Virginia have sustained, respectively, as a result of the Defendant's actions, as well as a civil penalty against the Defendant of a statutory maximum for each violation of each State's FCA;

(g) In favor of the Relator and the Plaintiff State of Michigan against the Defendant for a civil penalty equal to one time the loss caused to the Michigan Medicaid program as a result of the Defendant's actions, plus damages equal to three times such loss;

(h) In favor of the Relator and the Plaintiff State of Texas against Defendant in an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendant's actions, as well as a civil penalty against the Defendant of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;

(i) In favor of the Relator for the maximum amount as a relator's share allowed pursuant to each State Plaintiff's FCA;

(j) In favor of the Relator for all costs and expenses associated with the pendent State claims, including attorney's fees and costs;

(k) In favor of the State Plaintiffs and the Relator for all such other relief as the Court deems just and proper;

(l) In favor of Relator Collins against PFIZER under Count Fifty-Eight for all available damages and relief under 31 U.S.C. section 3730(h), including, without limitation, two times back pay plus interest (and prejudgment interest), reinstatement or in lieu thereof front pay, and compensation for any special damages, and litigation costs, and attorneys' fees; and

(m) Such other relief as this Court deems just and appropriate.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

Dated: August 13th, 2007

Respectfully submitted,

Robert M. Thomas, Jr.
(Mass. BBO #645600)
Rory H. Delaney
(Mass. BBO #655666)
THOMAS & ASSOCIATES
Federal Reserve Building
600 Atlantic Avenue, 12th Floor
Boston, MA 02210
(617) 371-1072
Facsimile (617) 371-1037
Email rmt@thomasandassoc.net

Suzanne E. Durrell
(Mass. BBO #139280)
DURRELL LAW OFFICE
180 Williams Avenue
Milton, Massachusetts 02186
(617) 333-9681
Facsimile (617) 333-0014
Email Suzanne.durrell@verizon.net