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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ET AL. EX REL. DR. JESSE POLANSKY,	)	04 CV 0704 (ERK)
Plaintiffs,	)	FOURTH AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729 *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt. Code § 12650 *et seq.*]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. § 1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. § 68.081 *et seq.*]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. § 661-21 *et seq.*]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. § 175 *et seq.*]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [Ind. Code Ann. § 5-11-5.5-1 *et seq.*]; LOUISIANA MEDICAL
v.	)	
PFIZER, INC.,	)	
Defendant.	)	

) ASSISTANCE PROGRAM INTEGRITY
) LAW [La. Rev. Stat. § 46:437.1 *et seq*.];
) MASSACHUSETTS FALSE CLAIMS LAW
) [Mass Gen Laws ch.12 § 5 *et seq*.];
) MICHIGAN MEDICAID FALSE CLAIMS
) ACT [Mich. Comp. Laws. § 400.601 *et seq*.];
) MONTANA FALSE CLAIMS ACT [Mont.
) Code Ann. § 17-8-401 *et seq*.]; NEVADA
) FALSE CLAIMS ACT [Nev. Rev. Stat. Ann.
) § 357.010 *et seq*.]; NEW HAMPSHIRE
) FALSE CLAIMS ACT [N.H. Rev. Stat. Ann.
) § 167:61 *et seq*.]; NEW MEXICO
) MEDICAID FALSE CLAIMS ACT [N.M.
) Stat Ann. § 27-2F-1 *et seq*.]; TENNESSEE
) FALSE CLAIMS ACT AND TENNESSEE
) MEDICAID FALSE CLAIMS ACT [Tenn.
) Code Ann. § 4-18-101 *et seq*. and § 71-5-181
) *et seq*.]; TEXAS MEDICAID FRAUD
) PREVENTION LAW [Tex. Hum. Res. Code
) Ann. § 36.001 *et seq*.]; VIRGINIA FRAUD
) AGAINST TAXPAYERS ACT [Va. Code
) Ann § 8.01-216.1 *et seq*.]; DISTRICT OF
) COLUMBIA PROCUREMENT REFORM
) AMENDMENT ACT [D.C. Code Ann. § 1-
) 1188.13 *et seq*.]; NEW YORK LABOR
) LAW § 740; NEW YORK HUMAN
) RIGHTS LAW ("HRL") NEW YORK
) EXECUTIVE LAW § 290; NEW YORK
) CITY HUMAN RIGHTS LAW "NYCHRL"
) [N.Y.C. Admin. Code § 8-101]; and TITLE
) VII OF THE CIVIL RIGHTS ACT of 1964,
) as amended, 42 U.S.C. §2000e *et seq*.

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Plaintiff and Relator Dr. Jesse Polansky, through his attorneys Hagens Berman Sobol Shapiro LLP and Jonathan A. Willens LLC, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of Tennessee, the State of Texas, the State of Virginia and the District of Columbia (collectively "the States"), and his attorneys Bantle & Levy LLP, for his Fourth Amended Complaint against defendant Pfizer Inc., alleges based upon personal knowledge and relevant documents, as follows.

I. INTRODUCTION

1. This is an action (1) to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendant Pfizer Inc. ("Pfizer") and/or its agents and employees in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended ("the FCA" or "the Act"); (2) to recover damages arising from defendant's wrongful termination of Relator's employment in violation of the anti-retaliation provisions of the FCA and the New York Whistleblower Statute, New York Labor Law § 740; and (3) to remedy retaliation for Relator's complaining of discrimination on the basis of sex and retaliation in the terms, conditions and privileges of employment, in violation of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. § 2000e *et seq.* ("Title VII"), New York State Human Rights Law, N.Y. Executive Law § 290 *et seq.* ("HRL"), and New York City Human Rights Law, N.Y.C. Admin. Code § 8-101, *et seq.*

2. As set forth below, Pfizer's acts also constitute violations of the California False Claims Act, Cal. Govt. Code § 12650 *et seq.*; the Delaware False Claims and False Reporting

Act, 6 Del. C. § 1201 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.5-1 *et seq.*; the Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. § 46:437.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 § 5 *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws. § 400.601 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-2F-1 *et seq.*; the Tennessee False Claims Act and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* and § 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 1-1188.13 *et seq.*

3. For more than five years, Pfizer, through a consistent series of false and misleading statements, has unlawfully marketed Lipitor to the public and prescribing physicians by intentionally misrepresenting the authoritative treatment guidelines established by the National Institutes of Health/National Heart Lung and Blood Institute/National Cholesterol Education Program/Adult Treatment Plan III (NIH/NHLBI/NCEP/ATP III) (hereinafter "Guidelines"). These Guidelines provide the basis for FDA-approved indications for the treatment of persons with elevated levels of low-density lipoproteins ("LDL"), so-called "bad cholesterol." As a result of Pfizer's deliberately false and misleading campaign, thousands of physicians have prescribed Lipitor to millions of patients for whom drug medication is not

recommended, and for whom the medication could be dangerous. Millions of those improper prescriptions were ultimately paid for by various government health plans.

4. This case arises because Pfizer realized that a lucrative American market existed for the off-label promotion of Lipitor. According to the Guidelines, over 100 million Americans have elevated cholesterol requiring either lifestyle modifications or lifestyle modification in conjunction with drug therapy. As explained further below, only 36.5 million of those persons are approved by the Guidelines for drug therapy (the majority of those being in the highest risk group). The largest group needing *only* lifestyle changes is the so-called "Moderate Risk" group – out of 17.4 million patients in that group, only 2.8 million are indicated for drug therapy. Pfizer realized that by off-label marketing to the balance of "Moderate Risk" patients, it could increase its revenues by billions.

5. In order to effectively market Lipitor off-label, Pfizer established an elaborate off-label marketing campaign by creating false and misleading core promotional materials and programs for its customer segments: Federal Programs (Medicare, Veterans Administration, Department of Defense), State programs (*e.g.*, Medicaid), Pharmacy Benefit Managers (PBMs), HMOs, employers, providers (*e.g.*, hospitals), physicians and other practitioners, patients, and investors. These approved Pfizer marketing materials include a purported NCEP ATP III "Guidelines" slide presentation used extensively in training Pfizer employees and in presentations to external audiences; software programs for practitioners; online and onsite educational programs that include continuing medical education and related educational credits; consumer and practitioner web-based programming such as Lipitor.com; health fair and screening programs; and a range of "promotional" and "non-promotional" detailing material including "leave behinds" and visual aids. These programs and materials were false and

misleading, and convinced their respective audiences to approve, prescribe, and take Lipitor off-label, resulting in false claims to government health care programs.

6. As alleged below, Pfizer has executed this national marketing campaign with the intent to improperly expand by millions of patients the population for whom Lipitor is prescribed. This off-label marketing of Lipitor has been immensely profitable. From 2001 through 2005 annual sales increased 126%, with global sales increasing from $5.4 billion in 2000 to $12.2 billion in 2005. 2006 sales exceeded 13 billion dollars, with $7.8 billion in U.S. sales alone, according to Pfizer. Quite simply, Lipitor is the best selling drug in history.

7. As a direct result of Pfizer's unlawful marketing campaign, federal and state health programs including, but not limited to, Medicare, Medicaid, Medi-Cal, CHAMPUS/TRICARE, CHAMPVA, the Veterans Administration and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement for prescriptions of Lipitor in populations other than those indicated for treatment – prescriptions that would not have been paid but for the defendant's illegal business practices.

8. *Qui tam* plaintiff seeks through this action to recover damages and civil penalties arising from Pfizer's making or causing to be made false or fraudulent records, statements and/or claims in connection with the marketing of its prescription drug Lipitor and the provision of inducements to physicians in order to induce *them* to prescribe Lipitor and/or recommend its purchase or prescription to others. Pfizer knew that its false and fraudulent marketing practices would cause the submission of millions of claims to federal and state health insurance programs for medically unnecessary and potentially harmful prescriptions for Lipitor.

II. PARTIES

9. Plaintiff/relator Dr. Jesse Polansky, M.D., M.P.H., is a resident of Maryland. From April 2001 until July 2003, Dr. Polansky was employed by Pfizer in New York City as

Director of Outcomes Management Strategies. Dr. Polansky also served as the medical director for the Local Marketing Team Review Committee that evaluates and approves the regulatory, legal, and scientific integrity of marketing programs for Pfizer's major metropolitan markets.

10. Defendant Pfizer Inc. is a publicly traded company, incorporated in Delaware, with corporate headquarters and its principal place of business in New York, New York. With over $48 billion in sales last year, Pfizer is the world's largest pharmaceutical company, selling the most widely prescribed pharmaceutical products in the world.

11. Lipitor is the best selling prescription drug in the United States and in the world. Lipitor became the pharmaceutical industry's first product to reach the $10 billion dollar a year mark. According to Pfizer's website, more than 26 million Americans have been prescribed Lipitor. In 2001, Pfizer reported that Lipitor was the statin most prescribed for Medicaid beneficiaries in California, and that over 90,000 MediCal recipients were "working to achieve their lipid goals with Lipitor." According to the Centers for Medicare & Medicaid Services ("CMS"), between July 2001 and June 2005, Medicaid paid $2.5 billion for Lipitor alone. Consumer Reports estimated in a 2006 study that the Medicare drug benefit program will spend 11% of its total drug spending on statins for approximately 12 million beneficiaries, and that with an estimated 6 million beneficiaries on Lipitor the cost would exceed $1 billion in 2007 alone.[1]

III. JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Plaintiff establishes subject

[1] Consumer Reports, *Best Buy Drugs*: *The Statin Drugs; Prescription and Price Trends*, Consumers Union, Nonprofit Publisher of Consumer Reports, at 11, January 2006.

matter jurisdiction under 28 U.S.C. § 3730(b). In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state-law claims asserted in this Complaint. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. This Court has jurisdiction over plaintiff's Title VII claim pursuant to 42 U.S.C. § 2000e-5 (f)(3) and 28 U.S.C. § 1331. This Court has diversity jurisdiction over plaintiff's state-law HRL and Whistleblower Statute violations under 28 U.S.C. § 1332(a)(1) because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and the parties are citizens of different states. This Court also has supplemental jurisdiction over Plaintiff's state and city law claims, pursuant to 28 U.S.C. § 1367(a). Plaintiff has complied fully with all administrative prerequisites to filing the Title VII action. Plaintiff filed a charge with the United States Equal Opportunity Commission ("EEOC") on or about October 22, 2003, complaining of sex discrimination and retaliation as alleged herein. The EEOC issued a Determination finding reasonable cause to believe that plaintiff was subject to retaliation, and issued a Notice of Right to Sue, which was received on March 10, 2005. This action has been filed within 90 days thereafter.

13. This Court has personal jurisdiction and venue over the defendant pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendant has minimum contacts with the United States. Moreover, the defendant can be found in, resides, transacts, or has transacted business in the Eastern District of New York.

14. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because the defendant can be found in and transacts or has transacted business in the Eastern District of New York. At all times relevant to this Complaint, defendant regularly conducted substantial business

within the Eastern District of New York, and made significant sales within the Eastern District of New York. Venue is proper in this District pursuant to 42 U.S.C. § 2000e-5(f)(3) because the unlawful practices complained of herein were committed within the State of New York.

IV. BACKGROUND

A. The FDA Regulatory System

15. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

16. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

17. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. § 355(d).

18. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for additional uses – *i.e.*, uses not listed on the approved label – the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. § 360aaa(b),

(c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label."

19. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or *treating a different patient population* (*e.g.*, treating a child when the drug is approved to treat adults).

20. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

21. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group unapproved. Specifically, under the Food and Drug laws, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

22. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. § 360aaa(b), (c).

23. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, the FDA regulates

two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

24. With regard to the first practice – disseminating written information – the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "*unsolicited* request from a health care practitioner." 21 U.S.C. § 360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and neither false nor misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1. The second practice, corporate funding of CMEs, is discussed *infra*.

25. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

B. Prescription Drug Payment Under Federal Health Care Programs

1. The Medicaid Program

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

27. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared

between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

28. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id*. § 1396r-8(k)(3).

29. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6). During the time period relevant to this Complaint, the off-label uses of Lipitor promoted by Pfizer were not eligible for reimbursement from Medicaid because the drug's off-label uses were neither listed in the labeling approved by the FDA nor included in any of the drug compendia specified by the Medicaid statute.

30. For Lipitor, indications listed on the FDA label and the authorized compendia are identical. Lipitor is a rare example of a drug for which the compendia have not expanded indications beyond the FDA label and the Guidelines.

2. The Medicare Program

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

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

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

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

35. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all beneficiaries, with low-income individuals receiving the greatest subsidies. According to a recent Pfizer investor presentation, Pfizer expects the Medicare Part D program to account for 46% of Lipitor sales in the future.

36. During the time period relevant to this Complaint, the off-label uses of Lipitor promoted by Pfizer were not eligible for reimbursement from Medicare because those off-label uses were neither listed in the labeling approved by the FDA nor included in any of the drug compendia specified by statute.

3. Reimbursement under other federal health care programs

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

38. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel

Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

39. During the time period relevant to this Complaint, the off-label uses of Lipitor promoted by Pfizer were not eligible for reimbursement under any of the various federal health care programs.

4. Direct purchases by federal agencies

40. In addition to reimbursing drug purchases through Medicare, Medicaid, and other federal health care programs, the United States is a significant *direct* purchaser of prescription drugs through various federal programs. Defendant's illegal and misleading off-label promotion of Lipitor has resulted in greatly increased purchases of Lipitor and other statins by these programs, including but not limited to the following.

a. Programs administered by the Department of Veteran Affairs

41. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans. The VA directly purchases prescription drugs, including Lipitor, that are dispensed through these facilities and programs.

b. Programs administered by the Department of Defense

42. The Department of Defense ("DOD") provides prescription drug coverage to approximately eight million active duty personnel, retirees, and their families through three points of service: military treatment facility outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program. DOD negotiates

independent contracts to purchase the majority of the prescription drugs, including Lipitor, provided through these programs.

C. The FDA-Approved Indications for Lipitor

43. Lipitor (atorvastatin calcium) is a statin which was FDA cleared for marketing on December 18, 1996. It is now the best selling statin in the United States. Statin drugs are a class of drugs that lower cholesterol levels by blocking enzymes that are essential to cholesterol production. Pfizer, known for its aggressive marketing, acquired exclusive rights to Lipitor when it acquired Warner Lambert in 2000.[2]

44. Lipitor, and similar statins, are not risk-free medications. They typically require *life-long use*. According to Lipitor's FDA label, patients on Lipitor may suffer potentially fatal complications of the liver and skeletal muscle (myopathy) dysfunction. Drug interactions with a variety of common medications – such as erythromycin, cyclosporine, immunosuppressant drugs, azole antifungals, and lipid lowering doses of niacin – can increase the risk of myopathy. Lipitor should be used with caution by patients who consume substantial quantities of alcohol or have a history of liver disease. Lipitor may cause fetal harm and should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.

45. Lipitor's label includes a wide range of precautions and adverse reactions. In 2007, the FDA requested that Pfizer add a new PRECAUTION, informing patients with recent

[2] The FDA issued untitled letters related to the improper marketing of Lipitor in 1998, 2001 and 2002. The FDA identified print and television advertisements that were false and misleading with respect to both safety and efficacy claims. Pfizer is currently operating under a Corporate Integrity Agreement based on a settlement reached for the off-label marketing of Warner Lambert's drug Neurontin. Upon information and belief, plaintiff-relator's efforts to obtain these documents via the Freedom of Information Act, 5 U.S.C. § 552, have been delayed by Pfizer's objection. Suffice it to say, Pfizer is intimately aware of the parameters of an on-label marketing campaign, and the subtleties of off-label promotion.

stroke or TIA (transient ischemic attack) that they are at an increased risk of "hemorrhagic stroke" from statin use.

46. Statins are relatively new medications, and the long-term morbidity and mortality associated with chronic use of these drugs are not yet known. In February of 2007, the Blue Cross Association in conjunction with Kaiser Permanente issued a "Special Report: The Efficacy and Safety of Statins in the Elderly." The Report concluded that there is "considerable uncertainty regarding the overall benefit/risk ratio of these agents [in the elderly]."[3] A 2006 editorial in the British Medical Journal outlined concerns that the adverse effects of statins are under-reported in clinical trials.[4]

47. New potential dangers caused by statin use are revealed on an ongoing basis, as studies continue. A 2007 analysis by the World Health Organization identified a potential link between statins and ALS (Lou Gehrig's disease).[5] An article in the 2007 Journal of the American College of Cardiology identified a potential relationship between cancer and the achievement of lower LDL cholesterol levels.[6] Scientists have expressed concerns in the New England Journal of Medicine regarding statins and bladder cancer growth, and, separately, concerns about the impact of statins on the integrity of the immunologic system.[7]

48. The NIH has funded a multi-year, $4.1 million randomized clinical trial at the University of San Diego to address questions about the potentially adverse non-cardiac impact of

[3] Blue Cross Blue Shield, Technology Evaluation Center "Special Report: The Efficacy and Safety of Statins in the Elderly," Vol. 21, No. 12, February 2007.

[4] Uffe Ravnskov, Paul Rosch, *et al.*, "Should we lower cholesterol as much as possible?," 332 Brit. Med. J., 1330-32, June 3, 2006.

[5] Avery Johnson, "Doctor's Dilemna: A Risk in Cholesterol Drugs is Detected, but Is It Real?...," Wall St. J., A1, July 3, 2007.

[6] Alawi A. Alsheikh-Ali, Prasad V. Maddukuri, *et al.*, "Effect of the Magnitude of Lipid Lowering on Risk of Elevated Liver Enzymes, Rhabdomyolysis, and Cancer," 50 J. of Amer. College of Cardiology 5, 409-18, July 31, 2007.

[7] Paul Hoffman, Thierry Roumeguere, *et al.*, "Use of Statins and Outcome of BCG Treatment for Bladder Cancer," 355 New Eng. J. Med. 25, 2705-07, Dec. 21, 2006.

statins with a particular focus on thinking, mood, behavior, and quality of life (http://:medicine.ucsd.edu/ses). The results of this study should be available soon.

49. In addition, the current system of relying on physicians to report adverse events to manufacturers leads to substantial under-reporting of safety issues. Indeed, given both the known and unknown risks of statins, experts are especially reluctant to expand statin treatment to new groups of moderate and low risk patients where the limited available evidence suggests only marginal benefits, at best, after many years (often decades) of treatment. According to a June 2005 editorial in *Circulation* by the Chairman of the National Cholesterol Education Program, "One must keep in mind that statins generally are safe and that they substantially reduce risk for coronary events in higher risk patients. Nonetheless, statins, like all drugs, can have side effects, and care must be taken in the use on persons with predisposing conditions. Moreover, it seems unwise to use statins outside current cholesterol-management guidelines." For this reason, as discussed further *infra*, clear limits are placed on the categories of patients for whom statin use is approved under the Guidelines.

50. Specifically, Lipitor's FDA-approved prescribing information states: "Therapy with lipid-altering agents should be a component of multiple-risk-factor intervention in individuals at increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol *only* when the response to diet and other non-pharmacological measures has been inadequate (see *National Cholesterol Education Program (NCEP) Guidelines*, summarized in Table 6)." (Emphasis added.) The "Table 6" cited in the label statement is as follows:

TABLE 6. NCEP Treatment Guidelines: LDL-C Goals and Cutpoints for Therapeutic Lifestyle Changes and Drug Therapy in Different Risk Categories

Risk Category	LDL Goal (mg/dL)	LDL Level at Which to Initiate Therapeutic Lifestyle Changes (mg/dL)	LDL Level at Which to Consider Drug Therapy (mg/dL)
CHD [a] or CHD risk equivalents (10-year risk >20%)	<100	≥100	≥130 (100-129: drug optional) [b]
2+ Risk Factors (10-year risk ≤20%)	<130	≥130	10-year risk 10%-20%: ≥130 10-year risk <10%: ≥ 160
0-1 Risk factor [c]	<160	≥160	≥190 (160-189: LDL-lowering drug optional)

[a] CHD, coronary heart disease

[b] Some authorities recommend use of LDL-lowering drugs in this category if an LDL-C level of < 100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL-C, e.g., nicotinic acid or fibrate. Clinical judgement also may call for deferring drug therapy in this subcategory.

[c] Almost all people with 0-1 risk factor have 10-year risk <10%; thus, 10-year risk assessment in people with 0-1 risk factor is not necessary.

51. Thus, Lipitor's FDA-approved labeling specifically incorporates the treatment Guidelines into the prescribing information. These Guidelines present four distinct risk categories within which to place patients, with four distinct "cutpoints" at which to consider beginning statin therapy, as discussed further *infra*. Accordingly, promoting Lipitor therapy for patients outside these risk categories and cutpoints, *i.e.*, those who do not meet FDA and NCEP indications for statin treatment, constitutes unlawful off-label promotion.

52. At all times relevant to this Complaint, the off-label and off-compendium uses of Lipitor promoted by Pfizer, as addressed in these allegations, did not qualify for reimbursement under any federally-funded health care program.

D. The NCEP ATP III Guidelines: Goals and Cutpoints

53. The FDA-approved indications for Lipitor, found in its label, incorporate, without modification, the Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults of the National Cholesterol Education Program ("NCEP").[8] The

[8] NCEP is a multimillion dollar clinical program of the National Institutes of Health, National Heart, Lung and Blood Institute.

most recent of these reports, known as ATP III (Adult Treatment Panel III), was issued in May 2001, and updated in July 2004. These constitute the aforementioned "Guidelines." The ATP III update reviewed the results of the five major clinical trials completed since publication of ATP III in 2001. The ATP III update recommended no changes to the goals or drug therapy cutpoints for the Moderate Risk group.

54. The Guidelines provide detailed information on classification of lipids and lipoproteins, coronary heart disease risk assessment, lifestyle interventions, drug treatment, specific dyslipidemias, and adherence issues. As detailed below, the governing principle of the Guidelines is that the intensity of cholesterol-lowering drug treatment should be adjusted to the patient's absolute risk for coronary heart disease (or, hereinafter, "CHD"). Patients with existing CHD are at the highest risk and, thus, have the lowest goal level for LDL cholesterol and receive the most intensive treatment. Patients without CHD have lower risk, higher goals and need less intensive treatment. In addition, patients are stratified into multiple risk categories based on their number of cardiac risk factors and the calculation of the patient's risk of having a heart attack within ten years.

55. The coronary heart disease risk level for persons without CHD or a CHD-risk equivalent (conditions such as Diabetic and Peripheral Vascular Disease that carry an absolute risk for developing new coronary heart disease equal to the risk for having recurrent CHD events) is generally evaluated through a two-step process:

a. count risk factors; and then

b. if there are two or more risk factors, calculate the risk of having a heart attack within ten years.

56. The risk factors for CHD events are: cigarette smoking, hypertension, low HDL-C (high-density lipoprotein cholesterol, so-called "good cholesterol"), family history of premature coronary heart disease, age, and diabetes mellitus.

57. For those patients with two or more risk factors, the Guidelines use standardized cardiac risk assessment tools to calculate the individual's risk of having a heart attack within 10 years. These tools are both paper-based and in electronic formats (for personal computer, internet, and handheld device-based computing). With paper-based tools, points are assigned to specific data elements regarding age, gender, total cholesterol, HDL-C, blood pressure, and cigarette smoking. Based on the total number of points, the patient is assigned a 10-year risk for having a heart attack. In the electronic formats, the user enters the patient-specific data and the software automatically calculates the 10-year risk using a *more accurate* mathematical model.

58. The Guidelines recommend that LDL cholesterol be the primary target of therapy. If the patient's LDL cholesterol levels are above the goal for a patient's given risk category, so-called "therapeutic lifestyle changes" (hereinafter "TLC") are recommended. Therapeutic lifestyle changes include change in diet, weight control, and increased physical activity.

59. The Guidelines differentiate between LDL *goals* and LDL *cutpoint levels* for *initiating drug therapy*. Cholesterol goals are the levels that patients should aspire to achieve in a particular risk category. However, such goals are *not* the levels at which statin therapy is approved under the Guidelines. LDL goals depend on the patient's absolute risk of having a coronary heart disease event. The higher the risk, the lower the goal.

60. The Guidelines' three LDL goal levels are as follows:

a. a patient with coronary heart disease or a CHD risk equivalent has a goal LDL level of less than 100;

b. a patient with multiple (2 or more) risk factors has a goal LDL level of less than 130; and

c. a patient with 0 or 1 risk factors has a goal LDL level of less than 160.

61. In addition, in the transition from ATP II to ATP III, NCEP updated the Guidelines to introduce two subcategories for the ATP II risk group of patients with multiple risk factors and up to a 20% chance of a heart attack within the next 10 years. This change created the Moderately High and Moderate Risk groups and was highlighted by NCEP as "the major thrust of ATP III." The Guidelines, thus, provide four patient risk categories. They are:

a. Highest Risk: patients with CHD or a CHD-risk equivalent, or with a greater than 20 percent risk of heart attack within ten years;

b. Moderately High Risk: patients with two or more risk factors, and a 10 to 20 percent risk of heart attack within ten years;

c. Moderate Risk: patients with two or more risk factors, and less than 10 percent risk of heart attack within ten years; and

d. Low to Moderate Risk: patients with zero or one risk factor.

62. The Guidelines set forth the following four cholesterol cutpoints at which to consider statin therapy (see also Table 6 above). In general, the Guidelines provide that drug therapy should be considered after three months of TLC, as follows:

a. For patients in the Highest Risk category: at LDL level greater or equal to 130 (drug therapy optional for LDL levels of 100-129 among highest risk patients);

b. For patients in the Moderately High Risk category: at LDL level greater or equal to 130;

c. For patients in the Moderate Risk category: at LDL levels greater or equal to 160; and

d. For patients in the Low to Moderate Risk category: at LDL levels greater or equal to 190 (drug therapy optional between 160 and 189).

63. Of particular importance here, the Guidelines specifically provide that patients with multiple (two or more) risk factors and a ten-year risk of CHD of less than ten percent – *i.e.*, patients in the Moderate Risk group, are not recommended for drug therapy until and unless the patient's LDL reaches 160. Pfizer has targeted these Moderate Risk patients with false and misleading information designed to encourage drug therapy at levels below the recommended and authorized 160-LDL.

64. Again, LDL *goals* are not the points at which the Guidelines recommend drug therapy – instead, drug therapy is only indicated if a person's LDL level equals or exceeds a different (and usually higher) *cutpoint* level. For Moderate Risk patients, the LDL goal is 130 – the *cutpoint* is 160. Pfizer has deliberately tried to remove this distinction, to encourage the onset of drug therapy among Moderate Risk patients at 30 points below the approved level. Erasing this distinction offers Pfizer the business opportunity to unlawfully reach the entire 17.5 million patients in the Moderate Risk group, rather than just the nearly three million within that group who are approved for Lipitor under the Guidelines.

65. Under the Guidelines, drug therapy is generally not suggested as a first treatment option, except in a small number of very high risk patients. Instead, the Guidelines recommend that the first measures that should generally be used to achieve these goals are TLC. Moderate Risk patients are recommended for TLC to reach their goal of 130 – only at a level of 160 are

drugs such as Lipitor to be considered for this group. Lipitor is not approved (or indicated) for use among Moderate Risk patients with LDL levels below 160.

V. ALLEGATIONS

A. Pfizer's Illegal Off-Label Marketing to Moderate Risk Americans

66. Pfizer created false and misleading core promotional materials and programs for its customer segments: Federal Programs (Medicare, Veterans Administration, Department of Defense), State programs (*e.g.*, Medicaid), Pharmacy Benefit Managers (PBMs), HMOs, employers, providers (*e.g.*, hospitals), physicians and other practitioners, patients, and investors. These approved Pfizer marketing materials include a purported NCEP ATP III slide presentation used extensively in training Pfizer employees and in presentations to external audiences; software programs for practitioners; online and onsite educational programs that include continuing medical education and related educational credits; consumer and practitioner web-based programming such as Lipitor.com; health fair and screening programs; and a range of "promotional" and "non-promotional" detailing material including "leave behinds" and visual aids. The false and misleading messages promoted by Pfizer (as described herein) are prevalent and identifiable across customer segment and type of material.

67. Pfizer's strategy to expand potential markets for Lipitor was designed to leverage new media and new technology (*e.g.*, clinical decision support software – including web, desktop, and handheld applications – Internet-based programming, email, distance learning) that are typically subject to minimal review by the FDA.[9]

68. Pfizer's off-label marketing strategy is delivered to its audiences through the reiteration and combination of several false and misleading themes: (1) "if you are not at your

[9] The FDA's oversight of pharmaceutical advertising remains primarily focused on the mediums of magazine and television.

LDL goal, you should consider drug therapy"; (2) "Get to Goal" with the use of Lipitor; (3) diet and exercise will not suffice to reduce your risk of heart disease; and (4) "Lower [cholesterol] is better" (infinitely, and irrespective of risk category). These themes are woven into the fraudulent Lipitor marketing scheme that relies on misrepresenting the Guidelines. Pfizer seeks to increase off-label use across the spectrum of risk categories (outlined above), but the campaign manifests itself most egregiously among the Moderate Risk group, the single largest potential market.

1. Misrepresenting the Lipitor label and the Guidelines to encourage off-label use

69. In order to increase further its unprecedented sales growth, Pfizer created a marketing campaign for Lipitor based on false, misleading and deceptive characterizations of the drug's FDA-approved indications based on the authoritative Guidelines. By targeting Moderate Risk patients, Pfizer's promotional activities and materials intentionally served to unlawfully broaden the patient population for which Lipitor is recommended.

70. According to NCEP, there are 101.8 million adults who could benefit from therapeutic lifestyle changes alone or combined lifestyle changes and drug therapy. Of that number, 36.6 million require drug treatment because their LDL levels exceed the Guideline cutpoints for commencing statin therapy. The remaining 65.2 million Americans need TLC, not drug therapy. There are 17.4 million Americans in the Moderate Risk category. Of that group, 14.6 million people (84 percent) need *only* therapeutic lifestyle changes. Drug therapy and therapeutic lifestyle changes are recommended for the remaining 2.8 million.

71. Pfizer's false and misleading marketing of Lipitor beyond FDA-approved labeling to Moderate Risk individuals whose LDL levels are below the drug treatment cutpoint has fraudulently added up to 14.6 million patients to the population of potential Lipitor users.

72. Simply put, the targeted capture and dosing of the enormous Moderate Risk patient pool with LDL levels below 160 is achieved by erasing the critical Guidelines distinction between the patient goal and the drug therapy cutpoint. This is a marketing priority because for the Moderately High Risk group there is no distinction between the patient goal and the drug therapy cutpoint – they are both at an LDL of 130. This is principally accomplished, as previously described, by the reiteration and combination of several false and misleading themes: (1) "if you are not at your LDL goal, you should consider drug therapy"; (2) "Get to Goal" with the use of Lipitor; (3) diet and exercise will not suffice to reduce your risk of heart disease; and (4) "Lower [cholesterol] is better" (infinitely, and irrespective of risk category).

73. Pfizer compounds these falsehoods by presenting, in its Guidelines slide presentation, its software programs for practitioners, its online and onsite educational programs that include continuing medical education and related educational credits, in its consumer and practitioner web-based programming such as Lipitor.com, in health fair and screening programs, and a range of "promotional" and "non-promotional" detailing material including "leave behinds" and visual aids, (a) only goals without discussion of drug therapy cutpoints, (b) omitting presentation of the Moderate Risk group, and/or (c) mislabeling the Moderately High Risk group as the Moderate Risk group. Finally, through the broad distribution of inaccurate electronic and paper cardiac risk calculators Pfizer is able to falsely classify many Moderate Risk patients as Moderately High Risk (making them "eligible" for drug therapy).

74. Pfizer executed this plan with full knowledge that millions of patients would have their prescription costs for Lipitor reimbursed, improperly, through false claims submitted for reimbursement by various federal and state health programs.

2. Pfizer's Lipitor "Operating Plan" and deceptive marketing materials

75. Pfizer's "new market expansion" strategy is presented in its confidential Lipitor 2002 Operating Plan (or "Plan"). The "market expansion" strategy presented was to "Leverag[e] the New Guidelines With Physicians" with a plan to: (1) "Educate Physicians on Guidelines"; and (2) "Emphasize New LIPITOR "Get to Goal" Messages." By misrepresenting the Guidelines to physicians, and emphasizing "goals" as though they were "cutpoints," Pfizer unlawfully marketed its top-selling drug for off-label uses.

76. Pfizer also recognizes in its Plan that "People believe they can treat with diet/exercise," (which the vast majority of patients in the Moderate Risk group are instructed to do by the Guidelines), and that failing to do so can lead to "guilt[]" and a sense of "failure[]." Pfizer's solution – "Absolution – Idea that we need to absolve them of this before we can get them interested in using Lipitor." This, Pfizer states, is "Key to reaching the consumer." Using this model, Pfizer created unlawful consumer marketing materials, presented in what follows, designed to obscure the clear fact that for the vast majority of patients in the Moderate Risk group, diet and exercise is the exclusive remedy authorized to address cholesterol concerns.

77. The 2002 Operating Plan is implemented as part of the first national sales training meeting of the year called POA 1 (Plan of Action). During training, Pfizer introduced a program entitled "POA 1 [Plan of Action] Strategic Selling Guide Featuring *Action Selling*." This Guide was created for the sales forces who detail physicians and physician offices. Three strategies are outlined: (1) to encourage physicians to identify new patients for treatment (*i.e.*, market expansion as described above); (2) to illustrate safety and efficacy; and (3) to dominate "share of voice"[10] with detail frequency and strategic sample distribution. The Guide references many of

[10] "Share of voice" describes the proportion of available physician time and attention given to any one pharmaceutical product or marketing representative. For example, if a physician is willing to spend five hours a

the false and misleading core sales programs and materials developed by the marketing team and described in this Complaint, including the "Cholesterol Management in the Workplace" and "Lipid Lowering and Prevention of Coronary Heart Disease: A Managed Care Perspective" materials, and the misleading "NCEP ATP-III Guidelines" presentation.

78. In December 2002, as part of POA 3, Pfizer distributed "The Lipitor Healthcare Cluster Playbook" ("Playbook"). The Playbook is intended for use by Pfizer's Health Care Cluster. This component of Pfizer's sales force includes hundreds of clinical and non-clinical staff of the National Health Organizations, the National Account Group, and the Clinical Education Consultants. These individuals' responsibilities are focused on increasing Lipitor utilization among, *inter alia*, large institutional customers, such as government programs, pharmacy benefit managers, HMOs, medical groups, and employers.

79. The Playbook's strategy also emphasizes "getting patients to NCEP ATP-III goals" and outlines many of the misleading and often false, approved core sales programs and materials identified in this Complaint, including the "Cholesterol Management in the Workplace" and "Lipid Lowering and Prevention of Coronary Heart Disease: A Managed Care Perspective" materials, and Lipitor.com.

80. Another unique sales resource identified in the Playbook is the Lipid Goal Manager (*see* Section c. *infra*). This program is only available to the Health Care Cluster, given that it is designed and resourced for physician groups and not individual physician practices.

81. Lipitor sales resources are limited to a core set of programs and materials, as the recurrence of these core materials is demonstrated herein. They are standardized and strictly regulated by the Lipitor corporate marketing team (designated the Lipitor Disease Management

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week listening to drug sales pitches, and a Pfizer representative spends two hours with that physician, then Pfizer will have achieved a 40% "share of voice."

Team). By company policy all sales recourses must be pre-approved for use by the Lipitor Review Committee. The Lipitor Review Committee is made up of a representative from Pfizer Corporate Medical, Legal, and Regulatory Affairs. Pfizer operates with a highly centralized, hierarchical structure, meant to ensure top-down management control, accountability, and uniformity of drug marketing messages.

a. Pfizer's false and misleading "Guidelines" presentation

82. Pfizer's centerpiece Guidelines marketing presentation is entitled "The Lipid Slide Library, Volume 2: National Cholesterol Educational Program Adult Treatment Panel III Guidelines" (BC684R01). This presentation is used in training both clinical and non-clinical personnel at Pfizer on the mission critical Guidelines. The Lipid Slide Library is also used in presentations to a range of Lipitor pharmacy benefit decision makers and consultants. Most importantly, these Slides were provided to Pfizer's paid physician consultants (*i.e.*, Pfizer's Physicians' Speakers Bureau) and serve as a basis for their promotional presentations to practicing physicians across the country. This presentation purports to give an accurate account of the authoritative Guideline regime. In addition to the content of the Slides, this slide deck comes with an associated paper guide providing speaker notes for use by the Pfizer presenter. These materials purport to fairly and objectively inform their audience about the Guidelines, but do just the opposite.

83. Slide 1 contains the following speaker commentary: "This program highlights the new NCEP ATP III guidelines for your clinical practice, as well as [sic] information on lipid-lowering therapy with atorvastatin calcium [Lipitor]." Slide 11 then presents the LDL goals without distinguishing between the Moderate and Moderate High risk categories, or the different cutpoints for initiating drug therapy. In other words, Pfizer omits, in its centerpiece training resource regarding the Guidelines, the most critical information regarding when to begin drug

therapy. More egregiously, the commentary for Slide 14 instructs that "Lipid-lowering drug therapy should be considered for patients not at LDL goal after 3 months of therapeutic lifestyle changes." This statement is false according to the Guidelines, and Lipitor's FDA label.

84. By omitting the cutpoints and falsely stating broadly that doctors and patients, *according to the Guidelines*, ought to consider drug therapy when patients do not achieve goal, irrespective of risk category, Pfizer is deceiving decision makers about the approved uses of Lipitor, and the Guidelines themselves.

b. Pfizer's false and misleading targeting of PBDMs and consultants

85. Pfizer created a Lipitor marketing program aimed at employer pharmacy benefit decision makers (PBDMs)[11]. The program is entitled "Cholesterol Management in the Work Place: Information for Benefit Decision Makers" (Pfizer tracking number BC704R01). The program includes a Lipitor-branded training compact disc and a "leave behind" brochure. The compact disc presentation includes a series of slides broken down into the following agenda items: (1) "The prevalence and cost of high cholesterol"; (2) "The treatment gap"; (3) "Therapeutic options"; and (4) "Workplace initiatives."

86. "The treatment gap" begins with a slide entitled "Guidelines exist for cholesterol management" that presents only the three LDL *goals* with no corresponding mention of the four distinct risk groups and their respective *cutpoints* for drug therapy. The series ends with a slide entitled "Most people do not reach their NCEP goals for LDL cholesterol."

87. "Therapeutic options" includes a slide entitled "When to consider drug therapy in the management of high cholesterol." At the bottom of the slide, in large font for speaker

[11] Many pharmacy benefit managers ("PBMs"), large employers, and large health care providers contract with or employ "pharmacy benefit decision makers" (PBDMs) to determine what policies and programs to use in conjunction with pharmacy benefits. These individuals have clinical and non-clinical backgrounds. Their work directly influences clinicians and patients in the selection of prescription drugs and the associated indications for use, because they approve formularies, coverage policies, educational programs, preauthorization programs, and other programs and policies that directly impact prescription drug access and utilization.

emphasis, is false and misleading commentary for the presenter to use with the slide: "[f]or individuals with <20% risk, drug therapy may be considered after lifestyle changes alone have failed to achieve LDL goal." This is false, and contrary to the Guidelines. Moderate Risk patients, and their physicians, are not instructed, according to the Guidelines and Pfizer's label, to consider drug treatment after failing to reach the 130 *goal* despite failed efforts at TLC. Only at a level 160 is drug therapy an approved consideration for the Moderate Risk group. Again, in this company-wide sales tool, Pfizer fraudulently presents the Guidelines to induce off-label prescriptions.

88. The printed component of the leave-behind material includes the more carefully constructed but still misleading statement that "If LDL-C goal is not achieved, additional therapeutic steps may be necessary. For people with higher risk of heart disease, initiating drug therapy may be appropriate." The elaborate Guidelines system of goals, cutpoints, and risk categories is obliterated by Pfizer's false and misleading off-label sales pitch.

89. Pfizer also created a Lipitor marketing program designed to influence PBDMs in managed care organizations. It is titled "Lipid Lowering and Prevention of Coronary Heart Disease: A Managed Care Perspective." The program includes an unbranded "leave behind" (LP103471) and a branded promotional compact disc set (LP103472). The "leave behind" "detail"[12] aid contains a chart of three LDL goal levels under the heading "Lowering lipid levels can help prevent CHD." Pfizer, once again, decided to omit describing the four distinct risk groups and the significant difference between the LDL *goal* and the respective LDL *cutpoints* level at which drug therapy is indicated.

[12] "Detailing" is the common term for the process whereby pharmaceutical marketing representatives promote their drugs to doctors and other key audiences in one-on-one or small group meetings.

90. The "Lipid Lowering Slide Kit" used for presentations includes specific instructions to not leave the CD with the client. The slide presentation is more aggressive than the leave-behind material in promoting off-label use of Lipitor. It includes compact disc 1 "Lipid Lowering and Prevention of Coronary Heart Disease" modules 1-7. Within the second module, "NCEP ATP III Guidelines," there is a slide entitled "The first step in reducing LDL-C: Therapeutic Life Changes (TLC)." It concludes with the false statement, "[i]f LDL-C goal is not achieved through TLC, drug therapy should be considered." This same fraudulent message is repeated, once again, in core marketing materials for Lipitor, contrary to the clear, unambiguous parameters of the Guidelines and the Lipitor label.

c. Pfizer's false and misleading targeting of physicians

91. Pfizer has saturated physicians with misleading information concerning Lipitor. In physician contacts, *e.g.*, CMEs, promotional and non-promotional meetings and teleconferences, internet-based educational programs, and cholesterol management computer software, Pfizer has misrepresented the Guidelines and its Lipitor label to induce doctors to initiate treatment outside the Guidelines.

92. Pfizer produces and distributes lipid management software and associated technical support in a program called the "Lipid Goal Manager" (order #LP102004). This software improperly directs physician and patient decision making at the point of care. The software is intended to be used by Pfizer Clinical Education Consultants to provide "support to customers [physicians] integrating NCEP ATP III guidelines into routine practice." The primary functions of the software are to "assess patients' risk classification and LDL-C goals according to NCEP ATP III guidelines" and then "generate reports identifying individuals and groups of patients *at goal, not at goal* . . ." (emphasis added). Pfizer adopted this particular software with

knowledge that it is both inaccurate, and artificially inflates the risk posed to many patients in the Moderate Risk group, *i.e.*, that it promotes off-label use.

93. For example, if the following patient information is entered into the software program – 43 year-old female with LDL-C of 135 and risk factors of smoking, hypertension, and a family history of heart disease – the following report is generated:

RISK ASSESSMENT AND LDL GOAL

NCEP Risk Category:	2 or more risk factors (10-year risk <20%)
NCEP LDL-C level:	<130 mg/dL
Patient's LDL-C level:	135 mg/dL
Patient's 10-year risk:	4 percent

TO MEET NCEP GOAL LDL-C, LEVELS SHOULD BE LOWERED BY 6 mg/dL OR MORE (4.44 percent)

94. Under the Guidelines, this patient is Moderate Risk, and unapproved for drug therapy. Despite this, the software *automatically* generates a prepared, personalized letter to the patient that advises the patient that "a low fat diet, proper exercise, *and medication* will help lower your cholesterol levels, especially your LDL-cholesterol (bad cholesterol) . . ." (emphasis added).

95. According to Lipitor's labeling and the Guidelines, no medication is indicated for either of these patients, as their risk of having a heart attack within 10 years was less than 10 percent and their LDL-C was less than 160. Both physicians and patients utilizing this Pfizer tool, however, have been falsely informed by Pfizer that drug therapy is needed. Yet again, Pfizer has obscured cutpoints from the calculus for drug therapy for the Moderate Risk group, and substituted cholesterol goals. In addition, the software does not integrate the essential role of TLC in cholesterol management.

96. Lipid Goal Manager also creates a patient information sheet entitled "What is your cholesterol goal?" The sheet contains misleading information. It identifies three broad goal levels and omits presenting the four patient risk groups and their distinct cutpoints for drug therapy. The patient would have no idea that there are critical treatment distinctions between Moderate and Moderately High Risk patients.

97. As recently as October 2006, Pfizer presented a similar, misleading Guideline message in the "health professionals" section of its Lipitor.com website, in a presentation titled "CVD Management Slide Kit." As with the training slide decks discussed *supra*, the presentation on Lipitor.com includes slides that fraudulently conflate the Moderate Risk and Moderately-High Risk groups into one treatment algorithm, and omit presenting the distinction between the *cutpoints* at which statin therapy is indicated and the Guideline *goals*. Lipitor.com incorrectly presents three risk groups and the goals of treatment: "High, Moderately High, and Low Risk Group." The Moderate Risk group is deliberately omitted from this slide.

98. A later slide indicates that for the "Moderate Risk group" the LDL goals for patients with two CHD risk factors have changed from 130 to an optional goal of 100. This is false. The Guidelines update published in July 2004 – which, to date, has not led to a Lipitor label change – only extended the therapeutic option of a reduced goal of 100 to the Moderately High Risk group.

99. As with all of these fraudulent materials, this scheme leads to the submission of more Lipitor claims, as well as for more expensive higher dosages. As a result, patients are once again placed at unnecessary risk and the government is fraudulently caused to spend more funds on Lipitor.

100. Pfizer's national, centerpiece marketing messages and resources are not only used in national sales activities. Local marketing efforts are required to amplify the national messages and resources. In 2002, Pfizer's Local Marketing Team in Atlanta created the Cardiovascular Leadership Council (LM112381) program with the express intention of "*targeting* influential cardiologists and PCPs [primary care physicians]" and "focusing on Lipitor product growth." (Emphasis added.) According to Pfizer, "The Pfizer field force will leverage this multi-tier program to increase access to thought leaders and targeted physicians and lead into product discussions on Lipitor. Subsequently, strengthening relationships with these key influentials (meeting speakers as well as attendees) will lead to an increase in market share."

101. The Atlanta program was designed to "leverage the introduction" of the Guidelines to build cardiovascular business "by educating physicians in the marketplace about the importance of treating patients to goal." The speakers were provided with, and instructed to use, a "Slide Resource Kit" that included the false "Lipitor pre-approved slide kit entitled, 'The Lipid Slide Library Volume 2,'" and the speaker notes described above. In other words, the centrally produced and approved, off-label, unlawful marketing pieces are used as a matter of policy in large promotional marketing programs developed for local metropolitan markets.

102. Another example of a Pfizer clinical program focused on the "importance of early diagnosis and treatment to NCEP ATP III goal levels," is "PFARM" or "Pfizer Facilitating the Advancement of Rural Medicine." These materials include a series of slides for Pfizer speakers to use in presentations aimed at rural physicians. Slide 10 ("Identifying Issues, Strategies and Actions") defines the "issue" as "many patients not at goal LDL-C levels" and the "strategy" as "increase physician awareness of importance of early diagnosis and treatment to NCEP ATP III goal levels." Slide 18 presents the NCEP ATP III goals without any mention of the risk

categories (or cutpoints) and their importance in determining when to initiate drug therapy. It presents the Guidelines with the second and third risk categories compressed into one category, and the LDL goal as less than 130. Notably absent is any accompanying slide that outlines the four risk categories and the approved drug initiation levels (such as Table 6, shown *supra*). The presentation misleads physicians by making it appear as though the Guidelines authorize initiating statin therapy on Moderate Risk patients with an LDL level greater than 130.

103. Pfizer does not simply present the aforementioned materials to various physicians in the *hope* that the materials might lead to greater numbers of Lipitor prescriptions. An internal document titled "Pull Through Resource Guide" (PG116578) showcases "several successful initiatives" (including promotion of Lipitor through the materials discussed in this Complaint). These "Impact Practices" are meant to highlight successful campaigns to be "adopt[ed]" in future Lipitor programs.

104. One such highlighted campaign, the "Lipitor Messaging Program," was aimed at a large Midwestern Tactical Area Coordination Unit (TACU), *i.e.*, a metropolitan market, with the hope of "accelerat[ing] sales" for Lipitor. This program utilized Pfizer's NCEP ATP-III Guidelines materials, and began by "recruit[ing]" physicians to participate in a Guidelines "symposium." Nearly 200 targeted physicians attended the symposium, and of those who attended, the volume prescription growth for Lipitor among that group was determined by Pfizer to be nearly 5% above that of non-attending physicians. Pfizer tracks to precision the effect that their off-label marketing campaign has on physicians through monitoring each physician's rate of prescriptions for Lipitor.

d. Pfizer's targeting of Moderate Risk patients with hypertension

105. Pfizer has also aggressively targeted a large subset of Moderate Risk patients for off-label Lipitor use – patients suffering from hypertension. In 1990, over forty-three million

Americans were reported to have hypertension. Pfizer promotes to physicians the false, off-label claim that all hypertensive patients, regardless of their risk category, should be on Lipitor. This campaign has a high profile. It is visible even in medical journal advertisements and on Lipitor.com.

106. As part of the off-label hypertension claim, Pfizer misrepresents the design and findings of a landmark Pfizer-funded clinical trial conducted and published in Europe. This study, known as the "ASCOT trial," did not find that all patients with hypertension benefit from the use of Lipitor. ASCOT was not designed to evaluate this question. ASCOT was only designed to address the role of Lipitor in hypertension patients that had at least three additional cardiac risk factors. Nonetheless, Pfizer presents that ASCOT's findings on the benefits of Lipitor are applicable to all hypertensive patients, including large numbers of patients in the Moderate Risk group. This is contrary to the FDA label and the ATP-III update that integrated findings based on the ASCOT study. In fact, the ATP-III update did not find evidence in ASCOT to change the indications for Moderate Risk patients.

107. Pfizer's Liptor.com website, in a section designed for practicing physicians, misinforms doctors visiting the site that the ASCOT study (inaccurately termed a "primary prevention" study) establishes the wisdom of prescribing Lipitor to persons with "mildly elevated cholesterol" and "*moderate* risk of CHD." (Emphasis added.)

108. A Pfizer Lipitor advertisement found in medical journals falsely proclaims that the ASCOT trial constitutes "[p]roof that Lipitor helps both moderate-risk and high-risk patients." This claim is particularly disturbing in American publications, because, as Pfizer well knows, the definition of "moderate risk" in Europe (and the corresponding use of the term in ASCOT) constitutes a higher cardiac risk than even "Moderately High Risk" in the United

States. The sole reason for the defendant to confuse these two designations is to unlawfully market Lipitor in the United States to all hypertensive patients, including the substantial market opportunity present for hypertensive patients in the Moderate Risk group.[13]

e. Pfizer's false and misleading targeting of consumers

109. Pfizer's off-label promotion of Lipitor directed at consumer-patients includes creation and promotion of the bi-lingual Sana La Rana program. Through local health fairs, print, radio, television and its website SanaLaRana.com, Pfizer promotes cholesterol treatment in "low health literacy" Spanish-speaking populations. The program began in New York City and has been expanded to other major Hispanic markets. According to the site, which simplistically references detailed NCEP concepts, "untreated high cholesterol can lead to serious medical conditions." The site goes on to advocate goals for LDL cholesterol and provides a table showing three, rather than four categories, and the oversimplified LDL goal of less than 130 for people with two or more risk factors. The program goes on to suggest consideration of drug therapy. This is done without ever presenting the relevant, controlling *cutpoint* levels for the Moderate Risk group at which drug therapy (for Lipitor) is approved for consideration. "Your LDL should not be greater than your goal but it is best to have an LDL below 100. Having a LDL between 130 to 160 is borderline high. . . ." Without further clarification of these broad statements, Pfizer's misleading marketing to this community provides incomplete information, and is designed to leave the consumer with the mistaken idea that anyone not at goal needs medication.

[13] In addition, Pfizer has created a false or purposefully misleading promotional and CME campaign to specifically target the twenty million Americans with chronic kidney disease for Lipitor therapy regardless of whether they are indicated for drug therapy based on the Guidelines (and Lipitor's label). This scheme includes a misrepresentation of the Guidelines. The campaign also carries significant patient safety issues given that published results from Pfizer's own landmark clinical trial identified no benefits and an increased risk of stroke among diabetes patients on dialysis.

110. This initiative has been tremendously successful during the cholesterol education campaign which ran from June to December 2003: 400,000 patient education brochures were distributed at doctors' offices and community events; the promoter hosted 282 community charlas (chats) that reached nearly 4,300 people in Miami and Houston; the website received more than 13,000 hits and the toll-free hotline received 5,300 calls.

111. Pfizer was also the sponsor of the Boston Health Party which it described as "Boston's leading cardiovascular disease awareness campaign for women." Valerie Sullivan, Pfizer's Director of Marketing for the Boston Local Market Team, described in an e-mail the Pfizer program imperative of educating physicians and patients of the need to use medication to achieve goal as follows: "the educational piece would highlight the importance of treating aggressively to goal, especially in light of the new ATP III goals."

112. Lipitor's label and the Guidelines are clear in stating the importance of diet, exercise, and weight loss on managing high cholesterol, and that many people with elevated cholesterol, if they make the appropriate behavioral changes, will not need to take expensive, potentially risky medications. Pfizer's direct-to-consumer branded messages, to the contrary, directly contradict Lipitor's labeling, and seek to undermine TLC as a critical component of a carefully designed risk/benefit and cost/benefit approach to managing high cholesterol, embodied in the Guidelines.

113. A further example of the direct-to-consumer strategy is Pfizer's 2003 internet-based campaign. Consumers who registered at the Lipitor.com site received a follow-up email. In the center of the email in large font was the message "Don't worry, a high cholesterol number may not be your fault. But it's probably time for some extra help." The consumer was also "alerted" that "what you can't feel can hurt you," and encouraged to click on six choices for

additional information. Choice number five – "Get up to $10 off a LIPITOR prescription. It's a great way to get started."

114. No information is provided on the e-mail page about when drug therapy should be initiated, or the role of TLC as a critical, initial step in treatment. Rather, Pfizer creates a sense of alarm regarding cholesterol levels, absolving consumers from taking responsibility for modifiable risk factors, and steering patients off-label to Lipitor.

f. Pfizer's promotion of inaccurate risk calculators to expand its market off-label

115. In addition to the inaccurate Lipid Goal Manager discussed above, Pfizer promotes additional decision-support software and tools – made available to practitioners seeking to assess a patient's cardiac risk – in order to promote the off-label and off-compendium use of Lipitor.

116. Under the Guidelines, cardiac risk calculation is a critical step in the process of determining what – if any – treatment regimen is required. NCEP uses a mathematical model (the Framingham equation) to calculate cardiac risk in electronic calculators (available, *inter alia*, on the NCEP website). NCEP also created a less accurate point based scoring system for use in its paper-based risk assessment. The paper calculator is intended *only for use if an electronic calculator is not available*. The paper calculator was created by NCEP because it viewed an inaccurate calculation in areas of clinical practice unable to access electronic formats as preferable to no risk assessment at all.

117. In computer-based applications (whether the application is on the web, a desktop computer or a hand held device), there is no advantage to using the less accurate point system designed for paper-based calculations. In fact, the point system systematically (and wrongly)

makes many patients appear to be in higher risk categories than they actually are, thus increasing the likelihood they will be treated improperly with drug therapy.

118. Pfizer systematically exploits this known inaccuracy in the point-based scoring system in its electronic media promotional activities. For example, the Lipitor.com website provides the inaccurate online cardiac risk calculation on its patient and practitioner pages. In 2002, as part of Pfizer's Olympic promotional activities, a CD-based risk calculator for use on desk top computers was distributed that used the point-scoring system. Pfizer's "Lipid Goal Manager" – described previously – also uses the inaccurate point-based cardiac risk calculation. "CV @ Goal" – another Pfizer cardiac risk calculator – also fails to accurately calculate cardiac risk. In no examples found by Relator has Pfizer noted that the less accurate scoring system is being used and that its use may impact clinical decision making.

119. Pfizer also sponsors an "NCEP" computer application for handheld devices (*e.g.*, PDAs), produced and distributed by ePocrates, Inc. This software is advertised on Lipitor.com and ePocrates.com, the industry leader in clinical decision support for personal computers. According to ePocrates, one in four physicians (and a greater number of medical students) use its software. The ePocrates "NCEP" software application, which is Lipitor branded, uses the less-accurate, points-based risk calculator.

120. Pfizer's statin competitors, including Merck and AstraZeneca, do not use the inaccurate point scoring system in their electronic applications. AstraZeneca provides a complimentary cardiac risk assessment tool for hand held devices called the "Mobile Lipid Clinic." Merck's Zocor.com has provided a web-based risk calculator. Both AstraZeneca and Merck, in the noted applications, use the accurate mathematical model to calculate cardiac risk.

121. The sole reason to maintain and promote the less accurate, point-based risk assessment is to encourage inflated risk calculations that result in more Moderate Risk patients using Lipitor without warrant.

B. Pfizer Reveals, and Presents Evidence of, its Off-Label Marketing Campaign to the Investment Community

122. Pfizer brazenly informed the investment community, in a series of public statements, that the potential market for *new* American Lipitor patients reaches into the tens of millions – far beyond any imaginable number of on-label patients. This despite the fact that Lipitor's own label, by incorporating the Guidelines, places a natural limit on the eligible number of new patients for the drug. At a June 17, 2003, analyst meeting, Karen Katen, the Pfizer Executive Vice President and President of Pfizer Global Pharmaceutical, presented a slide titled "Patient Growth Opportunities: Market Expansion." The slide displayed a pyramid of 64 million Americans that she described as the "platform for growth," *i.e.*, potential patients for Lipitor. The 64 million Lipitor candidates were subdivided into 22 million people being treated, 22 million people diagnosed but not treated, and 20 million people undiagnosed. Ms. Katen stated that Pfizer would take advantage of this opportunity for growth through a combination of educational and promotional activity. As explained below, this constitutes a commitment, by Pfizer, to a program of off-label marketing.

123. According to the Guidelines, there are approximately 37 million Americans eligible for statins, far less than the 64 million promised by Pfizer's Vice President. In fact, Pfizer's own Operating Plan, discussed *infra*, states unequivocally that only 36 million Americans are "Eligible for a Cholesterol-lowering Drug." The gap of 28 million Americans (the difference between the 64 million Pfizer unlawfully markets to and the 36 million Pfizer believes are approved for statin use) represents a pool of patients who do *not* meet Lipitor's

labeling and associated Guidelines, and toward whom any marketing for Lipitor would be unlawful. Half of that "gap" (14.6 million) is filled with Moderate Risk patients unapproved by the Guidelines for Lipitor use.

124. Again, in Pfizer's Second-Quarter 2004 Performance Report, Karen Katen noted, "fresh evidence on statins, and the new U.S. guidelines it has driven, portend more growth potential for Lipitor. Landmark studies such as ASCOT-LLA, CARDS, PROVE-IT, REVERSAL, and Alliance have demonstrated the dramatic health benefits of ever-lower cholesterol, as effected by Lipitor, benefits such as reduced strokes, heart attacks, and the need for invasive procedures. The medical community's growing recognition of this value means in the United States alone, 18.5 million new patients could benefit from lipid-lowering therapy, *elevating the number of Americans Lipitor could help to about 79 million, or 40 percent of all adults*. This new evidence on Lipitor underscores the opportunities for even our major products to help substantially more patients." (Emphasis added.) Only through a highly funded and highly organized fraudulent off-label marketing campaign could this inconceivable number of patients be placed on Lipitor.

125. Pfizer reveals its off-label marketing scheme when it speaks to the investment community, persuading investors that it can expand the market for Lipitor, thereby increasing profit and improving stock performance. Unfortunately, by its illegal, false and misleading off-label promotion of Lipitor, Pfizer has caused millions of ineligible claims to be submitted to federal and state health insurance programs for prescriptions that were medically unnecessary and would not have been written but for Pfizer's fraudulent marketing scheme.

126. As a result of Pfizer's illegal and fraudulent practices, federal and state health programs have suffered and continue to suffer direct and substantial damage. Lipitor "dominates

the statin market" and costs roughly $100 per month depending on dose.[14] Suffice it to say, billions of dollars of potential revenue have been fraudulently taken from the public fisc as a result of Pfizer's deliberate off-label marketing campaign.

C. Pfizer's Improper Use of "Third Party" Organizations and Continuing Medical Education Programs

127. As detailed above, Pfizer has engaged in a massive off-label marketing campaign to expand the market for Lipitor. A significant component of this campaign has included a concerted effort to mislead, confuse and improperly induce physicians to prescribe Lipitor for off-label uses, specifically targeting the Moderate Risk group.

128. Lipitor's commercial success is, in part, the result of Pfizer's false and purposefully misleading marketing of Lipitor and its promotion of statin therapy for patients with LDL levels below treatment cutpoints – *i.e.*, patients for whom the Guidelines do not authorize treatment with Lipitor (or any other statin). Moreover, Pfizer has misled physicians by improperly promoting the idea that all patients should be treated with Lipitor unless they are at their "goal" LDL levels – even if such treatment is not authorized under the Guidelines (and thus under Lipitor's FDA label). In addition to the off-label marketing campaign outlined above, Pfizer has also engaged in a widespread, multi-faceted campaign, designed to provide direct and indirect inducement to physicians who participate in Pfizer-funded "medical educational programs" that recommend off-label, non-reimburseable, uses for Lipitor. Pfizer utilizes "third party" organizations, which they fund through unrestricted educational grants, to promote this campaign.

[14] Consumer Reports, *cited supra* n.1, at 10.

1. Pfizer's unlawful "Medical Education" programs

129. Pfizer acknowledged in its aforementioned "Operating Plan" the importance of "Medical Education Platforms" to promote its off-label marketing agenda. The Plan lists a number of these Pfizer-funded "Medical Education" programs, programs used to promote and amplify Lipitor core marketing messages – including the National Lipid Education Council (NLEC); Emerging Science in Lipid Management (ESLM); and the Vascular Biology Working Group (VBWG). These organizations are an important component of Pfizer's off-label marketing of Lipitor, and provide a more indirect, though no less effective, venue for such marketing.

130. Central to this campaign, Pfizer has sponsored continuing medical education (or "CME") programs, through organizations that fail to meet standards for independence established by the FDA – in effect, little more than sales pitches for off-label uses of statin therapy (and Lipitor in particular). Clinicians who participate in these programs are provided free CME credits – a valuable commodity that clinicians often must accrue in order to maintain their licenses.

131. The substantial promotional use of continuing medical education[15] through unrestricted educational grants is also a cornerstone of the marketing scheme and an area of limited FDA scrutiny. As noted by a leading marketing executive in documents produced in Pfizer's Neurontin off-label marketing litigation, "CME drives this market."

132. Many of these CME programs also include dinner, alcoholic beverages, and valet parking at high-end restaurants. As such, these free CME credits (and accompanying dinners

[15] In 2003, providers accredited by the Accreditation Council for Continuing Medical Education ("ACCME") received commercial support in excess of $971 million, representing a 30% increase over 2002. Overall (and for the first time according to ACCME) commercial support for CME in 2003 exceeded the revenue generated by physicians attending CME programs.

and other perks) are inducements to these doctors in exchange for the doctors' agreement to, often unknowingly, listen to Pfizer's false and misleading off-label sales pitch, and consequently prescribe Lipitor for off-label uses.

133. The previously discussed Cardiovascular Leadership Council program planned CME teleconferences "featuring a nationally-recognized and well-respected cardiologist," "targeting physicians too busy to attend one of the physician education programs [sic] will offer the *incentive* of [free] CME credit for participation." (Emphasis added.)

134. Pfizer engaged in aggressive efforts to "build relationships" with national and local "thought leaders" – doctors who can profoundly influence national and local treatment guidelines and standards of practice. To this end, many of the members of NCEP (the Guidelines sponsor) are also members of, and receive substantial benefits for their participation in, Pfizer-sponsored educational programs. These programs include entities such as the National Lipid Education Council ("NLEC") and the Emerging Science of Lipid Management (see chart below). These benefits include, but are not limited to, indirect benefits such as being selected by Pfizer as investigators on multimillion dollar research grants. Direct benefits include honorarium, speaker fees, travel, entertainment, and having the opportunity to attend meetings and network with luminaries in the cardiovascular disease world. As such these direct and indirect benefits induce leading physicians to serve as faculty in these "educational programs" designed to misrepresent the Lipitor Label and promote off-label prescription of Lipitor.

135. By expanding the pool of patients who were treated with Lipitor to include patients with LDLs below their Guideline treatment thresholds, Pfizer increased its potential market by billions of dollars annually. As a direct result of Pfizer's illegal practices, federal

government health programs have been induced to reimburse claims for prescriptions that they otherwise would not have.

a. Off-Label promotion of Lipitor through the National Lipid Education Council

136. Through an unrestricted educational grant to Thomson Professional Postgraduate Services® (PPS) ("Thomson") – a division of Thomson Corporation's healthcare group – Pfizer funds the National Lipid Education Council (www.ccmdweb.org). (NLEC should not be confused with the NIH NCEP).

137. Pfizer extensively uses free CME programs provided by the NLEC and ESLM (discussed *infra*) to induce clinicians to participate unknowingly in promotional activities with substantive off-label content.

138. These CME programs, which purport to be independent of Pfizer's influence, violate many of the requirements for independence from commercial sponsorships outlined in the FDA, OIG guidance, and even the new ACCME CME standards. Furthermore, by offering free CME credits in conjunction with the programs, Pfizer is inducing practicing physicians in the community to prescribe Lipitor off-label and off-compendium.

139. Thomson "develops medical education activities designed to meet the needs of practicing physicians. PPS, working with medical leaders, designs and implements effective programs to meet specific educational objectives." Educational program formats used by Pfizer (through Thomson) include dinner meetings, congresses, tutorials, audio conferences, seminars, monographs, newsletters, and web-based activities.

140. According to Thomson, "gathering in-depth market intelligence and having a strong marketing and strategic plan in place are critical to the successful launch of a new drug." Thomson Healthcare's sales solutions offer extensive expertise in market research and marketing

and strategic consultancy. Solutions include brand management, clinical trials, continuing medical education, decision support, directories, events, newsletters, specialty guides, and websites.[16] The healthcare division recently accounted for $780 million of Thomson's annual revenues of $7.8 billion.

141. The NLEC Education Initiative was launched in 1996 as the Lipid Management in Clinical Practice program. NLEC represents that its primary focus is to educate physicians and other healthcare professionals about the rationale for cholesterol-lowering therapy, "[t]hrough multifaceted educational activities – including national and regional symposia as well as a variety of print, audio, and visual media – the NLEC strives to reach healthcare professionals nationwide to effect better health outcomes for patients."

142. Many of the members of NCEP are also members of – and receive substantial benefit for their participation in – NLEC (and ESLM).

143. As of 2003, there were a total of 14 members of the NCEP. The chairman of NCEP is a NLEC Steering Committee member and primary contributor to a recent Pfizer-funded Lipitor clinical trial. Seven of the NCEP members have participated in the Pfizer-funded NLEC. There are twenty-two Reviewers of the Full Report ("RFR") of ATP III. Eight of the NCEP RFRs were active participants in the Pfizer-funded NLEC (and/or ESLM). Dr. Antonio M. Gotto, a NCEP RFR, is the Chairman of both the NLEC and ESLM.

144. The chart below shows the overlap between membership on the NCEP ATP-III publication, the NLEC, and ESLM. The column on the right shows which members are primary authors of Pfizer-funded drug research on hyperlipidemia.

[16] In addition, Thomson Micromedex is the publisher of the drug compendiums DrugDex and USP-DI (authorized Medicaid, Medicare Prescription Drug Card, and Medicare Part D compendia). USP-DI is also an authorized Medicare Part B drugs and biologics compendium. Thomson purchased USP-DI from USP in late 2004. The only compendium used by Medicaid, Medicare Prescription Drug Card, and Medicare Part D that is not under the editorial control of Thomson is the American Hospital Formulary System compendium.

Name	NCEP Role	NLEC Role	ESLM Role	Primary Author for major Pfizer funded Clinical Trials
S. Grundy	Chairman and American Heart Association Representative	Steering Committee		TNT (Intensive Lipid Lowering with Atorvastatin in Patients with Stable Coronary Artery Disease)
H. Brewer[17]	Ex-Officio (NIH)	Faculty		
L. Clark	Member and National Medical Association Rep.	Council Member		
S. Haffner	Consultant	Steering Committee		Member, Data Safety Monitoring Board of TNT
D. Hunninghake	Member	Former Council Member		
J. McKenney	Member and American Pharmaceutical Association Rep.	Council Member		
P. McBride	Member	Council Member		
R. Pasternak[18]	Member, and American College of Cardiology Rep.	Former Council Member		
N. Stone	Member	Council Member		
W. Brown	RFR	Council Member		
H. Ginsberg	RFR	Council Member		
A. Gotto	RFR	Chairman	Chairman	TNT
R. Krauss	RFR	Steering Committee		

[17] Resigned during Congressional NIH conflict of interest hearings.

[18] Joined Merck three months after the publication of the ATP III update.

Name	NCEP Role	NLEC Role	ESLM Role	Primary Author for major Pfizer funded Clinical Trials
J. LaRosa	RFR	Steering Committee CME Planning Committee		TNT
T. Pearson	RFR	Steering Committee		
D. Rader	RFR	Council Member		Effects of CETP on HDL Cholesterol
N. Wenger	RFR	Council Member	National Faculty (Steering Committee)	TNT
S. Nissen		Council Member	National Faculty (Steering Committee)	Celebrex Safety trial ILLUSTRATE – Torcetrapid safety and efficacy trial REVERSAL (Reversal of Atherosclerosis with Aggressive Lipid Lowering) Statin Therapy, LDL Cholesterol, C-Reactive Protein, and Coronary Artery Disease
G.G. Schwartz			National Faculty (Steering Committee)	MIRACL (Effects of atorvastatin on early recurrent ischemic events in acute coronary syndromes)
M. Clearfield	American Osteopathic Association Rep.	Council Member		

145. Many of the NLEC and ESLM faculty receive direct or indirect funding from Pfizer through travel, entertainment, honorarium, speaker fees, and other remuneration. Many of the faculty are also active participants in the NCEP, and are actively engaged in multi-million dollar Pfizer-funded clinical trials. Through their various activities, these physicians are compensated by Pfizer for their recommendations of Lipitor outside the Guidelines, thus encouraging practicing physicians to prescribe Lipitor for such uses.

146. In February 2003, NLEC held its Annual Update Meeting in Half Moon Bay, California. (Meetings for the NLEC are typically held at high-end resorts and restaurants.) The gathering, with an agenda entitled "Strategies for CVD Risk Reduction," was attended by more than 50 of the NLEC steering committee and council members, many of whom were noted by NLEC to be the leading experts in lipids and cholesterol control.

147. In addition, NLEC convenes meetings for practicing physicians and provides free CME activities. Free CME is provided at conferences, dinner meetings at high-end restaurants, through newsletters, and by the Internet.

148. The NLEC uses a general disclaimer in its printed materials and in live presentations that "discussions are present of off-label, non-FDA approved uses of certain therapies." In the live NLEC presentation experience of the relator, a general disclaimer is made at the beginning of the presentation, but the on vs. off-label materials and topics are never clarified. NLEC on the internet, in the "Introduction" to the "Virtual Case Studies" in the online section on "technical instructions and CME," notes "that some treatment outlined in these cases may not adhere to National Cholesterol Education Treatment Panel III (ATP III) guidelines." However, in general, deviations from Lipitor labeling and Guidelines are not readily apparent during the "educational" activities of the NLEC. This general "disclaimer" utterly fails to clarify

to its audience which parts of the materials are in compliance with the Guidelines (and FDA label) and which constitute off-label marketing.

149. For example, practicing physicians seeking CME credits are invited to a case study on the NLEC website that unabashedly promotes off-label use of Lipitor among Moderate Risk patients. In a case titled "46 Year-Old Carpenter," a patient with two risk factors and a 10-year risk of having a heart attack of less than 10 percent with an LDL below 160 (*i.e.*, below *cutpoint*), Jerome D. Cohen, M.D., a clinical investigator for Pfizer, recommends statin therapy for the Moderate Risk patient. No notation is present during the case or case discussion that identifies the treatment decision recommended as being contrary to the Guidelines and the FDA labeling for statins. The patient is falsely described at various parts of the case as being at "moderately high risk," "relatively high risk," and at "high risk."

150. The NLEC Winter 2004/2005 Newsletter (Vol. 9 No. 4 with CME Post-test) provides another example of the off-label promotion and misrepresentation of the Guidelines. The newsletter provides a CME case study of a 74 year-old white female with respect to whom the author recommends statin therapy off-label, and outside the Guidelines. The author, Dr. McCann, is a paid member of Pfizer's speaker's bureau and is a consultant to Pfizer. She recommends statin therapy, and, as with Pfizer's marketing materials, she misrepresents the Guidelines, suggesting that the 74 year-old female is "not at ATP III guidelines," (*i.e.*, not at goal) when in fact she is in the Low Risk group not in need of statin therapy with an LDL below her cutpoint. Pfizer compensates physicians such as Dr. McCann and Dr. Cohen to promote off-label uses at the targeted Moderate Risk group – just as Pfizer set out to do in its Operating Plan (discussed *supra*).

b. Off-Label Promotion of Lipitor through the Emerging Science in Lipid Management program and other organizations

151. As mentioned, ESLM (www.eslm.org) is also identified as a key component of Pfizer's 2002 Lipitor Operating Plan. As with the NLEC program, the ESLM program remains active and is designed to employ established and early-career thought leaders to promote off-label use of statins, in general, and Lipitor, in particular. ESLM is funded, in total, by an unrestricted educational grant from Pfizer.

152. According to the ESLM website, ESLM was begun in 2001 to provide "a strategy for educating physicians across the country about fundamental changes in the scientific and clinical understanding of atherosclerosis and heart disease."

153. The website also states: "Under the guidance of national Co-Chairs Antonio M. Gotto, Jr., MD, DPhil, and Peter Libby, MD, a distinguished national faculty meets each year to identify the Key Challenges that clinicians face in assessing, preventing, and treating cardiovascular disease." Since its inception in 2001, the ESLM Program has sponsored numerous CME-accredited live dinner meetings, teleconferences, and online activities that underscore the importance of early, aggressive management of dyslipidemia. ESLM also publishes Lipid Letter, a CME-accredited quarterly newsletter, with in-depth articles by regional faculty addressing the full range of lipid-related topics.

154. The website notes that "ESLM is intended to reach thousands of cardiologists, cardiology fellows, and other physicians through a series of CME-accredited educational activities. In addition, 18,000 cardiologists and 60,000 internal medicine physicians will receive the quarterly *Lipid Letter*, a 12-page newsletter that disseminates the latest findings on managing dyslipidemia."

155. The ELSM annually assembles "Regional Working Groups" of distinguished clinicians to assist with the program. These working groups were aligned and named identically to the eight domestic Pfizer "Primary Care Sales Regions: Western, Southwest, Midwest, Southeast, Great Lakes, Mid-Atlantic, and Northeast." (emphasis added). This is not a coincidence – the Regional Work Groups are part of the Pfizer marketing machine.

156. A 2004 invitation was mailed to physicians inviting participation in the ESLM national program "New Paradigms in Cardiovascular Risk Reduction: A CME Teleconference," indicating that free CME is provided. The "Learning Objectives" state: "At the conclusion of this activity, participants should be able to apply NCEP guidelines and other data to management of patients who have, or who are at risk of, coronary heart disease." However, this Pfizer-funded organization provided little clarity as to when the Guidelines-conforming information ended, and the "off-label" information began. The program's slide booklet merely notes "Off-Label Product Discussion: In the event that a speaker discusses a product that is either not approved or the product is investigational, the speaker will disclose this information to the audience at the time of the presentations." The disclaimer does not begin to address the wide ranging discussions in the program of off-label uses of FDA approved cholesterol-lowering drugs.

157. ESLM, as part of their website and CME activities, promotes the use of a web-based "NCEP" decision support tool. The tool was produced by Jon Keevil, M.D., an ESLM faculty member, and is available at www.heartdecision.org. The tool calculates cardiac risk and provides treatment recommendations. However, contrary to the Guidelines (and thus, contrary to Lipitor's FDA label), the ESLM promoted-tool indicates that Moderate Risk patients be given statin even when their LDL levels are below the NCEP drug therapy cutpoints.

158. ESLM's free online CME called "Online Grand Rounds" also promotes off-label use of statins, through the presentation of hypothetical patients for whom drug therapy is recommended outside the Guidelines.

159. Clinical case history 21 ("Lipid Management in a Middle-Aged Woman in the Moderate-Risk Category: Determining Appropriate Statin Use") provides a response in the "Ask the Author" section of the program, recommending Lipitor therapy for a 49-year old Moderate Risk patient with a proposed 10-year risk of 6%. This is plainly contrary to the Guidelines and Lipitor's FDA label which provide that such a patient would be in the "Moderate Risk" group, and thus statin therapy would *only* be authorized if her LDL level was 160 or higher.

160. Pfizer has sponsored, through educational grants, a range of other sophisticated national and regional "educational programs" designed to promote off-label use of Lipitor. These include, *inter alia*, the Vascular Biology Working Group (www.vbwg.org); Heart Advocacy Network (www.healthadvocacy.org); the Coalition for the Advancement in Cardiovascular Health (www.coachcvhealth.org); and the Association for Eradication of Heart Attacks (www.aeha.org). The Vascular Biology Working Group is listed in Pfizer's 2002 Operating Plan alongside ESLM and NLEC. The Association for Eradication of Heart Attacks is noteworthy for its focus on encouraging the rapid diffusion of unproven diagnostic tests to identify "at risk" patients. Once identified, correctly or incorrectly, this group of patients becomes a new pool of patients for Lipitor therapy.

161. In sum, the design and effect of these Pfizer-sponsored "medical educational groups" is to encourage physicians in attendance to either directly increase their off-label prescriptions for Lipitor and/or to recommend that other physicians do the same. These efforts

result directly in an increase in off-label prescriptions for Lipitor, with a corresponding increase in sales for Pfizer and false claims to government programs.

D. Pfizer Violated the Anti-Retaliation Provisions of the False Claims Act

162. In his capacity as Medical Director for the Local Marketing Team Review Committee, Dr. Polansky was a member of the corporate team which included representatives from Legal, Regulatory Affairs and Medical Affairs and which was responsible for approving "local" marketing activities related to the promotion of Pfizer drugs, including Lipitor. Local marketing consisted of marketing programs tailored for local major markets such as New York, Boston, Miami, Atlanta, Chicago, and San Francisco.

163. Dr. Polansky represented medical affairs on the Local Marketing Team Review Committee and was principally accountable for the clinical integrity of local marketing activities.

164. In reviewing local marketing efforts related to cardiovascular disease, Dr. Polansky reviewed local programs such as the Atlanta Cardiovascular Leadership Council and the Boston Heart Party. He also requested and became familiar with many of the "national" marketing materials for Lipitor.

165. In reviewing both local and national Lipitor marketing materials, Dr. Polansky began to have concerns about the integrity of the materials used in the cardiovascular marketing programs, including both promotional and non-promotional material.

166. Specifically, Dr. Polansky became concerned that Pfizer's use and communication of NCEP/ATP III information in marketing materials, messages and programs seemed potentially misleading and inaccurate. He was concerned, among other things, that Pfizer marketing materials contained oversimplified messages concerning high cholesterol, that the role of diet and exercise in lipid management was being minimized, that cholesterol goals

and cutpoints were being confused, and that the four patient risk categories established by NCEP/ATP III were being compressed into three categories.

167. Based on his review of the aforementioned marketing materials, Dr. Polansky was concerned that Pfizer was being overly aggressive in marketing Lipitor and that this could have negative consequences for the company, including causing substantial damage to Pfizer's reputation in the marketplace if its marketing materials were discovered to be inaccurate or misleading.

168. Based on his review of the marketing materials, Dr. Polansky also was concerned that overly aggressive marketing of Lipitor would likely lead to over-prescription of the drug, which could, *inter alia*, compromise patient health, result in unnecessary billings to patients in the form of co-pays, and result in fraudulent billings to insurers and the federal government for prescription of drugs that were not medically indicated.

169. As a result of the aforementioned concerns, Dr. Polansky began to more fully investigate the propriety of Pfizer's Lipitor marketing program.

170. Beginning in the Fall of 2002, Dr. Polansky began to request and compile a more comprehensive inventory of the corporately developed and approved Lipitor marketing materials.

171. As part of this activity he attended Plan of Action (POA) meetings at which sales representatives are trained on company marketing plans.

172. His assessment of the POA and the associated materials added to his concerns that Lipitor was being marketed too aggressively.

173. Beginning in the fall of 2002, Dr. Polansky sought to alleviate his concerns about the Lipitor marketing programs by meeting with physicians who worked in conjunction with the

Corporate Lipitor Review Committee. He met at least twice with Connie Newman, M.D. from Regulatory Affairs. At one of the meetings they were joined by a physician colleague of Dr. Newman.

174. Dr. Newman and her colleague both agreed that the Pfizer produced paper-based cardiac risk assessment (PCRA) needed to be removed from circulation and rewritten immediately.

175. Dr. Polansky's inquiries regarding risk categories, treatment cutpoints, and treatment goals were not answered by Dr. Newman or her colleague.

176. Shortly after Dr. Polansky made his inquiries about Lipitor marketing to Dr. Newman, she moved from Regulatory Affairs to the Lipitor Disease Management Team (the group accountable for creating and managing the national Lipitor marketing efforts).

177. During 2002, Dr. Polansky also contacted Dr. Gary Palmer a senior physician on the Lipitor Disease Management Team to set up a meeting to discuss the marketing plan and materials for Lipitor. Dr. Palmer would not schedule a meeting with Dr. Polansky.

178. In early 2003, Dr. Polansky spoke to Pat Andrews, the Senior Director for Local Marketing and advised her of some of his concerns regarding approved materials. He also noted his difficulty in getting his questions answered by Dr. Newman.

179. Ms. Andrews acknowledged the importance of Dr. Polansky's concerns and advised him to convene a meeting to further explore the issues.

180. Ms. Andrews identified as potential attendees a list of Pfizer medical directors involved in producing key documents such as the Pfizer/NBC Mayor's Health Challenge 2002 screening tool.

181. Dr. Polansky had identified this document as potentially inaccurate and misleading because it listed three cardiac risk categories in contrast to the four risk categories with which Dr. Polansky was familiar.

182. In mid-February 2003, Dr. Polansky met with Pfizer's Compliance Unit. During this meeting, Dr. Polansky restated his concerns about Lipitor being marketed too aggressively, including, for example, commenting that he had come to believe that some of the product marketing teams were not being adequately monitored and that their review committees were not being permitted to do their jobs. He said that this was putting Pfizer at risk.

183. Dr. Polansky advised the Compliance Unit that he was arranging for a meeting of relevant medical directors because of his concerns regarding the materials used in marketing Lipitor.

184. Dr. Polansky also communicated that the Local Marketing Team Review Committee had been told that Lipitor local marketing programs would no longer be reviewed by the Local Marketing Team Review Committee and that these programs would only be reviewed by the "national" Lipitor Review Committee.

185. This change in procedure followed a critical initial review of the Cardiovascular Leadership program in Atlanta by the Local Marketing Team Review Committee.

186. Dr. Polansky also communicated that one of the junior members of the Local Marketing Team Review Committee had been intimidated by Pfizer officials after the Local Marketing Team Review Committee had been critical of a marketing proposal for the drug Zoloft.

187. By reason, *inter alia*, of Dr. Polansky's meetings and communications with Dr. Newman, Ms. Andrews and the Compliance Unit, Pfizer was well aware of Dr. Polansky's

ongoing concerns regarding aggressive and potentially illegal marketing of Lipitor, and knew that his activity concerned potentially false or fraudulent claims against the federal government which could be asserted in a False Claims Act action.

188. At the time of Dr. Polansky's investigation of Lipitor marketing activities and his internal reporting of serious concerns about those activities, both Dr. Polansky and Pfizer were well aware of the ongoing False Claims Act litigation initiated by a former Pfizer employee regarding the off-label promotion of the Pfizer drug Neurontin.

189. Within days of his meeting with the Compliance Unit, and before he had an opportunity to assemble the relevant medical staff, on February 20, 2003, Dr. Polansky's employment with Pfizer was terminated.

E. Pfizer Violated the Anti-Retaliation Provisions of Title VII, the New York State Human Rights Law, the New York City Human Rights Law and the New York State Whistleblower Statute

190. In November 2001 and continuing into January 2002 as part of Pfizer's annual performance assessment process, Dr. Polansky met with his immediate supervisor, Andrew Baker and independently with Baker's supervisor, Benjamin Eng, MD. They provided feedback on plaintiff's performance and the performance of the OMS team, telling plaintiff that he "was an outstanding performer, highly valued by Pfizer, and had a bright future." In addition, Dr. Eng coached plaintiff that the OMS Team was "undergoing routine challenges faced by a newly formed team," and that plaintiff "had no reason to be concerned." He also said that this was Baker's first management assignment and this inexperience would contribute to difficulties the team was experiencing.

191. During his discussions with Dr. Eng, Dr. Polansky broached his concerns about Baker's "fraternity house" behavior, including hostile behavior to women. Dr. Polansky noted his discomfort with Baker's comments in November 2001 about Lisa Ladieri, a member of their

department leadership team, when Mr. Baker called her "Lisa Lardass" and referred to her as a "disgusting fat bitch." Dr. Eng stated that he could not respond to something that occurred while he was not present and advised Dr. Polansky that going to Human Resources about his concerns was not going to be productive for his career. Baker also asked Dr. Polansky to be "patient" and to not engage human resources in a discussion about the team's performance.

192. On February 28, 2002, based on his annual performance review by Baker and Dr. Eng, which was approved by the department's Vice President, Lisa Egbuono-Davis, M.D., Dr. Polansky received a substantial bonus and raise. The amounts far exceeded the targets established when he was hired and confirmed the verbal communications about outstanding performance. During 2001, Dr. Polansky had also achieved the maximum amount of company awards for exceptional behavior in "innovation, leadership, performance, and respect." These awards based on nominations from superiors and peers are part of the Pfizer "Stars" program. Additionally, on March 11, 2002, Dr. Polansky received a significant number of Pfizer stock options.

193. On March 20, 2002, Dr. Polansky met with Maile Dooley, Manager, Human Resources, Worldwide Medical and Regulatory. During this meeting, he complained, providing specific examples that Baker had created a sexually hostile and harassing work environment. Dooley assured Dr. Polansky that "these are issues Pfizer takes seriously, an investigation will be rapidly undertaken, and no retaliation will take place." In addition, Dooley instructed him to "immediately report any new instances of sexual harassment." Upon information and belief, Pfizer's investigation confirmed Dr. Polansky's allegations. On April 17, Dr. Polansky met with Rob Morrow, an outside consultant hired by Baker to improve team performance. Morrow suggested to Dr. Polansky that he was placing his Pfizer career at risk and contributing to team

disharmony because his ideals and high standards of integrity were making his supervisor and teammates uncomfortable.

194. Pfizer has a national sales force, including representatives in New York state, numbering thousands of individuals. Since mid-2001 until at least December 2003, they have had the ability to order and detail to physicians and physician offices, and have distributed, medical advertising material on a compact disc ("CD"). In addition to reporting a hostile work environment, Dr. Polansky also raised concerns that this CD contained an electronic copy of a flawed and hazardous paper-based cardiac risk assessment ("PCRA") described below.

195. In addition, the promotional CD, including the PCRA, has been actively used in marketing and sales activities directed at the public through health education activities at Pfizer's large segment clients such as employers, managed care organizations, etc. The promotional materials, including the PCRA, are also distributed to, read by and used by non-physician "laypersons" without concurrent or scheduled consultation with physicians.

196. Pfizer's Lipitor health education compact disc includes a flawed and hazardous PCRA, Pfizer/FDA tracking number LP102919. The PCRA is an inaccurate reproduction of a cardiac risk assessment produced by the National Heart and Blood Institute of the National Institutes of Health (NIH) National Cholesterol Education Panel/Adult Treatment Panel III ("NCEP/ATP III"). The PCRA was approved for use, according to Pfizer policy, by Pfizer's Lipitor Review Committee in 2001 and other Pfizer committees, and was actively used by Pfizer's sales force as part of the promotional campaigns surrounding Lipitor and NCEP/ATP III for several years.

197. The PCRA is a worksheet designed for use by patients and physicians to calculate an individual's cardiac risk. The PCRA is integrally combined with other information about

Lipitor on the CD such that the reader of the information would use it to assess the suitability of treatment with Lipitor. Calculating cardiac risk and using cardiac risk to assess the need for drug treatment under Lipitor's directions for use is an essential component of Lipitor's FDA approved labeling. Lipitor's labeling is regulated under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA").

198. As summarized below, the PCRA is flawed and hazardous for multiple reasons. First, although the PCRA actually calculates the risk of heart *attack*, Pfizer's instructions incorrectly state that the PCRA calculates risk of heart *disease*. Second, the PCRA neglects to instruct high risk patients that the PCRA is not intended for their use, *e.g.*, that the high risk group of diabetics should not use the instrument. At the time Dr. Polansky was discussing his concerns at Pfizer about the PCRA he was not yet aware of the bias in the paper calculators to overestimate risk for many other patients (as discussed above).

199. According to NCEP/ATP III, risk assessment for determining 10-year risk (the risk of having a heart attack within ten years) is carried out according to the Framingham heart study risk scoring, which derives from an update of the Framingham database and methodology. As a result, the revised scoring applies specifically to heart attack rather than heart disease. Previous Framingham risk scoring provided estimates of total heart disease. Generally, estimates for heart attack are about two-thirds to three fourths of those for heart disease.

200. In addition, NCEP/ATP III issued guidelines for the indications for drug treatment for patients with high cholesterol. These guidelines are included in Lipitor's labeling as Lipitor's FDA approved treatment indications. For example, if a patient with two cardiac risk factors has a ten year risk of having a heart attack of 10% to 20%, Lipitor is approved for use in patients with an LDL cholesterol level of greater than 130. However, if a patient with two cardiac risk

factors has less than 10% chance of having a heart attack within ten years, the threshold for drug treatment is an LDL level of greater than 160.

201. As illustrated above, risk assessment has an essential role in cholesterol management, and errors in risk assessment calculation can make substantial differences in patient treatment. Patients who are misclassified as being lower in risk are significantly more likely not to receive the necessary guidance and treatment, and significant segments of patients with cardiovascular risk are exposed to unnecessary morbidity and mortality. Moreover, because the PCRA underestimates the risk of heat attack, it provides incorrect and misleading information for deciding whether Pfizer's indications for use of Lipitor, which are included in the package insert portion of the product labeling, are met.

202. Cardiovascular disease is the number one cause of mortality in the United States. An estimated 17.5 million adult Americans without coronary heart disease ("CHD"), or a CHD risk equivalent, have two or more risk factors. All of these patients, according to national treatment guidelines, should undergo a cardiac risk assessment using a cardiac risk assessment. Therefore, at a minimum, more than 10% of adult Americans should be undergoing risk assessment, according to the guidance of ATP III.

203. According to NCEP/ATP III, the cardiac risk assessment "tool is designed to estimate risk in adults aged 20 and older who do not have heart disease or diabetes."

204. According to the American Heart Association, almost 13 million Americans have heart disease; according to the American Diabetes Association, 17 million Americans have diabetes. People with existing heart disease and diabetes are in the high risk treatment group according to ATP III, but the Pfizer risk calculator, depending on their individual risk factors, may rate them in a lower risk category. If patients and/or their physicians falsely believe the

patient is not at high risk, the necessary health interventions are likely not to occur, exposing substantial numbers of patients to complications from heart disease or possible heart attack.

205. The impact of the two errors Dr. Polansky identified during his tenure at Pfizer was to underestimate cardiac risk for many of the people who most need to have an accurate understanding of their risk of having a heart attack. He was not aware of the additional, and more hazardous, error that the PCA overstated risk for many other patients.

206. There has been a substantial and specific danger to the public health and safety created by Pfizer's use of the flawed and hazardous PCRA, and by its refusal, despite Dr. Polansky's ongoing efforts since May 2002, to stop national and local distribution of the PCRA. The PCRA directly impacts clinical decision makers and the patients who rely on its scientific integrity. A patient who is misclassified as having lower cardiac risk than is actually present is less likely to seek and be provided with the necessary medical care to prevent subsequent cardiovascular morbidity and mortality. A patient who has been identified as having greater risk than is actually present may be prescribed expensive and potentially dangerous medications that are not necessary.

207. Section 301 of the FDCA, 21 U.S.C. § 331(a) and (b), prohibits "misbranding" drugs. Section 502 of the FDCA, 21 U.S.C. § 352(a), provides that misbranding includes false or misleading labeling. FDA regulations at 21 C.F.R. § 202.l(l)(2), promulgated pursuant to the FDCA, define labeling to include brochures and detailing pieces, like the PCRA distributed on Pfizer's CD. Under 21 U.S.C. § 352(a), a drug is misbranded if its labeling is false or misleading in any particular. The FDCA, 21 U.S.C. § 352(f)(1), requires that a drug's labeling bear adequate directions for its use. Further, the FDCA, 21 U.S.C. § 352(n), prohibits misleading

labeling or advertising, including representations that fail to reveal facts material to the conditions of use prescribed in the labeling or advertising.

208. The false and misleading statements in the PCRA described above constitute misbranding, in violation of the FDCA and regulations cited above, which violation presents a substantial and specific danger to the public health and safety.

209. In May 2002, colleagues provided Dr. Polansky with a copy of the Lipitor Disease Management Team PCRA to use in a project on which he was working. After months of discussions with his immediate work group (Outcomes Research), Dr. Polansky was successful in convincing his supervisors not to use the PCRA on this project because it was flawed and hazardous. However, Dr. Polansky was unsuccessful in convincing Pfizer and the Lipitor Marketing Team to remove supplies of the PCRA from warehouses and cease the ongoing distribution of the misleading, dangerous and illegal PCRA contents described above.

210. Dr. Polansky's efforts to stop use of the PCRA began in early May 2002 and continued for the rest of his employment, and even after his firing. Dr. Polansky used Pfizer's Open Door Policy extensively to communicate his concerns about the PCRA remaining in circulation to leadership in Outcomes Research and Human Resources. Baker told Dr. Polansky that if he contacted physicians on the Lipitor Disease Management Team directly with his concerns about the PCRA, he would be fired. Dr. Eng told Dr. Polansky that his inquiries into the PCRA were "none of [his] business" and "would only cause [him] hardship." Dr. Newell McElwee, another member of the Outcomes Research Senior Management Team, told Dr. Polansky that "the marketing team can and will do what they want regardless of the clinical integrity of the materials." Jack McMillan, another member of the Outcomes Research senior

management team, told Dr. Polansky that his "problem" was that he "was looking into issues that [were] none of [his] business."

211. Dr. Polansky also served, independently of his work in Outcomes Research, as the Medical Director for the Local Marketing Team Review Committee. As part of this responsibility, he met with Dr. Connie Newman, who is on the Lipitor Review Committee, in December 2002, on issues related to cardiovascular risk assessment. During this meeting he presented his concerns about the PCRA and was assured that his concerns were legitimate and that the "materials should be immediately removed from circulation." Once again, no action was undertaken.

212. Prior to and including the date of his termination, Pfizer progressively retaliated against Dr. Polansky in a variety of ways, including: threats, reprimands, false evaluations, substantially reduced incentive compensation, harassment, significant adverse changes in work duties and responsibilities, cancellation of agreed upon educational/development benefits, interference with transferring to other positions within Pfizer, and other adverse treatment. Despite Dr. Polansky's attempt to redress that harassment, defendant took no appropriate remedial action. Rather, he suffered retaliation for daring to complain.

213. On May 30, 2002, Baker and Dooley held a formal meeting with Dr. Polansky, in which they "warned" him about "Teamwork" and related behavior. Dr. Polansky's supervisors had previously viewed alleged interpersonal issues as only "minor team issues" related to a formation of a new team; but they now presented these as serious issues about his performance. They threatened him with disciplinary action and told him that he had sixty days to make the necessary corrections.

214. Dr. Polansky met multiple times during the summer and early fall of 2002 with Vice President of Human Resources Kathy Donovan to provide additional details about the hostile work environment and complain that he was being retaliated against for raising the above concerns about the PCRA and sexual harassment, but she did nothing to stop the retaliation.

215. On October 21, 2002, two days after his last meeting with Donovan, Pfizer placed Dr. Polansky on a formal Performance Improvement Plan. This plan was extended on January 16, 2003.

216. Dr. Polansky's 2002 annual evaluation was discussed and provided to him in December 2002. As part of the evaluation process, the company requests formal feedback from a range of employees, approved by the supervisor, who have worked closely with individual being reviewed. Most of the employees giving feedback on Dr. Polansky provided him, as a courtesy, their evaluations, all of which were overwhelmingly positive. Baker's evaluation, however, was negative and grossly misstated Dr. Polansky's technical and interpersonal achievements, contrary to the employees' feedback on which it was designed to be based. Baker wrote that "Jesse was relentless in conveying his desire to have direct access to members of the Lipitor Disease Management Team, despite being advised on numerous occasions that Outcomes Research's approach is to maintain a single point of contact with product teams."

217. The week before he was terminated in February 2003, Dr. Polansky met with Pfizer's Compliance Unit to discuss various issues, including restating his concerns about retaliation against him because of his efforts to stop sexual harassment and to correct the PCRA.

218. The Compliance Unit falsely assured Dr. Polansky that no adverse employment action would be taken until they had investigated his "claims." Notwithstanding this assurance, Pfizer fired Dr. Polansky on February 20, 2003, a few days after the meeting with the

Compliance Unit. Pfizer subsequently placed Dr. Polansky back on the payroll, but not at work, until July 31, 2003, as an interim measure, while the Compliance Unit completed its investigation. The Compliance Unit inadequately investigated and did not respond adequately to the facts Dr. Polansky showed, and, in further retaliation, concluded that Dr. Polansky's dismissal was not improper.

219. Upon information and belief, since firing Dr. Polansky, Pfizer has interfered in Dr. Polansky's search for subsequent employment and has attempted to discredit him.

220. After his firing, Dr. Polansky continued his efforts to have Pfizer cease distribution of the flawed and hazardous PCRA through ongoing efforts with the Compliance Unit. The Compliance Unit first maintained a position that the PCRA was never put into circulation, and then changed to asserting that the clinical integrity of the PCRA was subject to different medical opinions, neither of which responses is supportable. In December 2003, Pfizer notified Dr. Polansky that it was stopping distribution of the PCRA, but Dr. Polansky was unable to verify this.

221. The foregoing retaliatory acts of defendant were performed willfully, intentionally, and with reckless indifference to plaintiff's protected rights.

COUNT I

FEDERAL FALSE CLAIMS ACT

31 U.S.C. §§ 3729(A)(1) AND (A)(2)

222. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

224. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

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

226. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

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

228. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

229. Efforts by plaintiff to assist the Government in learning about this fraudulent scheme include requests made by plaintiff-relator for records submitted by Pfizer to the Government, and various government health care expenditure documents, under the Freedom of Information Act 5 U.S.C. § 552. Plaintiff has been informed by the Office of Inspector General, as recently as June, 2007, that Pfizer is objecting to the release of various documents.

230. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. Federal health insurance programs have paid millions of claims, amounting to billions or many hundreds of millions of dollars, for off-label prescriptions for indications that were not approved by the FDA.

COUNT II

FALSE CLAIMS ACT

31 U.S.C. § 3730(H)

231. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-221 of this Complaint.

232. By terminating the employment of Dr. Polansky, and otherwise retaliating against him, Pfizer violated 31 U.S.C. § 3730(h), which prohibits an employer from discharging or otherwise discriminating against an employee because of lawful acts undertaken by that employee in furtherance of investigating False Claims Act violations.

233. As a result of these wrongful actions, Dr. Polansky suffered and continues to suffer substantial damage.

COUNT III

CALIFORNIA FALSE CLAIMS ACT

CAL. GOVT. CODE § 12651(A)(1) AND (2)

234. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

236. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

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

238. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

240. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

241. By reason of the defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

242. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT IV

DELAWARE FALSE CLAIMS AND REPORTING ACT

6 DEL. C. § 1201(A)(1) AND (2)

243. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

245. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

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

247. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

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

continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

250. By reason of the defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

251. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT V

FLORIDA FALSE CLAIMS ACT

FLA. STAT. ANN. § 68.082(2)

252. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

254. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

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

256. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

258. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

259. By reason of the defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

260. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT VI

HAWAII FALSE CLAIMS ACT

HAW. REV. STAT. § 661-21(A)

261. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

263. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

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

265. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

267. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

268. By reason of the defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

269. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT VII

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. § 175/3(A)(1), (2)

270. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

272. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

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

274. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

276. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

277. By reason of the defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

278. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT VIII

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE ANN. § 5-11-5.5-2(B)(1)-(2)

279. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

281. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

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

283. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

284. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities,

across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

285. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

286. By reason of the defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

287. The State of Indiana is entitled a penalty of at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT IX

LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW

LA. REV. STAT. § 46:437 *ET SEQ*.

288. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

290. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

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

292. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

294. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

295. By reason of the defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

296. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT X

MASSACHUSETTS FALSE CLAIMS LAW

MASS. GEN. LAWS CH. 12 § 5B(1), (2)

297. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

299. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

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

301. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

303. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

304. By reason of the defendant's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

305. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XI

MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS. § 400.601 *ET SEQ*.

306. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

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

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

310. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

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

continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

313. By reason of the defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

314. The State of Michigan is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XII

MONTANA FALSE CLAIMS ACT

MONT. CODE ANN. § 17-8-403(1)(A)-(B)

315. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

317. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

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

319. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

321. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

322. By reason of the defendant's acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

323. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XIII

NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. ANN. § 357.040(1)(A), (B)

324. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

326. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

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

328. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

330. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

331. By reason of the defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

332. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XIV

NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. REV. STAT. ANN. § 167:61-B(I)(A)-(B)

333. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

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

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

337. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

339. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

340. By reason of the defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

341. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XV

NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. § 27-2F-4(A)-(C)

342. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

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

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

346. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

348. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

349. By reason of the defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

350. The State of New Mexico is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XVI

TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS ACT

TENN. CODE ANN. §§ 4-18-103(A) *ET SEQ.* AND 71-5-182(A)(1) *ET SEQ.*

351. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

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

353. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

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

355. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

357. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

358. By reason of the defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

359. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XVII

TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE ANN. § 36.002

360. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

361. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

362. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

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

364. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

366. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

367. By reason of the defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

368. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XVIII

VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. CODE ANN. § 8.01-216.3(A)(1), (2)

369. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

370. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

371. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

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

373. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

374. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Pfizer's conduct. The false claims were presented by thousands of separate entities,

across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

375. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

376. By reason of the defendant's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

377. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XIX

DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

D.C. CODE ANN. § 1-1188.14(A)(1), (2)

378. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 161 of this Complaint.

379. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

380. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

381. By virtue of the acts described above, Pfizer knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

382. Each prescription that was written as a result of defendant's illegal marketing practices represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

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

384. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for Pfizer's false and illegal off-label marketing practices.

385. By reason of the defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

386. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Pfizer.

COUNT XX

TITLE VII

42 U.S.C. §2000E *ET SEQ*.

387. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 190-221 of this complaint.

388. Defendant has violated Title VII by discriminating against plaintiff by retaliating against him because he complained of, reported and opposed sexual harassment and a discriminating work environment, and because he complained of retaliation for such opposition.

389. Defendant acted intentionally and with malice and/or reckless indifference to plaintiff's rights protected by Title VII.

390. Plaintiff has suffered, is now suffering, and will continue to suffer irreparable injury and monetary damages as a result of defendant's retaliatory conduct until and unless this Court grants relief.

COUNT XXI

NEW YORK HUMAN RIGHTS LAW ("HRL")

NEW YORK EXECUTIVE LAW § 290

391. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 190-221 of this complaint.

392. Defendant has violated the HRL by discriminating against plaintiff by retaliating against him because he complained of, reported and opposed sexual harassment, and a discriminatory work environment, and because he complained of retaliation for such opposition.

393. Plaintiff has suffered, is now suffering, and will continue to suffer irreparable injury and monetary damages as a result of defendant's retaliatory conduct until and unless this Court grants relief.

COUNT XXII

NEW YORK CITY HUMAN RIGHTS LAW ("NYCHRL")

NEW YORK CITY ADMINISTRATIVE CODE § 8-101, *et seq.*

394. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 190 through 221 of this complaint.

395. Defendant has violated the NYCHRL by discriminating against plaintiff by retaliating against him because he complained of, reported, and opposed sexual harassment, and a discriminatory work environment, and because he complained of retaliation for such opposition.

396. Plaintiff has suffered, is now suffering, and will continue to suffer irreparable injury and monetary damages as a result of defendant's retaliatory conduct until and unless this Court grants relief.

COUNT XXIII

NEW YORK WHISTLEBLOWER STATUTE

NEW YORK LABOR LAW § 740

397. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-221 of this Complaint.

398. Defendant has violated the Whistleblower Statute by retaliating against plaintiff because plaintiff threatened to disclose to supervisors, actually disclosed to supervisors, and otherwise opposed and tried to stop the distribution of the false and misleading contents of the CRA materials that violated the FDCA and constituted a substantial and specific danger to the public health and safety, and because he complained of retaliation for having acted as he did.

399. Defendant acted intentionally and with malice and/or reckless indifference to plaintiff's rights protected by the Whistleblower Statute.

400. Plaintiff has suffered, is now suffering, and will continue to suffer irreparable injury and monetary damages as a result of defendant's retaliatory conduct until and unless this Court grants relief.

401. Defendant has violated the Whistleblower Statute by retaliating against plaintiff because plaintiff threatened to disclose to supervisors, actually disclosed to supervisors, and otherwise opposed and tried to stop the distribution of the false and misleading contents of the CRA materials that violated the FDCA and constituted a substantial and specific danger to the public health and safety, and because he complained of retaliation for having acted as he did.

VI. PRAYER

WHEREFORE, plaintiff prays for judgment against the defendant as follows:

A. That defendant cease and desist from violating 31 U.S.C. § 3729 *et seq*. and the equivalent provisions of the State statutes set forth above;

B. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of defendant's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

C. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of California has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code § 12651(a);

D. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendant's actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a);

E. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082(2);

F. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a);

G. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

H. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendant's actions, plus a civil penalty of at least $5,000 for each violation of Ind. Code Ann. § 5-11-5.5-1.2(b);

I. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. § 46:438.6(C)(1)(a);

J. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B;

K. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendant's actions, plus civil penalties for each violation of Mich. Comp. Laws. § 400.601 *et seq.*;

L. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Montana has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Mont. Code Ann. § 17-8-401;

M. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1)(a), (b);

N. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I);

O. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendant's actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-2F-4;

P. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 4-18-103(a) and § 71-5-182(a)(1);

Q. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

R. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3(a)(1), (2);

S. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 1-1188.14(a)(1), (2);

T. That plaintiff be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the equivalent provisions of the State statutes set forth above;

U. That plaintiff be awarded reinstatement, two times the amount of back pay, with interest, compensation for special damages, including litigation costs and reasonable attorneys' fees pursuant to § 3730(h) of the False Claims Act;

V. That this Court enter judgment against defendant on plaintiff's Title VII, HRL, and NYCHRL claims enjoining continued violation of those laws and any further retaliation against plaintiff; awarding plaintiff reinstatement; awarding plaintiff compensation for lost salary, wages, benefits and other forms of compensation or remuneration, including front pay; awarding plaintiff compensatory damages for the emotional distress defendant's unlawful conduct has caused plaintiff; and awarding punitive damages in sufficient amount to punish the defendant for its conduct;

W. That this Court enter judgment against defendant on plaintiff's Whistleblower Statute claim, enjoining continued violation of the Whistleblower Statute and retaliation against plaintiff; awarding plaintiff reinstatement; awarding plaintiff compensation for lost salary, wages, benefits and other forms of compensation or remuneration, including front pay, as a result of defendant's violation of the Whistleblower Statute; and directing defendant to pay plaintiff compensatory damages for the emotional distress defendant's unlawful conduct has caused plaintiff;

X. That plaintiff be awarded all costs of this action, including attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and (h) and the equivalent provisions of the State statutes set forth above; and Title VII, the HRL, the NYCHRL, and the Whistleblower Statute; and

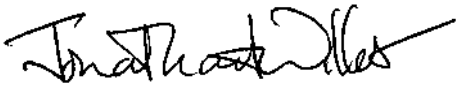
Y. That the United States, the States, and plaintiff/relator be granted all such other relief as the Court deems just and proper.

VII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Dated: March 14, 2008

JONATHAN A. WILLENS, LLC



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