UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

———————————————————————x

UNITED STATES OF AMERICA, ET AL. *ex rel.* DR. JESSE POLANSKY,

Plaintiffs,

vs.

PFIZER, INC.,

Defendant.

No. 04-cv-0704 (ERK) (ALC)

FIFTH 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 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*.
)
)
————————————————————————————x

TABLE OF CONTENTS

PAGE

I. INTRODUCTION 1

II. PARTIES 4

III. JURISDICTION AND VENUE 6

IV. BACKGROUND 7

A. Overview: Drug Coverage under Federal Healthcare Programs 7

B. The FDA Regulatory System 8

C. Prescription Drug Payment Under Federal Health Care Programs 11

1. The Medicaid Program 11

2. The Medicare Program 14

3. Reimbursement Under Other Federal Health Care Programs 16

D. Insufficient Evidence Of Safety And Efficacy For Off-Label Uses. 17

E. False Claims Submitted For Off-Label Non-Compendium Usage Of Lipitor, In Violation Of Pre-Conditions Of Payment And Corporate Integrity Agreements 22

F. The FDA-Approved Indications For Lipitor 27

G. The NCEP ATP III Guidelines: Goals And Cutpoints 29

V. ALLEGATIONS 33

A. Pfizer's "Stealth" Marketing and Its Impact on Physicians 33

1. Strategy of Covert Influence: The Parke-Davis Marketing Study 34

2. Covert Influence Through "Educational Programs" And CME 35

3. Covert Influence Through "Detailing" 36

4. Covert Influence And Off-Label Promotion 38

B. Pfizer's Illegal Off-Label Marketing Targeted Moderate Risk Americans 39

C. Misrepresenting The Lipitor Label And The Guidelines To Encourage Off-Label Use 40

D. Pfizer's Lipitor "Operating Plan" And Deceptive Marketing Materials 41

1. Pfizer's False And Misleading ATP-III "Guidelines" Presentation 44

2. Best Medical Group Practices.....45

3. Other Physician Detailing - The Hard Sell At Ventura County Ambulatory Care Network.....47

4. Pfizer's False And Misleading Targeting Of PBDMs And Consultants ...48

5. Pfizer's False And Misleading Targeting Of Physicians.....50

a. Lipid Goal Manager.....50

b. Lipitor.com Professional.....54

6. Pfizer's Misrepresentation Of TNT To Promote Lower Is Better 56

7. Pfizer's Selective Reporting of Clinical Trial Data 59

8. Pfizer's Targeting Of Moderate Risk Patients With Hypertension 60

9. Pfizer's Illegal Off-Label Marketing To Chronic Kidney Disease Patients, Including Those With End Stage Renal Disease 62

a. Pfizer Has Targeted Patients With CKD 62

b. Pfizer Has Targeted Patients With ESRD.....66

c. Pfizer Has Compromised The Distribution Of Critical Clinical Trial Information.....67

d. Pfizer Relies On Off-Label Messages In Medical Journal Review Articles.....68

e. The Impact Of Pfizer's Illegal ESRD Off-Label Marketing 70

10. Pfizer's False And Misleading Targeting Of Patients 70

11. Pfizer's Promoted And Disseminated Inaccurate Computerized Risk Calculators With The Purpose And Effect Of Expanding The Off-Label Use Of Lipitor.....72

12. Getting To Goal 76

13. Software vs. Paper NCEP Guidelines.....77

14. Off-Label Promotion.....78

15. Omitting/Downplaying Side Effects 80

16. "Speaker Fees" 81

17. Pfizer Reveals, And Presents Evidence Of, Its Off-Label Marketing Campaign To The Investment Community 81

18. Pfizer's Improper Use Of "Third Party" Organizations And Continuing Medical Education Programs 84

a. Off-Label Promotion Of Lipitor Through The National Lipid Education Council 87

b. Off-Label Promotion Of Lipitor Through The ESLM Program 94

c. Off-Label Promotion of Lipitor Through VBWG And COACH 96

d. Off-Label Promotion of Lipitor Through Other Organizations 100

e. Conclusion 101

19. Pfizer's Sampling Program 101

a. Limiting Supply Of Lower Dosage Samples Increases False Claims 103

b. Samples To Physicians 105

c. Sampling Raises Additional Safety Concerns 106

d. Sampling Corrupts The Physician-Patient Relationship 106

E. A Case Study: Pfizer's Aggressive Targeting Of An Ohio Doctor Leads Directly To Off-Label Prescribing Of Lipitor 107

VI. False Claims for Off-Label Use Submitted to Government Healthcare Programs 111

A. NHANES 111

1. Off-Guideline Prescription of Lipitor 111

2. Individual Claims 115

B. Pfizer's Own Analysis of the Effects of Its False and Misleading NCEP-Based Programs 116

C. Individual Claims 119

VII. Pfizer Violated The Anti-Retaliation Provisions Of The False Claims Act 121

B. 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.....125

COUNT I Federal False Claims Act 31 U.S.C. §§ 3729(a)(1) And (a)(2).....134

COUNT II False Claims Act 31 U.S.C. § 3730(h).....135

COUNT III California False Claims Act Cal. Govt. Code § 12651(a)(1) And (2).....136

COUNT IV Delaware False Claims And Reporting Act 6 Del. C. § 1201(a)(1) And (2).....137

COUNT V Florida False Claims Act Fla. Stat. Ann. § 68.082(2).....138

COUNT VI Hawaii False Claims Act Haw. Rev. Stat. § 661-21(a).....139

COUNT VII Illinois Whistleblower Reward And Protection Act 740 Ill. Comp. Stat. § 175/3(a)(1), (2).....140

COUNT VIII Indiana False Claims And Whistleblower Protection Act Ind. Code Ann. § 5-11-5.5-2(b)(1)-(2).....141

COUNT IX Louisiana Medical Assistance Program Integrity Law La. Rev. Stat. § 46:437 *Et Seq.*.....142

COUNT X Massachusetts False Claims Law Mass. Gen. Laws Ch. 12 § 5b(1), (2).....143

COUNT XI Michigan Medicaid False Claims Act Mich. Comp. Laws. § 400.601 *Et Seq.* 144

COUNT XII Montana False Claims Act Mont. Code Ann. § 17-8-403(1)(a)-(b).....145

COUNT XIII Nevada False Claims Act Nev. Rev. Stat. Ann. § 357.040(1)(a), (b).....146

COUNT XIV New Hampshire False Claims Act N.H. Rev. Stat. Ann. § 167:61-B(I)(a)-(b) ...147

COUNT XV New Mexico Medicaid False Claims Act N.M. Stat. Ann. § 27-2f-4(A)-(C).....148

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.*.....149

COUNT XVII Texas Medicaid Fraud Prevention Law Tex. Hum. Res. Code Ann. § 36.002 ..150

COUNT XVIII Virginia Fraud Against Taxpayers Act Va. Code Ann. § 8.01-216.3(a)(1), (2)151

COUNT XIX District Of Columbia Procurement Reform Amendment Act D.C. Code Ann. § 1-1188.14(a)(1), (2).....152

COUNT XX Title VII 42 U.S.C. §2000 *Et Seq.*.....153

COUNT XXI New York Human Rights Law ("HRL") New York Executive Law § 290 154

COUNT XXII New York City Human Rights Law ("NYCHRL") New York City Administrative Code § 8-101, *Et Seq.* 154

COUNT XXIII New York Whistleblower Statute New York Labor Law § 740 155

PRAYER FOR RELIEF 155

DEMAND FOR JURY TRIAL 159

Plaintiff and Relator Dr. Jesse Polansky ("Relator" or "Dr. Polansky"), on behalf of the United States of America, and on behalf of the sovereign states of California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Mexico, Tennessee, Texas, the Commonwealths of Massachusetts and Virginia, and the District of Columbia ("the Certain States"), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), and the false claims acts of the Certain States (the "State False Claims Acts"), files this Fifth Amended Complaint against Defendant, Pfizer, Inc. ("Pfizer"). In support thereof, Relator alleges, based upon personal knowledge, relevant documents and investigation, 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 Certain 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 seven years, Pfizer has unlawfully marketed Lipitor to the public and prescribing physicians by intentionally misrepresenting the authoritative treatment guidelines established by the National Institutes of Health ("NIH")/National Heart Lung and Blood Institute("NHLBI")/National Cholesterol Education Program("NCEP")/Adult Treatment Plan III ("ATPIII") (hereinafter the "Guidelines"). These Guidelines provide the basis for Food and Drug Administration ("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 therapy is not recommended, and for whom the

medication could be dangerous. Millions of those improper prescriptions were ultimately paid for by various government healthcare 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 of dollars.

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 the following customer segments: Federal Programs (Medicare, Veterans Administration, Department of Defense), State programs (*e.g.*, Medicaid), Pharmacy Benefit Managers, HMOs, employers, providers (*e.g.*, hospitals), physicians and other practitioners, patients, and investors. These Pfizer-appoved 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 expand improperly the population for whom Lipitor is prescribed by millions of patients. This off-label marketing of Lipitor has been immensely profitable. Annual Lipitor sales increased 126%, with global sales increasing from $5.4 billion in 2000 to $12.2 billion in 2005. According to Pfizer, 2006 Lipitor sales exceeded 13 billion dollars, with $7.8 billion in U.S. sales alone. 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 Pfizer's illegal business practices.

8. Dr. Polansky 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 Lipitor. Pfizer knew and intended its false and fraudulent marketing practices to 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. Dr. Polansky 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. Dr. Polansky's duties at Pfizer included heavy involvement in marketing, including off-label marketing, of Lipitor. Among other things, Dr. Polansky designed and implemented quality improvement solutions for managed care organizations, employers, government healthcare programs and medical groups; led group informatics including creation of internet, personal computer and PDA-based applications; served as medical director for Pfizer's Local Markets Review Committee; and acted as liaison for Pfizer European Projects.

11. Dr. Polansky holds a Bachelor of Science degree in chemistry from Wesleyan University, a Doctor of Medicine degree from Mount Sinai School of Medicine, and a Masters in Public Health from Columbia University. He is also board-certified in Public Health and Preventive Medicine. Dr. Polansky is licensed to practice medicine in Florida, New York, and Massachusetts.

12. Pfizer 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.

13. 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 sales of $10 billion a year. 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 Medicare beneficiaries on Lipitor, the cost of Lipitor to Medicare would exceed $1 billion in 2007 alone. (Consumer Reports, *Best Buy Drugs*: *The Statin Drugs; Prescription and Price Trends*, Consumers Union, Nonprofit Publisher of Consumer Reports, at 11, January 2006).

III. JURISDICTION AND VENUE

14. 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. Dr. Polansky establishes subject 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 Dr. Polansky'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 Dr. Polansky'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 Dr. Polansky's state and city law claims, pursuant to 28 U.S.C. § 1367(a). Dr. Polansky has complied fully with all administrative prerequisites to filing the Title VII action. Dr. Polansky 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 Dr. Polansky was subject to retaliation, and issued a Notice of

Right to Sue, which was received on March 10, 2005. This action was filed within 90 days thereafter.

15. This Court has personal jurisdiction and venue over Pfizer 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 Pfizer has minimum contacts with the United States.

16. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Pfizer can be found in and transacts or has transacted business in the Eastern District of New York. At all times relevant to this Complaint, Pfizer 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 Title VII, 42 U.S.C. § 000e-5(f)(3), because the unlawful practices complained of herein were committed within this District.

IV. BACKGROUND

A. Overview: Drug Coverage under Federal Healthcare Programs

17. Congress has the authority to decide which drugs and uses will be paid for by federal healthcare programs. As alleged below, Congress has exercised this authority in very specific and considered ways regarding each federal program. For "covered outpatient drugs," as that term is defined by statute, Congress has integrated FDA drug restrictions into federal health program restrictions regarding what drugs will be covered and paid.

18. Congress has not delegated authority to the FDA to decide which drugs and uses will be paid by federal healthcare programs. Instead, the FDA's primary function with respect to drugs and their uses is to receive, evaluate and approve specific labels under the 1966 Fair Packaging and Labeling Act, 15 U.S.C. § 1451. Another FDA function is to monitor and enforce manufacturers' compliance with advertising and promotional restrictions under the Food, Drug,

and Cosmetics Act ("FDCA") and the Food and Drug Administration Modernization Act of 1997 ("FDAMA").

19. Under the FDCA, pharmaceutical drug companies cannot distribute a drug in interstate commerce unless the FDA has approved its use. 21 U.S.C. §§ 355(a) & (d). After extensive testing, the FDA will approve a pharmaceutical drug for use according to the label. Use of an approved drug outside of the label (which specifies indication, usage, dose, route of administration) is referred to as an "off-label" use. The FDCA does not prohibit physicians from prescribing an FDA approved drug for off-label uses. The FDCA does, however, prohibit drug manufacturers from marketing or promoting a drug for off-label uses. 21 U.S.C. §§ 331 & 352.

20. Federal and state health care programs establish conditions under which they will pay for prescription drugs dispensed to beneficiaries. As alleged more specifically below, these conditions incorporate the FDCA restrictions to define the drugs which will be covered and reimbursed by public healthcare programs. As a general rule, federal and state health care programs do not reimburse the cost of drugs prescribed for off-label uses.

21. As such, the knowing and undisclosed failure to comply with FDCA regulations regarding the marketing of approved uses of drugs will cause the government to pay out benefits it did not intend for noncovered and nonreimburseable drugs.

22. The details of each of the relevant statutory and regulatory systems are included below.

B. The FDA Regulatory System

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

24. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved as safe and effective for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use includes a range of specifications outlined in the label, including indications and usage, dose and route of administration.

25. 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 only approves the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. § 355(d).

26. Under the 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 which supported 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." Off-label marketing restrictions are a safety-related feature of the FDAMA because these restrictions maintain a sponsor's incentive to apply for additional approved uses rather than skirt FDA review.

27. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than the indications approved by the FDA and described in the drug's labeling. Off-label use includes treating beyond the indications and use, 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).

28. Although the FDA is responsible for ensuring that a drug is safe and effective according to the specifications on the label, 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.

29. 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 the FDA has not approved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

30. In addition to prohibiting manufacturers from directly marketing and promoting a drug'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.

31. 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. 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 are neither false nor misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1. The second practice, corporate funding of CMEs, is discussed *infra*.

32. 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.

33. While the FDA has authority to enforce compliance with its advertising and promotional restrictions for the purpose of protecting the public, it has no authority to enforce compliance for the purpose of protecting federal healthcare programs against false claims or remedying such claims already submitted.

34. As a practical matter, off-label Lipitor prescriptions will continue to be paid for by federal healthcare programs notwithstanding this action. Claims for payment by pharmacies do not distinguish between on-label and off-label uses, nor contain enough information to allow federal programs to make that determination. This makes it all the more important to end Pfizer's off-label promotion to at least minimize such claims to those patients who truly need it.

C. Prescription Drug Payment Under Federal Health Care Programs

1. The Medicaid Program

35. 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.

36. 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).

37. Under the Medicaid statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the FDCA, 21 U.S.C. §§ 355 & 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

38. The statute defines "medically accepted indication" as:

> any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

Id. at § 1396r-8(k)(6). The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and the Drugdex Information System. *Id*. at § 1396r-8(g)(1)(B)(i).

39. Thus, setting aside on-label uses, whether an FDA-approved drug is listed in one or more of these three compendia for a particular indication determines whether a prescription for that use may be reimbursed under Medicare and Medicaid and other federal health care programs.

40. In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the CMS, which administers the program on behalf of the Secretary of Health and Human Services. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10), (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, i.e., reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. *Id*. at §§ 1396b(a)(1), 1396d(b).

41. States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

42. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. *See* 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1).

43. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97, 98.

44. A State may exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication," i.e., a use which is not listed in the labeling approved by the FDA, or which is not included in one of the drug compendia identified in the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6); § 1396r-8(d)(1)(B)(i). Most states comparably restrict coverage of drugs in accord with the Social Security Act, including the federal restrictions on medically accepted indications.

45. State Medicaid agencies administer Medicaid and reimburse pharmacies for drugs, which submit claims on behalf of individual Medicaid beneficiaries. The State agencies in turn submit claims to the United States for the federal financial participation ("FFP") of claims submitted on behalf of Medicaid beneficiaries.

46. Medicaid claims, depending on the circumstances, may be submitted by pharmacies electronically or on paper, but in most cases use a standard Form, such as the CMS-Form 1500, or other similar claim form (in Florida, for example, a "Universal Claim Form" is

used) which records among other things, the identity of the beneficiary, the provider, and the drug.

47. Drugs are identified on Medicaid claims and the Medicaid computer system drug file by the National Drug Code ("NDC"). The NDC is an 11-digit number. The first 5 digits identify the manufacturer or supplier, the next 4 digits identify the product, and the last 2 digits identify the package size.

2. The Medicare Program

48. 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.

49. 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.

50. 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.

51. 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.

52. For those beneficiaries with dual eligibility under both Medicare and Medicaid, their prescription drugs are covered exclusively under Medicare Part D. Thus, the responsibility for providing pharmacy benefits for dually eligible beneficiaries was transferred from Medicaid to Medicare Part D on January 1, 2006.

53. According to a Pfizer investor presentation, Pfizer expects the Medicare Part D program to account for 46% of future Lipitor sales.

54. The Part D prescription drug program provides comparable benefits and exclusions as the Medicaid program.

55. Specifically, a Part D covered drug is available only by prescription, if approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Social Security Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug includes, *inter alia*, prescription drugs.

56. The definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents.

57. Medicare Part D is administered through CMS, with coverage provided through private prescription drug plans. Plan sponsors are authorized to negotiate independently pharmacy reimbursement and price concessions with manufacturers and pharmacies, and then to seek reimbursement from Medicare.

58. All plan sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse. The specific requirements of the compliance program for the Part D benefit includes directions to specific kinds of fraud and abuse in violation of program requirements, such as non-compendia drug payments.

59. For example, the Prescription Drug Benefit Manual ("PDBM") issued by CMS identifies an example of Sponsor fraud, waste and abuse as "Non-compendia payments: Payments for Part D drugs that are not for a 'medically accepted indication.'" PDBM, Ch. 9, § 70.1.1. The PDBM further specifically identifies an example of pharmaceutical manufacturer fraud, waste and abuse as "Illegal Off-Label Promotion: Illegal promotion of off-label drug

usage through marketing, financial incentives, or other promotional campaigns." PDBM, Ch. 9, § 70.1.6.

3. Reimbursement Under Other Federal Health Care Programs

60. 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 programs administered by the Department of Defense (the "DOD"), the Department of Veteran's Affairs (the "VA") and the Office of Personnel Management (the "OPM").

61. Specifically, DOD administers TRICARE (formerly CHAMPUS), a health care program for individuals and dependents affiliated with the armed forces. The VA administers its own health program, along with CHAMPVA (a shared cost program) for the families of veterans with 100 percent service-connected disabilities. OPM administers the Federal Employee Health Benefit Program, a health insurance program for federal employees, retirees, and survivors.

62. Conditions for, and payment of claims for off-label prescription drugs under these programs are comparable to coverage under the Medicaid program. *See* 32 C.F.R. § 199.4(g)(15); TRICARE Policy Manual 6010.47-M, Chapter 8, Section 9.1 (February 1, 2008); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002) (coverage considered for off-label usage only upon review for medical necessity and demonstration of a nationally-accepted standard of practice and other reliable evidence).

63. Reimbursement for drugs under these programs may occur either through direct purchase of drugs later administered at government facilities, or through coverage of drugs administered by other providers to veterans and members of the armed forces eligible for benefits under these programs.

D. Insufficient Evidence Of Safety And Efficacy For Off-Label Uses.

64. Congress limits federal healthcare programs to paying for drugs and uses meeting objective standards of safety and effectiveness, namely the FDA-approved label. Pfizer never applied to the FDA for approval of off-guideline use of Lipitor, i.e., uses outside the scope of the NCEP guidelines. Pfizer could have applied (21 U.S.C. §§ 360aaa(b)(c)); but it chose not to or did so unsuccessfully. Presumably, Pfizer did not apply because it did not have sufficient evidence to support FDA approval of off-guideline uses of Lipitor or its applications were denied by the FDA for that reason. Either way, Pfizer did not obtain FDA approval for uses here challenged. The NCEP guidelines are the authoritative, government-backed authority on when the use of statins is justified, and Pfizer should have obtained revised rulings from the FDA approving the use of Lipitor for a category of patients for whom the existing guidelines indicate statin use is *not* justified.

65. So long as drug manufacturers are limited to promoting on-label uses, they have every incentive to conduct their own studies and fund third-party studies in an effort to support applications for expanded FDA approval or inclusion in compendia. On the other hand, if drug manufacturers may freely promote off-label uses, they have an incentive not to conduct and fund studies because they have little to gain and much to lose; their drugs might be proven ineffective and/or harmful for off-label uses.

66. "No studies have examined the impact of statins in randomized trials in those over age 75. Epidemiological studies show higher cholesterol to be protective, rather than harmful, in this age group, so it cannot be assumed that lowering cholesterol confers benefit exceeding risk." *Id*. According to one recent report, there is "considerable uncertainty regarding the overall benefit/risk ratio of these agents [in the elderly]." Blue Cross Blue Shield, Technology Evaluation Center "Special Report: The Efficacy and Safety of Statins in the Elderly," Vol. 21,

No. 12, February 2007. Of course, statins are routinely prescribed to the elderly. Indeed, statin therapy generally continues for life once commenced.

67. Additionally, one efficacy study concluded that statins reduce strokes in people with previous strokes by only two percent. "Lipitor Shows Limited Benefit for Stroke," The Wall Street Journal, Aug. 10, 2006. "Meanwhile, the financial ties of the 11 study co-authors to Pfizer raised questions about their impartiality. The study was funded by Pfizer, and every one of the researchers had connections to Pfizer and other drug companies, ranging from research grants, to consultancies, to being Pfizer employees with stock ownership. In addition, even the doctor selected by the New England Journal of Medicine to write an opinion piece on the study also has gotten grant support from Pfizer." *Id.*

68. Thus, there are good reasons why the FDA-approved label and compendia exclude certain uses of statins. Quite simply, there is an insufficient basis on which to find statins safe and effective for those uses. Indeed, there are growing concerns in the medical community that statins are both ineffective and unsafe for some off-label uses, although it is difficult to be sure because only statin proponents have unfettered funding to conduct studies that would establish this one way or the other. Nonetheless, the emerging portrait of statins is more complicated and sobering than manufacturers would have physicians and patients believe, both in terms of safety and effectiveness.

69. It is clear that statins generally reduce cholesterol whether the use is on-label or off-label. However, it is not clear that reducing cholesterol always improves overall health. Pfizer's FDA-approved Lipitor label reflects a determination by public medical experts that reducing cholesterol generally improves overall health for on-label patients because their risk of stroke and heart attack are sufficiently high to outweigh potential side-effects and long-term implications, whatever they may be. However, the label's careful division of patient populations

by risk factors and cut-points also reflects that public medical experts have not reached the same conclusion as to off-label patients because the benefits of statin therapy are insufficiently clear to outweigh the known and unknown potential side-effects and long-term implications.

70. For example, one issue not yet fully explored is aching muscles ("myopathy"), one of the leading side effects of statin use. Sen. Charles Grassley recently wrote the FDA asking whether the agency has sufficiently considered potential problems caused by statins, in particular myopathy. "Grassley to the FDA: Are Statins Really Safe?", BusinessWeek, Sep. 18, 2009. "Grassley's investigators were struck by the number of people who have come to them with tales of serious side effects and long-lasting injuries after taking the drugs. The aches usually go away if people stop taking the drugs, but there's growing evidence that pain - and worse - can continue for years afterward." *Id.*

71. Another issue not yet fully explored is a possible link between statins and cognitive interference. "Can a Drug That Helps Hearts Be Harmful to the Brain?", The Wall Street Journal, Feb. 12, 2008. "The brain is largely cholesterol, much of it in the myelin sheaths that insulate nerve cells and in the synapses that transmit nerve impulses. Some doctors theorize that lowering cholesterol could slow the connections that facilitate thought and memory. Statins may also lead to the formation of abnormal proteins seen in the brains of Alzheimer's patients." *Id.*

72. Additional issues are known to, and are consciously ignored by, Pfizer. Even a Pfizer-funded study "rais[ed] red flags concerning a higher incidence of potentially devastating brain hemorrhages" among Lipitor users. "Lipitor Shows Limited Benefit for Stroke," The Wall Street Journal, Aug. 10, 2006. But Pfizer steered the study away from these red flags to avoid creating any problematic evidence. "Researchers didn't explain whether the brain hemorrhages occurred primarily in people who had had previous brain hemorrhages, leaving open the question

of whether the patients' histories, or the drug itself, may have been the primary factor." *Id.* Moreover, the Pfizer study "didn't describe the extent of disability among people who had hemorrhagic strokes." *Id.*

73. In that instance, Pfizer may have learned a lesson about conducting or funding studies that could potentially harm its marketing goals even when the results are manipulated; the FDA required Pfizer in 2007 to add a new precaution to the Lipitor label advising patients with recent stroke or transient ischemic attacks that statin use increases the risk of hemorrhagic stroke.

74. Not only does Pfizer choreograph studies in its favor, but it choreographs presentations to physicians as well. For example, Dr. Paul Phillips is Director of Interventional Cardiology at Scripps Memorial Hospital in San Diego, California, is a specialist in statin myopathy who was scheduled to speak at a Pfizer national research meeting in or around 2003. His presentation was summarily cancelled the day before because Pfizer "did not want to hear too much about muscle toxicity."

75. While Pfizer restricts dialogue about the safety of Lipitor, it engages academics to exaggerate the safety and efficacy of Lipitor. Dr. Terry Jacobson, professor of medicine in the Department of Medicine at the Emory University School of Medicine and director of the Office of Health Promotion and Disease Prevention at Grady Memorial Hospital is one such physician. A press release from Emory University proclaims, that "The benefits of these drugs are huge," says Dr. Jacobson, noting that statins are the leading class of medications taken by Americans. "People taking these drugs not only live longer, but they live better. Statins are as safe as taking an aspirin a day, yet people are afraid to take these drugs because they've heard media reports and direct-to-consumer ads. Rarely in medicine do you have a class of medicines that are so safe that the benefits go way beyond any risks. These drugs prevent one in three heart attacks,

strokes, angioplasty, even death. That means the risks turn out to be much smaller than anyone expected."

76. Dr. Jacobson claims that statins do not cause liver damage and, therefore, that it is unnecessary for doctors to monitor patients' liver function. Rather, statins are safe enough to even prescribe to certain patients with liver disease. "These drugs do not damage the liver," he says. "Liver failure is unheard of, and liver damage does not really occur. That's why there is no reason to subject people to all of this measuring and monitoring of their liver. If people don't fear these drugs, they are more likely to take them. "

77. Many other issues concerning statin side effects also have not been explored fully. A 2007 analysis by the World Health Organization identified a potential link between statins and Lou Gehrig's disease. "Doctor's Dilemma: A Risk in Cholesterol Drugs is Detected, but Is It Real?...," The Wall Street Journal, p. A1, July 3, 2007. An article in the 2007 Journal of the American College of Cardiology identified a potential relationship between cancer and inducing lower LDL cholesterol levels. 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. 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. 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.

78. These issues may be only the tip of the iceberg and further research may show a broader and more acute scope of both immediate and long-term side effects to statins. For example, a 2006 editorial in the British Medical Journal outlined concerns that the adverse

effects of statins are under-reported in clinical trials. Uffe Ravnskov, Paul Rosch, *et al*., "Should we lower cholesterol as much as possible?," 332 Brit. Med. J., 1330-32, June 3, 2006.

79. In short, to satisfy the FDA or the authorized medical compendia that any given use is safe and effective drug manufacturers need to present evidence. The manufacturers, including especially Pfizer, largely control their own destiny in that regard, having immense resources at their disposal. So long as drug manufacturers, particularly Pfizer, can promote off-label uses with impunity, they have little reason to satisfy either the FDA or the compendia. Congress has been clear, however, that until manufacturers find or create the necessary clinical evidence and obtain FDA approval or compendia status with respect to a given use, federal healthcare programs will not pay for that use.

E. False Claims Submitted For Off-Label Non-Compendium Usage Of Lipitor, In Violation Of Pre-Conditions Of Payment And Corporate Integrity Agreements

80. As a condition of payment of Medicare, Medicaid and other federal healthcare programs, claims can only be submitted for "covered outpatient drugs," that are the subject of a rebate agreement with a pharmaceutical manufacturer. To be covered, drugs must be used for a medically-accepted indication, including a use approved by its label or approved by published compendia authorized by the Medicaid statute.

81. Because those programs specifically exclude coverage and reimbursement for off-label non-compendia uses of drugs, claims submitted for such drugs prescribed for such uses violate statutory pre-conditions of payment.

82. Claims submitted to federal and state healthcare programs in violation of conditions of payment are false claims. Submission of such claims materially misrepresents that the claims are eligible for reimbursement consistent with applicable statutes and regulations, and results in the disbursement of public funds never intended to be used for that purpose.

83. As alleged below, Pfizer illegally marketed and promoted Lipitor for off-label, non-compendia use. The off-label uses of Lipitor promoted by Pfizer were neither approved by the FDA nor included in any of the drug compendia specified by the Medicaid statute. Rather, indications listed on the Pfizer's FDA-approved label and the authorized compendia for Lipitor are identical. Lipitor is a rare example of a drug for which the compendia have not expanded indications beyond the FDA label even though, like the FDA, the compendia authorities may be solicited for favorable treatment by manufacturers showing proper supporting evidence.

84. As a result of Pfizer's aggressive and illegal marketing campaign, claims have been submitted for Lipitor in violation of statutory conditions of payment.

85. Pfizer's illegal actions were the substantial factor in causing the submission of claims in violation of known conditions of payment, and the resulting claims were the foreseeable result of Pfizer's illegal campaign.

86. Indeed, Pfizer's illegal off-label marketing campaign was the driving factor causing the submissions for reimbursement for Lipitor to Medicare, Medicaid and other healthcare programs for non-reimbursable uses.

87. Thus, every claim which Pfizer caused to be submitted for non-medically-indicated uses of Lipitor is a false claim. Pfizer's knowing conduct in causing the submission of such claims violated the False Claims Act.

88. Pfizer has long been aware that its illegal actions caused false claims to be submitted to Medicare, Medicaid, and other federal healthcare programs. In addition to its obligation to know and to comply with the law in order for its drugs to be covered by those programs, Pfizer has entered into an Agreements with the United States to further certify its ongoing compliance with those laws in order to continue participating in such programs.

89. For example, on May 11, 2004, Pfizer entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("the 2004 CIA", a copy of which is annexed hereto, incorporated herein, and made a part hereof as Exhibit A). The stated purpose of the 2004 CIA was

> to promote compliance by [Pfizer's] officers, directors, employees, contractors, and agents with the statutes, regulations and written directives of Medicare and Medicaid, and all other Federal healthcare programs (as defined in 42 U.S.C. §1320a-7b(d) (Federal health care program requirements) and the applicable statutes, regulations and written directives of the Food and Drug Administration (FDA requirements)

(See Ex. A at I on p. 1). The 2004 CIA was part of the settlement of a *qui tam* action in which the relator alleged that Pfizer had violated the FCA by marketing and promoting its drug Neurontin for off-label use, thereby causing false claims for such use to be submitted to Government healthcare programs.

90. In the 2004 CIA, Pfizer agreed to submit annual reports to the OIG containing certifications of Pfizer's compliance with laws and regulations applicable to its marketing and promotion activities, including the FDA prohibition on off-label marketing. (See Ex. A, V., B). Pfizer's annual certifications applied to its marketing and promotion of *all* drugs, including Lipitor. (*Id.*)

91. More specifically, the 2004 CIA provides (Ex. A, V., C., at 27):

> C. Certifications. Except as otherwise stated above, the Annual Reports shall include a certification by the Compliance Officer that:
>
> 1. Pfizer's: (i) Policies and Procedures as referenced in Section III.B.2. above; (ii) templates for standardized contracts and certifications associated with Promotional and Product Services Related Functions as set forth in Pfizer's Orange Book; and (iii) promotional materials that are reviewed by a Review Committee and are submitted to the FDA; have been reviewed by legal counsel for compliance with the requirements of the Federal anti-kickback statute and other Federal health care program requirements, and FDA requirements, as applicable;

> 2. to the best of his or her knowledge, except as otherwise described in the applicable report, Pfizer is in compliance with all of the requirements of this CIA[.]

92. The "Policies and Procedures" referred to in paragraph 1(i) of the "Certifications" are, in applicable part:

> 2. Policies and Procedures. Prior to the Effective Date, Pfizer implemented written Policies and Procedures regarding the operation of Pfizer's compliance program and its compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures address and shall continue to address:
>
> * * *
>
> c. methods for selling, marketing, and promoting Pfizer products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b;
>
> d. methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all applicable FDA requirements;
>
> * * *
>
> g. speaker meetings, advisory board meetings, and all other consultant arrangements (including those for speakers, mentors, or preceptors) or related events. The policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about off-label uses of products. The policies shall include requirements about the content and circumstances of such arrangements and events;
>
> h. sponsorship or funding of continuing medical education (CME) programs that are designed to ensure that Pfizer's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements. The policies and procedures shall require the disclosure of Pfizer's financial support of the CME program and any financial relationships with faculty, speakers, or participants at such CME program; shall require that the CME program have an educational focus; shall require that the CME program be independent; and shall require that the CME program be balanced. (See Ex. A, III. B. 2, at 8-9).

93. The "Promotional and Product Services Related Functions" also attested to be lawful in paragraph 1(ii) of the "Certifications" are defined as "the sales, marketing, or promotion of Pfizer products or the provision of information about or services relating to Pfizer's products." (See Ex. A, II. C. 2. c, at 4-5).

94. The 2004 CIA superseded a prior Corporate Integrity Agreement entered into by Pfizer with the OIG in October 2002 (the "2002 CIA"), which was part of the settlement of a *qui tam* action in which the relator alleged that Pfizer had violated the FCA by charging Government healthcare programs more than its "best price" for Lipitor. On information and belief, the 2002 CIA contained provisions similar to the 2004 CIA requiring Pfizer to certify annually to compliance with applicable laws and regulations, including the FDA prohibition on off-label marketing. (See Ex. A, I, at 1-2).

95. As discussed more fully below, the 2002 CIA, 2004 CIA and each of Pfizer's Annual Reports submitted to the OIG for 2003, 2005, 2006, 2007, 2008 and 2009 falsely certified its compliance with federal program requirements.

96. Pfizer entered into a new CIA in 2009 (attached as Ex. B) and paid $2.3 billion, double the previous largest FCA settlement, to settle allegations that it continued widespread off-label marketing even after entering into the 2004 CIA. Pfizer also settled several FCA cases involving off-label marketing of a number of its drugs. Among other things, according to a HHS and DOJ settlement "fact sheet", Pfizer's marketing team positioned drugs for off-label uses, created off-label sales pitches, commissioned market research to test off-label sales materials, and allowed the use of such materials; Pfizer's sales team delivered off-label materials to physicians and hospitals; used "advisory boards" and other forums to promote off-label uses; salespersons also distributed drug samples for off-label uses; and Pfizer funded "independent" CME programs to "disseminate specific messages" about off-label uses.

97. Pfizer's false certifications to the Government concealed the massive number of false claims that were being submitted to federal healthcare programs for reimbursement of off-label, non-compendia uses of Lipitor in violation of conditions of participation and payment for federal and state healthcare programs. Pfizer's false certifications were false statements made to get false or fraudulent claims paid or approved, and were false statements material to false or fraudulent claims.

98. Pfizer's false certifications were false statements made to get false or fraudulent claims paid or approved by the Government, and were also false statements material to false or fraudulent claims submitted to the Government.

F. The FDA-Approved Indications For Lipitor

99. Lipitor® (atorvastatin calcium) was cleared by the FDA for marketing on December 18, 1996, and belongs to a class of drugs called statins that lower cholesterol levels by blocking enzymes essential to cholesterol production. According to IMS Health, over 29 million people in the United States have been prescribed Lipitor and it is the top prescribed branded cholesterol-lowering medication in the world. IMS Health. IMS National Prescription Audit Plus™. (March 2008). -- available at Lipitor.com (last visited 1/27/2010). Pfizer acquired exclusive rights to Lipitor when it acquired Warner Lambert in 2000.

100. 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 NCEP:

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

101. Specifically, Pfizer's FDA-approved Lipitor 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).

Table 6 of the Lipitor label in effect during the relevant time period reads 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.

102. 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.

103. At all times relevant to this Complaint, the off-label and off-compendium uses of Lipitor promoted by Pfizer did not qualify for reimbursement under any federally-funded health care program, and any claim for reimbursement for prescriptions for off-label, non-compendium uses caused by Pfizer's unlawful promotion constitute false claims.

G. The NCEP ATP III Guidelines: Goals And Cutpoints

104. The FDA-approved indications for Lipitor, found in its label, incorporate, without modification, the NCEP Guidelines. *See* Exs. C-L. The most recent version of these Guidelines, ATP III, was issued in May 2001, and updated in July 2004. 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.

105. 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. *See* Ex. N; *see also* Ex. M. 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 should 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.

106. 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 the risk factors; and then

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

107. Specifically, 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.

108. 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.

109. The Guidelines recommend that lowering 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. TLC include change in diet, weight control, and increased physical activity.

110. 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.

111. 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.

112. 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.

113. 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).

114. 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.

115. 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.

116. 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 "Stealth" Marketing and Its Impact on Physicians

117. Drug manufacturers like Pfizer spend billions of dollars annually on broad, multi-faceted and psychologically sophisticated marketing campaigns to influence physicians to increase their prescriptions of the manufacturers' drugs. Critical to the manufacturers' strategy is avoiding or minimizing any sense by physicians that they are being influenced, and "drug makers have seized upon an effective tool for getting their message across to doctors: other doctors." "New Treatment: To Sell Their Drugs, Companies Increasingly Rely On Doctors," The Wall Street Journal, Jul. 15, 2005.

118. Stealth marketing works, which is why drug manufacturers continue to pour billions of dollars into the effort annually. "Pharmaceutical companies monitor the return on investment of detailing—and all promotional efforts—by prescription tracking." "Following the Script: How Drug Reps Make Friends and Influence Doctors," PLoS Medicine, 4:e150, 0621-25, Apr. 2007. Drug makers buy prescription records from pharmacies, match them with information on individual physicians purchased from the American Medical Association, and carefully examine each physician's prescribing habits. *Id*.

119. For example, one drug manufacturer "calculated that the 'return on investment' of the doctor-led discussion group was 3.66 times the investment, versus 1.96 times for a meeting with a sales representative." "New Treatment: To Sell Their Drugs, Companies Increasingly Rely On Doctors," The Wall Street Journal, Jul. 15, 2005.

1. Strategy of Covert Influence: The Parke-Davis Marketing Study

120. Pfizer acquired Parke-Davis in 2000. Parke-Davis manufactured Neurontin (gabapentin), and engaged in extensive off-label marketing of the drug. (Parke-Davis also manufactured Lipitor, and as alleged herein its off-label marketing practices regarding Lipitor largely mirror those of Neurontin).

121. A study summary published in the Annals of Internal Medicine in 2006 lifted the veil of secrecy and revealed a highly disturbing picture of Parke-Davis' methods of influencing physicians. The study, supported by the Department of Veterans Affairs and not-for-profit foundations, was based on documents obtained from Parke-Davis and Pfizer in an FCA case alleging off-label marketing of Neurontin. See Steinman, M., MD, et al., "Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents," Ann. Intern. Med. 2006; 145:284-293 ("Parke-Davis Marketing Study").

122. The litigation documents revealed that Parke-Davis annually established broad marketing and promotional goals, and designed specific programs to meet those goals. "Professional education" constituted one-half to two-thirds of the company's projected promotional budget. It targeted specific groups of physicians to hear or carry its messages, including high-prescribers, "local champions of the drug, who were recruited and trained to serve as speakers in 'peer-to-peer' selling programs", and "thought leaders" who were influential physicians generally affiliated with major academic medical centers. *Id*., at 285.

123. Tactics to meet marketing goals included manipulating CME to carry a fundamentally promotional rather than educational message. Parke-Davis paid speakers generously to conduct "educational" events, and at times helped establish the agenda and secretly listened in on their teleconferences with physicians. Regarding off-label promotion in particular, it often funded "education" by third-parties who had incentive to develop programs consistent

with marketing goals and control content in a way that reflected favorably on the manufacturer. *Id*., at 286-88.

124. The conclusion of the Parke-Davis Marketing Study was that "Activities traditionally considered independent of promotional intent, including continuing medical education and research, were extensively used to promote gabapentin. New strategies are needed to ensure a clear separation between scientific and commercial activity." *Id*., at 284. Moreover, "Since the promotional intent of these activities may not have been widely recognized, their impact on physicians was probably greater than interactions with known commercial intent, which are typically approached with greater skepticism." *Id*., at 290. Beyond not being widely recognized, the promotional intent of Parke-Davis' activities were partially or largely obscured by their methods of delivery. *Id*.

2. Covert Influence Through "Educational Programs" And CME

125. "'The most effective marketing is the marketing you're not aware of,' says Dr. Peter Rost, a one-time pharmaceutical company marketing executive who has become an Internet-based industry watchdog. 'If you see an ad, you know its marketing. But if a friend or your doctor talks to you about a drug, you don't." "Under the Influence: Savvy Marketing Whets Our Appetite for prescription Pharmaceuticals, Consumers, Doctors, Researchers—No One Is Immune," Los Angeles Times, Aug. 6, 2007.

126. A Senate report noted that physicians are typically a skeptical audience for direct pitches, but "when the favorable message is delivered in the context of education—even if corporate sponsorship is disclosed—there is an imprimatur of credibility and independence. "Doctor, Just A Little Something For You: Complex Sales Strategies Go Way Beyond Freebies," Los Angeles Times, Aug. 6, 2007.

127. "'[Physicians] have almost always a universal view that none of this has an influence on them because they are scientists and accustomed to evaluating data objectively,' said Jerome Kassirer, former editor of the New England Journal of Medicine…'that's a lot of baloney." "UC-Davis May Curb Doctors' Drug-Company Freebies," Sacramento Bee, Oct. 3, 2006.

128. Even physicians who deliver the drug manufacturers' messages are often unaware of the extent to which they are being used. "I have learned that human beings, physicians included, are incapable of recognizing bias in themselves, and even when you try not to be biased it is impossible to avoid it, especially when money is involved." "Side Effects: Are Doctors' Loyalties Divided? Physician Found Money, Acclaim Seductive," Milwaukee Journal Sentinel, Apr. 29, 2009, quoting cardiologist James Stein, MD. "I was naïve to think I was not influenced by the money and power of the drug and device companies." *Id*.

129. The answer to finding physicians to deliver the drug manufacturers' message is money and prestige. ""I was really flattered because over and over again I was told I was a future thought leader…I did my talk. I got a $750 honorarium and I was hooked.' Stein said he now realizes that the speech at the hospital was just an audition. 'They wanted to know what I would say and how I would deliver…and I think they also wanted to know what I would say about their product.'" "Side Effects: Are Doctors' Loyalties Divided? Physician Found Money, Acclaim Seductive," Milwaukee Journal Sentinel, Apr. 29, 2009, quoting cardiologist James Stein, M.D. In 2005, "Pfizer paid [Dr. Stein] between $10,000 and $20,000 for four days of work as a speaker and advisory board member…and he considered himself an educator, not a salesman." *Id*.

3. Covert Influence Through "Detailing"

130. "Each day in the United States, an army of roughly 100,000 pharmaceutical

company sales reps ["detailers"] storms the waiting rooms and offices of the nation's 311,000 office-based physicians." "Doctor, Just A Little Something For You: Complex Sales Strategies Go Way Beyond Freebies," Los Angeles Times, Aug. 6, 2007. In the year 2000, more than $4.8 billion was spent on detailing. "Following the Script: How Drug Reps Make Friends and Influence Doctors," PLoS Medicine, 4:e150, 0621-25, Apr. 2007.

131. Detailing involves small gifts and drug samples, which generates influence "because psychologists have shown consistently that a small token or gesture of friendship often inspires a sharper sense of obligation in the recipient than does a showy gift, for which reciprocation is impossible." "Doctor, Just A Little Something For You: Complex Sales Strategies Go Way Beyond Freebies," Los Angeles Times, Aug. 6, 2007.

132. Of more than 3,000 physicians surveyed, 28% received payments of consulting, lecturing or enrolling patients in trials; 35% received money in connection with professional meetings or CME; 78% received drug samples; 83% received food in the workplace, and 94% reported some type of relationship with drug manufacturers. "A National Survey of Physician-Industry Relationships," N. Engl. J. Med. 356;17, 1742-50, Apr. 26, 2007.

133. Sales representatives carefully study individual physicians. "They are also trained to assess physicians' personalities, practice styles, and preferences, and to relay this back to the company." "Following the Script: How Drug Reps Make Friends and Influence Doctors," PLoS Medicine, 4:e150, 0621-25, Apr. 2007. There are specific tactics for manipulating physicians with specific personality types. *Id*. Additionally, drug manufacturers use prescription tracking to that end. "The goal of this demographic slicing and dicing is to identify physicians who are most susceptible to marketing efforts." *Id*. Understandably, "in recent years, physicians have become aware of - and dismayed by - script tracking." *Id*.

134. "Physicians underestimate their own vulnerability. The think they are smarter…but they are not trained in recognizing this kind of manipulation." So said the author of one study detailing the elaborate methods by which drug sales representatives woo physicians and concluding that this can have a big impact on what drugs they prescribe. "Reps scour a doctor's office for objects—a tennis racquet, Russian novels, '70s rock music, fashion magazines, travel mementos or cultural or religious symbols—that can be used to establish a personal connection with the doctor." "Friendly Drug Reps Sway Doctors' Choices," Reuters, April 23, 2007.

4. Covert Influence And Off-Label Promotion

135. Both educational programs and detailing are methods through which drug manufacturers effectively promote off-label use of their drugs. "Educational grants are an important tool by which drug companies promote their drugs. Many are used to fund physician education seminars where off-label uses of drugs are discussed." "Two Senators Studying Ties Between Drug Makers and Purchasers for Federal Programs," New York Times, June 10, 2005.

136. "A Congressional investigation of the money that drug companies give as supposed educational grants has found that the payments are growing rapidly and are sometimes steered by marketing executives to doctors and groups who push unapproved uses of drugs." "Drug Makers Scrutinized Over Grants," New York Times, Jan. 11, 2006. "There is no doubt that off-label use of drugs is big business for the pharmaceutical industry. It has been estimated that more than half of all prescriptions written nationwide are for off-label uses." *Id*.

137. "Some of those [educational] programs appear to have been forums for pushing 'off-label' uses for prescription drugs, a back-door means of expanding its market…[even though] it is illegal for a drug manufacturer to market its drugs for off-label uses." "Doctor, Just

A Little Something For You: Complex Sales Strategies Go Way Beyond Freebies," Los Angeles Times, Aug. 6, 2007.

138. One study, funded by the Department of Veterans Affairs and various National Institutes and foundations, concluded that "detail visits [by Pfizer reps for Neurontin] were of high perceived information value and often involved messages about unapproved uses. Despite their short duration, detail visits were frequently followed by physician intentions to increase their future recommending or prescribing of the drug." Steinman, M. et al., "Characteristics and Impact of Drug Detailing for Gabapentin," PLoS Med 4(4): e134, 0743-51, Apr. 2007. The study revealed that in 38% of detailing visits to physicians, the "main message" included at least one off-label use. *Id*.

B. Pfizer's Illegal Off-Label Marketing Targeted Moderate Risk Americans

139. Pfizer created false and misleading core promotional materials and programs for physicians and patients. 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.

140. 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 and distance learning) that are typically subject to minimal review by the FDA. (The FDA's oversight of

pharmaceutical advertising remains primarily focused on the mediums of magazine and television).

141. 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 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.

C. Misrepresenting The Lipitor Label And The Guidelines To Encourage Off-Label Use

142. 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.

143. 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.

144. 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. Pfizer has principally accomplished its marketing

priority by reiterating and combining 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).

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

146. 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.

D. Pfizer's Lipitor "Operating Plan" And Deceptive Marketing Materials

147. Pfizer's "new market expansion" strategy was presented in its confidential Lipitor 2002 Operating Plan (or the "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.

148. Pfizer also recognized in the Plan that "People believe they can treat with diet/exercise," and that failing to do so successfully 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 stated, is the "Key to reaching the consumer." Using this model, Pfizer created unlawful consumer marketing materials designed to obscure the fact that for the vast majority of patients in the Moderate Risk group, diet and exercise is the exclusive remedy authorized by the Guidelines, and thus by Pfizer's labeling, to address cholesterol concerns.

149. The 2002 Operating Plan was 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 selling Guide was created for the sales forces who detail physicians and physician offices. Three strategies were 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" with detail frequency and strategic sample distribution. ("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 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.") The selling Guide referenced many of the false and misleading core sales programs and materials developed by Pfizer's Lipitor 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" as well as the misleading "NCEP ATP-III Guidelines" presentation.

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

151. The Playbook's strategy emphasized "getting patients to NCEP ATP-III goals" and outlined many of the misleading and often false Pfizer-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", and Lipitor.com.

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

153. Lipitor sales resources was limited to a core set of programs and materials, as the recurrence of these core materials is demonstrated herein. They were standardized and strictly regulated by the Lipitor corporate marketing team, designated the Lipitor Disease Management Team. Pursuant to Pfizer corporate policy, all sales resources had to be pre-approved for use by the "Lipitor Review Committee". The Lipitor Review Committee was made up of representatives 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.

1. Pfizer's False And Misleading ATP-III "Guidelines" Presentation

154. Pfizer's centerpiece Guidelines marketing presentation is entitled "The Lipid Slide Library, Volume 2: National Cholesterol Educational Program Adult Treatment Panel III Guidelines." This presentation was, and still is used in training both clinical and non-clinical personnel at Pfizer on the Guidelines. The Lipid Slide Library was 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 referred to as Pfizer's Physicians' Speakers Bureau and served as a basis for their promotional presentations to practicing physicians across the country. This slide presentation purported to give an accurate account of the authoritative Guideline regime. In addition to the content of the Slides, the 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 the audience about the Guidelines, but do just the opposite.

155. An example of the use of the slide deck by Pfizer's Speaker's Bureau were presentations in the Minneapolis St. Paul Market in 2002. Of note, Dr. Dan Ries, a physician affiliated with Kidney Specialists of Minnesota was a speaker, illustrating the priority Pfizer assigned to the nephrology community in doctor to doctor detailing. Local Pfizer saleas representatives Gary Parenteau, Joy Thewis, Kathleen Ziegler, Larry Ober, and Steve Voller assisted in identifying the speakers and participants. Speakers were selected for their influcnce in their clinical communities, their high Lipitor prescribing patterns, their willingness to speak enthusiastically about Lipitor and, most importantly, their willingness to strictly follow the false and misleading ATP-III slide deck and speaker notes. Participants were chosen for their Lipitor prescribing potential. Promotional events were held at some of the finest dining establishments

in the area, including Zelo, Cio Bella, Capital Grill, Awadas, Morton's, McCormick and Schmicks, and the City Grill. Each speaker was paid approximately $1,000 plus expenses.

156. 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 omitted, 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 flatly contradicts and misrepresents both the Guidelines and Pfizer's FDA approved label.

157. 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 deceived decision makers about the approved uses of Lipitor, and the Guidelines themselves.

2. Best Medical Group Practices

158. The 2002 Lipitor Healthcare Cluster Playbook which addresses strategies, tactics, and materials to increase Lipitor sales in organizational customers had a section devoted to best practice regarding the implementation of key sales tools including the pivotal ATP-III Lipitor branded slide deck discussed above titled "The Lipid Slide Library, Volume 2: National Cholesterol Educational Program Adult Treatment Panel III Guidelines."

159. The Kelsey-Seybold Clinic in the southwest region was the site of Best Practice #2. The clinic provided care to over 350,000 patients including those with prescription drug

coverage paid for by government programs like Medicare and Medicaid. The patient educational coordinator and the Pharmacy team were targeted to receive materials to increase Lipitor prescriptions. Resources utilized included the inaccurate paper-based risk calculator discussed in this Complaint. The sales team also staffed and funded a health fair that used the inaccurate and biased point based CHD Risk Calculator to drive Lipitor prescriptions.

160. In addition, the Pfizer sales team "supported the Department of Pharmacy in its presentations to the medical group's practitioners". This included the use of the Managed Care Slide Deck which contained false and misleading ATP-III information. This presentation included the false ATP-III recommendation to treat patients with Lipitor if they were not at goal and deliberately omitted presentation of the relevant ATP-III drug therapy cutpoints. The sales team was applauded for "segueing (the deployment of resources) into a discussion about the effectiveness of Lipitor in helping patients reach their ATP-III goals".

161. The Camino Medical Group in California was best practice #3. The group serves over 165,000 patients, including patients with prescription drug coverage from government programs. The medical director, quality manager, and the CEO in 2002 launched a "collaborative intervention focusing on lipid management". The stated goal of the initiative was to help patients reach goal.

162. The paper-based risk calculators were provided to distribute to patients and practitioners. The clinical education consultant worked closely with the IT staff to identify patients not at goal and to design programs to increase the number of patients at goal. In May of 2002, Pfizer funded a health fair that used the point-based CHD Risk Calculator to mobilize patients to seek lipid evaluation and treatment. In October 2002, Pfizer paid for a "national recognized" speaker to discuss the importance of lipid lowering with physicians. "Lipid Rountables" (ie lectures by the Pfizer clinical education consultants" were also convened it Q3

and Q4. Measurement of the results of the false and misleading off-label get to goal agenda were differed until Q2 2003.

3. Other Physician Detailing - The Hard Sell At Ventura County Ambulatory Care Network

163. According to interviews conducted with practitioners in the ambulatory care network affiliated with Ventura County Medical Center (California) they were saturated with the "Get to Goal" and "Lower is Better" off-label messages by the Pfizer sales force during the period of the complaint. The Ventura County Ambulatory Care Network ("VCACN") provides care to a range of Medicare, MediCal (Medicaid of California) and uninsured patients. It is a vital safety net to its community.

164. Pfizer's detailing included frequent visits by the sales representatives and endocrinologists as paid speakers to discuss lipid management in VCACN's clinical sites. VCACN physicians were induced to participate by catered lunches and drug samples.

165. At these Pfizer "lunch and learns", the endocrinologist counter-detailed the NCEP guidelines, explaining to the busy primary care physicians that risk assessment was not necessary for multiple risk patients. Such patients simply needed, in Pfizer's view, to be prescribed Lipitor immediately. This violates the Guidelines and places patients at risk for being prescribed outside the safe and effective boundaries of the label. These false Pfizer statements also lead to false claims being submitted to public payors such as MediCal and Medicare Part D. Clearly, these marketing practices place patients at risk and compromise the fragile financial stability of public programs such as Medicare and Medicaid.

166. VCACN physicians were also detailed with promotional materials such as the "TNT Trial: Diabetes Subanlysis" sell sheet that included a reprint of one of the series of post-hoc analyses (i.e., exploratory studies, not results, from prospective controlled clinical trials conducted in patient subgroups by Pfizer and published in second tier journals.) The article for

the diabetes sell sheet was from June 2006 Diabetes Care titled "Effect of Lowering LDL Cholesterol Below Currently Recommended Levles in Patients With Coronary Heart Disease and Diabetes." The paper was sponsored by Pfizer and was co-written by Pfizer Medical Affairs staff. Authors included Judith Hsia, at the time a preventive cardiologist at George Washington University. She was at the time a local speaker in the Pfizer funded ESLM program. She later joined Pfizer as an employee.

167. The sell sheet was emblazoned with the banner that "Lipitor is widely accepted nationally on Medicare" and the representative was reminded to "insert the regional Medicare Sell Sheet".

4. Pfizer's False And Misleading Targeting Of PBDMs And Consultants

168. Pfizer created a Lipitor marketing program aimed at employer pharmacy benefit decision makers ("PBDMs"). The program is entitled "Cholesterol Management in the Work Place: Information for Benefit Decision Makers". 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."

169. Many pharmacy benefit managers ("PBMs"), large employers, and large health care providers contract with or employ 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.

170. "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."

171. "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 emphasis, is the following 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 misrepresented the Guidelines so as to induce off-label prescriptions for Lipitor.

172. The printed component of the leave-behind material included 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 was obliterated by Pfizer's false and misleading off-label sales pitch.

173. 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" and a branded promotional compact disc set. The "leave behind" "detail" 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 the four distinct risk groups and the significant difference between the LDL *goal* and the respective LDL *cutpoints* at which drug therapy is approved. "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.

174. The "Lipid Lowering Slide Kit" used for presentations included specific instructions not to leave the CD with the client. The slide presentation is more aggressive than the leave-behind material in promoting off-label use of Lipitor, and includes compact disc 1 "Lipid Lowering and Prevention of Coronary Heart Disease" modules 1-7. The second module, "NCEP ATP III Guidelines," contains a slide entitled "The first step in reducing LDL-C: Therapeutic Life Changes (TLC)" which concludes with the false statement that, "[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.

5. Pfizer's False And Misleading Targeting Of Physicians

175. Pfizer has saturated physicians with misleading information concerning Lipitor. Through 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 in an effort to induce doctors to initiate treatment outside the Guidelines, *i.e.*, off-label.

a. Lipid Goal Manager

176. Pfizer produced and distributed inaccurate and misleading lipid management software and associated technical support in a program called the "Lipid Goal Manager" ("LGM"). The software was intended to be used by Pfizer Clinical Education Consultants to provide "support to customers [physicians] integrating NCEP ATP III guidelines into routine

practice." According to Pfizer, the primary functions of the software was, first, to "assess patients' risk classification and LDL-C goals according to NCEP ATP III guidelines" and, then to "generate reports identifying individuals and groups of patients *at goal*, *not at goal* . . ." (emphasis added). Pfizer produced and distributed this software knowing that it was inaccurate and that it artificially inflated the risk posed to many patients in the Moderate Risk group. In short, the software promoted the off-label prescription and use of Lipitor.

177. Pfizer's knowledge of the inaccurate risk calculator imbedded in the software is evident in the software engineering. Although LGM's programming includes both the Framingham risk functions and the point system, the default option for the risk calculator is the point system. The risk calculator cannot easily be switched to the Framingham risk function, but if the user selects the option of the European region, the risk calculator switches to the more accurate underlying Framingham risk functions. The use of the point system systematically leads to more patients being treated with drug therapy outside of the FDA label. Thus Lipid Goal Manager produced and distributed by Pfizer causes false claims to be submitted to public payors for patients with government financed insurance.

178. For example, if the following patient information is entered into the software program – 65 year-old female with a total cholesterol of 240, HDL of 59, LDL-C of 15, and risk factors of age, and hypertension, 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:	15 mg/dL
Patient's 10-year risk:	11 percent

TO MEET NCEP GOAL LDL-C, LEVELS SHOULD BE

LOWERED BY 15 mg/dL OR MORE (14 percent)

179. However, if the Framingham function designed for computing by the NCEP is used the patient only has a 10 year risk of 6%. This patient although misclassified by Lipid Goal Manager as Moderately High Risk and eligible for drug therapy according to the label is actually correctly classified as only Moderate Risk. The deliberate integration of the point calculator in the Lipid Goal Manager has materially impacted the patient's risk score and risk category and likely led to off-label prescribing of Lipitor.. The inaccurate calculation misinforms both the patient and physician and corrupts optimal clinical decision making.

180. The Pfizer-produced software automatically generates a prepared, personalized letter to the patient advising 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). The software was also programmed to send the same letter to the patient encouraging drug therapy even if the patient does not meet the ATP-III guidelines for drug therapy. The patient is falsely informed by Pfizer that drug therapy is needed likely causing the patient to seek drug therapy from their practitioner.

181. According to Pfizer's Lipitor labeling and the Guidelines, no medication is indicated for this patient, as her risk of having a heart attack within 10 years was less than 10 percent and her LDL-C was less than 160. Both physicians and patients utilizing Pfizer's software were falsely informed by Pfizer that drug therapy was needed.

182. Lipid Goal Manager also creates a patient information sheet entitled "What is your cholesterol goal?" The sheet identifies three broad goal levels and omits presenting the four patient risk groups and their distinct cutpoints for drug therapy. This is one more example of how Pfizer has obscured cutpoints from the calculus for drug therapy for the Moderate Risk group, and has substituted cholesterol goals. Patients and physicians utilizing Lipid Goal

Manager are not informed would have no idea that there are critical treatment distinctions between Moderate and Moderately High Risk patients.

183. Lipid Goal Manager was implemented by Pfizer's sales force in medical groups across the country. Representative sites included the Granite Multispecialty Clinic in Massachusettes, the New Hamshire Correctional System, the Arnette Clinic in Indiana, the Lipid Clinic of Kathleen Dively, NP in Kentucky, the End Stage Renal Disease Unit at Walter Reade Hospital in Washington, DC ,

184. Inducements were provided to sites to encourage the implementation and integration of Lipid Goal Manager into the practice. These inducements included technical support from Pfizer's sales force in implementation, scientific support to publish papers to enhance the careers of the staff at the site, and technical support from contractors hired by Pfizer to assist the practice. Kathleen Dively, NP noted that when she stopped using the Lipid Goal Manager her ample supply of samples ended. Tom Algozzine, PharmD, the Pfizer Clinical Education Consultant in Manchestor, New Hampshire assisted the state pharmacist in publishing a research paper related to the use of the Lipid Goal Manager in "achieving goal". The Arnette Clinic staff with support from Pfizer did a poster presentation at an American Heart Association meeting once again using Lipid Goal Manager to evaluate the impact of the Arnette clinic in having patient's achieve NCEP goals. Lipid Goal manager was also used at Walter Reade to evaluate "getting to goal" and a paper was generated that was ultimately published in BMJ Nephrology.

185. Evaluating whether patients were appropriately begun on drug therapy was not the focus of Lipid Goal Manager or the related "research projects" supported by Pfizer. In stark contrast, Lipid Goal Manager was engineered as an effective tool to integrate the false and

misleading Lipitor messages in a software program and induce practice sites unknowingly to use the software to increase off-label use of Lipitor.

b. Lipitor.com Professional

186. 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 above, the presentation on Lipitor.com included slides that conflate the Moderate Risk and Moderately-High Risk groups into one treatment algorithm, and omit the distinction between the *cutpoints* at which statin therapy is indicated and the Guideline *goals*. In the Lipitor.com presentation, Pfizer intentionally omitted the Moderate Risk group and misleadingly presented only three risk groups and the goals of treatment: "High, Moderately High, and Low Risk Group."

187. In the Lipitor.com presentation, Pfizer falsely states that for the "Moderate Risk group" the LDL goals for patients with two CHD risk factors changed from 130 to an optional goal of 100. In fact, the Guidelines update published in July 2004 – which 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.

188. Pfizer's materially false and misleading Lipid Goal Manager, as with each of Pfizer's false and misleading materials, led to the submission of substantial numbers of false Lipitor claims, as well as to the submission of substantial numbers of false Lipitor claims for more expensive, unnecessary higher dosages.

189. 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. For example, in 2002, Pfizer's Local Marketing Team in Atlanta created the Cardiovascular Leadership Council 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."

190. 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 were used as a matter of policy in large promotional marketing programs developed for local metropolitan markets.

191. Another example of a Pfizer clinical program focused on the "importance of early diagnosis and treatment to NCEP ATP III goal levels," was "PFARM" or "Pfizer Facilitating the Advancement of Rural Medicine." These materials included a series of slides for Pfizer speakers to use in presentations aimed at rural physicians. Slide 10 entitled "Identifying Issues, Strategies and Actions" defined 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 presented the NCEP ATP III goals without any mention of the risk categories or cutpoints and their importance in determining when to initiate drug therapy. Slide 18 presented the Guidelines with the second and third risk categories compressed into one category, and the LDL goal as less than 130. Notably absent was any accompanying slide that outlined the four risk categories and the approved drug initiation levels. The presentation

mislead physicians by making it appear as though the Guidelines authorized initiating statin therapy on Moderate Risk patients with an LDL level greater than 130.

6. Pfizer's Misrepresentation Of TNT To Promote Lower Is Better

192. Pfizer sponsored the Treatment to New Targets ("TNT") clinical trial, which was designed to assess the safety and efficacy of aggressively lowering cholesterol levels for patients with existing heart disease. TNT is considered a pivotal clinical trial concerning how aggressively to treat high risk patients with Lipitor. TNT was not designed to evaluate the safety or efficacy of high dose Lipitor in patients without heart disease. Pfizer has misrepresented the findings of TNT and created an extensive series of *post hoc* analyses to drive off label use of Lipitor.

193. On March 14, 2005, results from the TNT trial were published in the New England Journal of Medicine ("NEJM"). The lead author was John C. LaRossa, M.D., who is a member of the NLEC "Education Council" and has chaired NLEC CME educational activities. The second author was Scott M. Grundy, M.D., PhD, an NLEC Education Council Member. Dr. Wenger, an NLEC "Faculty Member," is also a listed author.

194. The March 14, 2005 TNT article in NEJM includes a calculation of an important clinical statistic – the Number Needed to Treat ("NNT"). NNT is widely used by clinicians and policy makers in evaluating the efficacy of a therapy.

195. NNT is defined as the number of patients that need to be treated in order to prevent an event. Thus, for example, if the NNT for a trial studying a drug's effect on the number of deaths caused by heart attack is 100, that means 100 people would have to take the drug in order to prevent a fatal heart attack.

196. The primary outcome being evaluated in the TNT trial was the "first cardiac event." However, the March 14, 2005 article did not calculate NNT based on the first cardiac

event – instead the Article used the total number of cardiac events as the basis for its calculation. As a result, the Article presented an NNT calculation that was significantly lower than it should have been. (i.e., 30 v. 45). Thus, the Article made it appear that Lipitor therapy was more effective than it actually was.

197. This deceptive use of NNT was not replicated in additional Pfizer sponsored TNT analyses and related commentary published subsequent to the primary publication in the NEJM. For example, in a September 9, 2006 commentary in the Lancet titled "Does the metabolic syndrome help to select patients requiring high statin dose", the NNT for TNT was appropriately presented as 45.

198. Dr. James LaRossa , the primary author of TNT, stated that the calculation and presentation of NNTs in the paper generated a number of inquiries by concerned readers. Neither Pfizer, nor the paper's authors, nor the NEJM issued clarification or correction related to this issue. In a subsequent trial sponsored by Pfizer, named SPARCL, which studied Lipitor and Stroke, Pfizer returned to the standard calculation of NNTs.

199. Significantly, the NEJM Article does not properly disclose that it is using an alternative methodology or provide readers with an NNT calculation using the standard methodology for comparison.

200. In addition, the TNT article's Figure Four misrepresents existing clinical data concerning the relationship between LDL cholesterol and CHD events. This figure purports to show a linear relationship between LDL cholesterol (LDL-C) and CHD events, using data points derived from previously-published statin trials. These statin trials include a variety of drugs, dosages, and study methodologies.

201. The NEJM's Article's "Figure Four" violated basic scientific principles by presenting a "seemingly straight forward" graphical analysis without describing the underlying

methodology that was used (if in fact a valid methodology was used). For example, no explanation was provided concerning (i) the criteria that were used to include and exclude clinical trials, (ii) the criteria that were used to select the relevant data points, and (iii) the statistical basis used to establish a linear relationship. The appropriate technique used to combine disparate data from multiple sources is called a meta-analysis which is complex and often controversial in its application.

202. Significantly, the linear relationship presented in Figure Four directly conflicts with the validated information provided in the NCEP ATP-III Update – upon which Pfizer's FDA-approved Lipitor label is based. The NCEP ATP-III Update concluded, based on a substantial body of epidemiologic data, that "[a]lthough the association between LDL-C levels and CHD risk is continuous, it is not linear." (emphasis added). Instead, the Update concluded that the relationship between LDL-C levels and CHD risk is "curvilinear, or log-linear."

203. The issue of whether LDL has a linear or curvilinear relationship with CHD risk is critical to clinicians and policy makers. If the relationship were, in fact, linear, then decision makers could (albeit incorrectly) conclude that the absolute benefits from Lipitor achieved at higher levels of LDL are also present at very low levels of LDL. Thus, the Pfizer-sponsored NEJM article, misrepresented the relationship between LDL-C level and CHD events in order induce clinicians and policy makers to accept the risk and cost of statin therapy in cases where otherwise they would not.

204. The misleading calculation and presentation of the NNT and the scientifically compromised and misleading "Figure Four" in the Article is exploited in Pfizer-sponsored educational programs such as the NLEC and ESLM. Figures analogous to "Figure Four" are also present in Pfizer promotional materials dating back to at least 2001.

205. Significantly, the linear relationship presented in Figure Four directly conflicts with the validated information provided in the NCEP ATP-III Update – upon which Pfizer's FDA-approved Lipitor label is based. The NCEP ATP-III Update concluded, based on a substantial body of epidemiologic data, that "[a]lthough the association between LDL-C levels and CHD risk is continuous, it is not linear." (emphasis added). Instead, the Update concluded that the relationship between LDL-C levels and CHD risk is "curvilinear, or log-linear."

206. The issue of whether LDL has a linear or curvilinear relationship with CHD risk is critical to clinicians and policy makers. If the relationship were, in fact, linear, then decision makers could (albeit incorrectly) conclude that the absolute benefits from Lipitor achieved at higher levels of LDL are also present at very low levels of LDL. Thus, the Pfizer-sponsored NEJM article, misrepresented the relationship between LDL-C level and CHD events in order induce clinicians and policy makers to accept the risk and cost of statin therapy in cases where otherwise they would not.

207. The misleading calculation and presentation of the NNT and the scientifically compromised and misleading "Figure Four" in the Article is exploited in Pfizer-sponsored educational programs such as the NLEC and ESLM. Figures analogous to "Figure Four" are also present in Pfizer promotional materials dating back to at least 2001.

7. Pfizer's Selective Reporting of Clinical Trial Data

208. Pfizer's exploitation of its "landmark" clinical trials is not new to Lipitor. Pfizer has also been alleged to have manipulated clinical research data related to to its research and publication campaigns surrounding its drug Neurontin (gabapentin). These violations of clinical research protocol are examined in great detail in a November 12, 2009 article in the New England Journal of Medicine (http://content.nejm.org/cgi/content/abstract/361/20/1963). The

article concludes that Pfizer used selective and miseading outcome reporting for Pfizer-funded trials of off-label use of gabapentin

209. Pfizer also manipulates clinical trial data by limiting the distribution of clinical trial data that is not favorable to Lipitor and by actively promoting clinical trial data that is favorable to Lipitor. In press releases, on Lipitor.com, in detailing, in both sponsored promotional and non-promotional venues Pfizer aggressively reports on the findings of favorable trials (and selectively advantageous trials of competitors). The integration of the Pfizer Landmark trials for Lipitor and the Lipitor marketing plan is outlined in the 2002 Lipitor operating plan, including principally the CARDS (Diabetes), ASCOT(High risk hypertensive patients), and TNT (safety and efficacy of high dose Lipitor) studies. Not only does Pfizer actively promote these studies, but, as part of its clinical trial strategy, it amplifies the results in large series of post-hoc analyses targeted to journals with more specialized readership. On the other hand, Pfizer routinely omits presenting studies that were not favorable to Lipitor, such as the 4D study, Belles (women), and SAGE (elderly).

210. A 2008 analysis of statins and moderate-risk females in the Journal of Empirical Legal Studies (Eisenberg and Wells) identified, in a review of the federal registry clinicaltrials.gov, a Lipitor trial, named Cashmire, in the subgroup of women that was never presented or published. Substantial controversy is present on the risk and benefits of statins in women without heart disease. The authors concluded that "each year reasonably healthy women spend billions of dollars in the hope of preventing heart attacks but the scientific evidence supporting their hope does not exist."

8. Pfizer's Targeting Of Moderate Risk Patients With Hypertension

211. 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 promoted to physicians Pfizer's materially false and misleading off-label claim that each hypertensive patient, regardless of his Guideline risk category, should be taking Lipitor. Pfizer's marketing campaign was high profile and even included medical journal advertisements and promotion on Lipitor.com.

212. In support of its off-label hypertension marketing campaign, Pfizer misrepresented the design and findings of a landmark Pfizer-funded clinical trial conducted and published in Europe known as the "ASCOT trial." Pfizer falsely claimed that the Ascot trial found that all hypertensive patients benefit from taking Lipitor. Not only did the Ascot trial not result in such a finding but the ASCOT trial was only designed to address the role of Lipitor in hypertensive patients who had at least three additional cardiac risk factors. Pfizer's claim is contrary to Pfizer's FDA Lipitor label and the 2004 ATP-III update which integrated findings based on the ASCOT Trial. In fact, the ATP-III update did not find any evidence in ASCOT to change the indications for Moderate Risk patients.

213. Pfizer's Liptor.com website, in a section intended for practicing physicians, misrepresented to doctors visiting Lipitor.com that the ASCOT Trial (which Pfizer falsely termed a "primary prevention" study) established the wisdom of prescribing Lipitor to people with "mildly elevated cholesterol" and "*moderate* risk of CHD." (Emphasis added.)

214. A Pfizer Lipitor advertisement which Pfizer published in medical journals falsely and misleadingly stated that the ASCOT trial constituted "[p]roof that Lipitor helps both moderate-risk and high-risk patients." Pfizer's 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 connection with the ASCOT trial) constitutes a higher cardiac risk than even "Moderately High Risk" in the United States. As a result, Pfizer's use of the European term "moderate risk" in its Lipitor advertisements as if it had the same meaning as the

American Guideline term "moderate risk," was materially false, fraudulent, and misleading and was intended 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.

9. Pfizer's Illegal Off-Label Marketing To Chronic Kidney Disease Patients, Including Those With End Stage Renal Disease

215. The National Institutes of Kidney Disease ("NIKD") estimates that currently 26 million Americans suffer from chronic kidney disease ("CKD"). CKD is the progressive loss of renal/kidney function.

216. End Stage Renal Disease ("ESRD"), also known as kidney failure, is the most severe stage of CKD. According to NIKD, as of 2005, more than 485,000 Americans were being treated for ESRD.

217. ESRD is a priority for the Medicare program because Medicare has an insurance benefit for eligible patients with ESRD.

218. Pfizer has misrepresented the ATP III guidelines and has limited the distribution of findings from landmark Lipitor clinical trials in order to promote the off-label use of Lipitor for patients with CKD. The estimated 26 million Americans suffering from CKD, including the subset of patients with ESRD, represent a substantial potential market for Lipitor.

a. Pfizer Has Targeted Patients With CKD

219. Pfizer has promoted the idea that CKD is an NCEP CHD risk equivalent. This is false – CKD is not a NCEP CHD risk equivalent. In addition, Pfizer promoted the idea that Lipitor slows the deterioration of kidney function in patients with CKD. While the role of statins, including Lipitor, in slowing the deterioration of kidney function is an important research question, data relating to that question is unclear at best. Lipitor does not have an FDA-approved

indication for more aggressive treatment to slow the deterioration of kidney function in patients with CKD.

220. Pfizer has illegally promoted this false message concerning CKD patients directly through its sales force. Pfizer has also promoted aggressive and off-label use of statins (particularly Lipitor) through third party educational programs. In addition, Pfizer has amplified its promotional message urging physicians to aggressively treat CKD patients with statins (particular Lipitor) in review articles written by authors who receive substantial payments from Pfizer for research and speaking engagements.

221. Patients with a CHD risk equivalent are automatically classified into the NCEP ATP III High Risk Category. According to the guidelines, these highest risk patients are treated most aggressively and are initiated on drug therapy at the lowest cutpoints. However, according to the Guidelines, patients with CKD are distributed throughout the four NCEP risk groups. By falsely promoting CKD as NCEP CHD risk equivalent, Pfizer intentionally has potentially caused millions of patients with CKD to be prescribed Lipitor off-label.

222. Until 2008, Mr. William Morant was a Pfizer sales representative in Pennsylvania. Morant was trained by Pfizer to tell physicians that CKD was a NCEP CHD Risk Equivalent in order to sell more Lipitor. This directive was later reversed. Morant states that Pfizer made a decision to cease this marketing message because the company "was trying to get a CKD indication from the FDA" for Lipitor and "continuing to market on this message created liability for the company."

223. Dr. William Chenitz, a board certified nephrologist, from Newark, New Jersey, recalls being detailed aggressively by sales representatives with the message that CKD was a CHD risk equivalent. Moreover, Dr. Chenitz was trained as a Pfizer speaker at an all expenses paid weekend in Miami, as part of which he received an honorarium. However, Dr. Chenitz

never gave any talks, and believes the training was designed to educate him on the issues that Pfizer saw as priorities.

224. Dr. Jhung was introduced to off-label marketing messages and inducements from Pfizer early in his career as a nephrologist. As a fellow at San Francisco General Hospital, Dr. Jhung was approached by a Pfizer sales representative and was asked to present a paper at a lavish dinner meeting sponsored by Pfizer. The paper that Dr. Jhung was asked to present was "A Controlled, Prospective Study of the Effect of Atorvastatin [Lipitor] on Proteneuria and Progression of Kidney Disease," which was published in the American Journal of Kidney Disease, March, 2003. The exploratory research concerning whether Lipitor stabilized renal function was funded by Pfizer. Dr. Jhung was "surprised and gratified" at the end of the dinner to receive a check for $200. A "fellow" is a physician who is still in training in his specialty, as a result of which $200 was a large amount for a fellow such as Dr. Jhung.

225. Third party programs sponsored by Pfizer, such as the ESLM, also widely promoted the false statements that "CKD is a NCEP CHD risk equivalent" and that Lipitor "Blunts Declines in Renal Function in CKD". These marketing messages were included in the 2006 ESLM national program entitled "Putting Lipid Management Knowledge into Clinical Practice". These statements were integrated into the program slides and were reinforced by the paid faculty. Program participants received valuable CME credits and fine dining as part of this program. Dr. Polansky attended several of these ESLM/Pfizer programs and attempted to correct the presentation but Dr. Polansky was ignored by the faculty and by ESLM, the for-profit medical education entity that administered the program for Pfizer. Pfizer's message reached substantial numbers of faculty and participating physicians during the programs. The Wall Street Journal reported on the issue of the scientific integrity of this program in a story on December 20, 2007.

226. Pfizer also funded educational programs such as the 2006 ESLM national program titled "Putting Lipid Management Knowledge into Clinical Practice". These Pfizer-funded educational programs omitted providing information about the 4D trial, which is discussed *infra*, at ¶¶ 232-234, despite multiple slides devoted to CKD. Notwithstanding the well recognized limit on the value of observational studies, Pfizer's ESLM programs relied upon observational studies and ignored the 4D trial and the NCEP guidelines to support its assertion that statin therapy (particularly Lipitor therapy) decreases cardiovascular events and decreases the erosion of renal function in all patients with CKD.

227. Pfizer has also promoted off-label use of Lipitor for CKD patients through its CME Programs produced by the ESLM. In particular, Pfizer uses ESLM's free online CME called "Online Grand Rounds" to promote off-label use of statins for CKD by presenting hypothetical patients for whom drug therapy is recommended outside the NCEP guidelines (and the clinical trial evidence). In many of the Grand Rounds case studies the use of Lipitor is recommended.

228. For example, the "Online Grand Rounds" program for "Case 3: Reducing Cardiovascular Risk in a 36-Year-Old Man with Chronic Kidney Disease," was designed to encourage clinicians to aggressively prescribe statins to patients with CKD and provided false and misleading content. ESLM's "Case 3" promoted guidelines created by the National Kidney Foundation – the foundation and its guideline development efforts are financed by the pharmaceutical industry—that advocated changing the goals for patients with CKD from the relevant NCEP goal to a universal goal of less than 100. The case concluded by, *inter alia*, recommending statin therapy for the patient described in the case. Although the case noted that this recommendation was contrary to ATP III, it failed to identify it as an off-label use of statins.

229. Pfizer's own website, Lipitor.com, proclaims that Lipitor treatment leads to "[s]ignificant improvement" in cardiovascular outcomes for patients with "renal dysfunction." This statement is based on a subgroup analysis in the ASCOT trial funded by Pfizer. The finding is only presented in a table and not discussed in the paper. In fact, the ASCOT trial was not designed to address the question of the relative benefits of Lipitor in high risk hypertensive patients with CKD versus comparable patients without CKD.

b. Pfizer Has Targeted Patients With ESRD

230. In stark contradiction to Pfizer's efforts to promote Lipitor for patients with ESRD, two major clinical studies have found that statins are not safe and effective in this sick and vulnerable population. In fact, one of the trials identified a two-fold increase in fatal strokes in patients who took Lipitor.

231. The first study was funded by Pfizer. It was published in the New England Journal of Medicine in 2005 and is referred to as the "4D" study. Its principal investigator was Dr. Christoph Wanner. In 4D, 1,255 ESRD patients on dialysis with type 2 diabetes were randomized to receive either 20-mg atorvastatin (Lipitor) or a placebo. The authors concluded that "statin therapy is not warranted in patients with type 2 diabetes who are undergoing dialysis treatment for chronic kidney disease". This conclusion was based on the trial's findings that: (1) statin therapy produced "limited" benefits for these patients; and (2) instead, statin therapy caused a statistically significant doubling in the risk of fatal strokes in these patients.

232. The 4D trial also concluded that "it is difficult to rely on uncontrolled observational studies" when assessing the efficacy and safety of statin therapy in patients with ESRD. Observational studies are non-experimental studies done by analyzing the data from a completed clinical trial in an effort to explore questions other than those rigorously controlled in that trial. The 4D trial noted that such "observational studies" had incorrectly "shown substantial

advantages of statins in the treatment of patients receiving hemodialysis." This view of the value of "observational studies" is consistent with the general understanding in medicine, that such studies are useful for generating research hypotheses, but are not appropriate for developing reliable clinical conclusions.

233. Furthermore, the 4D finding of the lack of efficacy of statins in ESRD has been reproduced in a recent clinical trial sponsored by Astra-Zeneca. The trial – called "An Assessment of Survival and Cardiovascular Events" ("AURORA") -- was published in the New England Journal of Medicine in 2009. AURORA concluded that, for patients undergoing hemodialysis, statins had no significant effect in preventing (i) death from cardiovascular causes, (ii) nonfatal myocardial infarction, or (iii) nonfatal strokes.

234. Pfizer has promoted increased stsatin use through the "Online Grand Rounds." For example, "Case 27: A Case Study in Cardiovascular Risk, Renal Disease and Lipid Management," concerns a hypothetical patient with ESRD and on dialysis. Pfizer discussed several observational studies to support its assertion that statin treatment improved cardiovascular outcomes of patients with ESRD, but failed to mention the 4D trial. Further, the program failed to disclose that the 4D trial specifically challenged the reliability of at least one of the observational studies cited in the program. Not surprisingly, the program concluded with the patient being prescribed a statin.

c. Pfizer Has Compromised The Distribution Of Critical Clinical Trial Information

235. According to Dr. Wanner, the Principal Investigator for 4D and the principal author of the 4D report, Pfizer delayed the publication of 4D. Given the 4D findings, the publication of 4D clearly would have limited Pfizer's ability to aggressively market Lipitor for use in patients with CKD and, in particular, with ESRD. Dr. Wanner also noted that Pfizer unsuccessfully applied considerable pressure to influence the published 4D results.

236. Since the publication of the 4D results, Pfizer has consistently omitted any mention of the 4D results in its promotional materials and in its programs funded through educational grants. Further, Pfizer has omitted the results of the 4D trial in the "Landmark Trial Slide Deck" on the health professional section of Lipitor.com. In contrast, this section of the website provides substantial details on trials with results favorable to Pfizer, such as ASCOT.

d. Pfizer Relies On Off-Label Messages In Medical Journal Review Articles

237. Pfizer has also been successful in getting its aggressive off-label message about using statins for ESRD by leveraging its relationships with "thought leaders" who are provided with a range of payments and inducements. These thought leaders have produced review articles in reputable medical journals that advocate aggressive use of statins for ESRD contrary to the NCEP guidelines.

238. Dr. Mario Tonelli is a nephrology thought leader with financial relationships with Pfizer who has advocated off-label use of statins. In March 2006, Dr. Tonelli was the principal writer of an "In Depth" review in the Peritoneal Dialysis International entitled "Statins for Treatment of Dyslipidemia in Chronic Kidney Disease." The article abstract notes that "Additional Consideration could be given to treating all dialysis patients felt to be at risk of cardiovascular disease (irrespective of cholesterol level) given the safety and potential efficacy of statins." At the time of publication, Dr. Tonelli disclosed that he served on a Pfizer advisory board in 2004 and had received honoraria from Pfizer for continuing medical education lectures in 2004-2005.

239. Dr. Tonelli is also the author of a paper (which is cited in ESLM slides) published in Circulation entitled "Effect of Pravastatin on Cardiovascular Events in People with Chronic Kidney Disease." This observational study was published in May 2004 and reported incremental

benefits for patients with CKD over those without CKD. In this article, Dr. Tonelli provided no disclosure concerning conflicts of interest.

240. Dr. Terry Jacobson, professor of medicine at Emory University, is another academic with financial relationships with Pfizer who has advocated off-label use of statins in patients with ESRD. In March 2008, he was the lead writer of a "State of the Art Paper" published in the Journal of the American College of Cardiology entitled "Managing Dyslipidemia in Chronic Kidney Disease." The paper concluded that "Because statins are relatively safe and the evidence for lowering cholesterol to reduce CVD is so overwhelmingly positive in non-hemodialysis patients , it is reasonable to continue treating these patients until future trials are present". According to the author's disclosure statement, Dr. Jacobson is a consultant to and on the speaker's bureau of Pfizer.

241. In 2008, Dr. Jacobson, was the principal author of a paper published in the Mayo Clinic Proceedings that compared Lipitor to its competitor Zocor. The Pfizer-funded study was coauthored by staff from Pfizer Outcome's Research Department and journal article writing consultants. As part of this effort, Dr. Jacobson received consulting fees for research design, data interpretation, and manuscript preparation.

242. Flaws in Dr. Jacobson's data were identified by an unnamed journal during a peer review submission. The Wall Street Journal, in a report on June 14, 2007 entitled "Pfizer Backtracks on Lipitor's Edge over Rival," reported that Pfizer disclosed the flaws in Dr. Jacobson's data to the Securities and Exchange Commission. Dr. Jacobson, through Emory University, also released false and misleading information about the safety of statins in (see section x).

e. The Impact Of Pfizer's Illegal ESRD Off-Label Marketing

243. Pfizer's Lipitor marketing effort for patients with ESRD has been extremely successful. The use of statins in ESRD patients has increased dramatically over the period of Pfizer's illegal marketing campaign. According to 2007 data published by the United States Renal Disease System of the National Institutes of Health, approximately forty percent (40%) of ESRD patients were taking a statin.

244. Similarly, a Canadian study published in Kidney International found that statin use in Ontario increased from 60% prior to publication of 4D in 2005 to 68% two and a half years later. The study concluded

> that publication of a large, expensive, randomized trial in patients receiving hemodialysis had no immediate impact on clinical practice. The use of a common cardiovascular medicine [i.e., statins] in this patient population [i.e., ESRD] appears to be influenced by other factors.

Pfizer's multidimensional off-label marketing scheme is a prominent factor influencing the extensive off-label use of Lipitor in ESRD patients.

10. Pfizer's False And Misleading Targeting Of Patients

245. Pfizer's FDA-approved Lipitor 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.

246. Pfizer's off-label promotion of Lipitor to 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 what Pfizer calls "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 Pfizer site, which Pfizer simplistically calls detailed NCEP concepts, "untreated high cholesterol can lead to serious medical conditions." On the site, Pfizer advocates goals for LDL cholesterol, provides a table showing three, rather than four categories, and refers to an oversimplified LDL goal of less than 130 for all people with two or more risk factors for whom Pfizer suggests consideration of drug therapy. Pfizer never presents the relevant, controlling *cutpoint* levels for the Moderate Risk group at which Lipitor therapy 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. . . ." 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.

247. Sana La Rana has been tremendously successful. During Pfizer's Sana La Rana cholesterol education campaign, which ran from June to December 2003, Pfizer distributed 400,000 patient education brochures at doctors' offices and community events, and hosted 282 community charlas (chats) that reached nearly 4,300 people in Miami and Houston. Moreover, the website received more than 13,000 hits and the toll-free hotline received 5,300 calls.

248. 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's imperative of educating physicians and patients on 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."

249. A further example of Pfizer's direct-to-consumer strategy is its 2003 internet-based campaign. Consumers who registered at Pfizer's Lipitor.com website 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." On the website, Pfizer also "alerted" consumers that "what you can't feel can hurt you," and encouraged them 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."

250. No information was 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 created a sense of alarm regarding cholesterol levels, absolving consumers from taking responsibility for modifiable risk factors, and steering patients off-label to Lipitor.

11. Pfizer's Promoted And Disseminated Inaccurate Computerized Risk Calculators With The Purpose And Effect Of Expanding The Off-Label Use Of Lipitor

251. Pfizer has promoted 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.

252. 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 complex mathematical equation called the "Framingham model" to calculate a person's 10 year risk of a major coronary event 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 to be used only if and when an electronic calculator is not available.

253. 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.

254. 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.

255. The Coordinator of the NCEP Division for the Application of Research Discoveries, Dr. James Cleeman, advised Relator in January 2010 that "[t]he electronic calculators yield more accurate results since they incorporate the risk factors as continuous variable whereas the point system necessarily assigns whole-number pints to discrete ranges of values for the risk factors."

256. 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.

257. These inaccuracies are recognized by the NCEP. Scott Grundy, the Chairman of the NCEP, stated to Dr. Polansky that the NCEP was aware that, with use of the paper, point based risk assessment, "there would be some errors in classification. Therefore we have subsequently pointed out that the computer system is preferred."

258. Pfizer could easily implement the original Framingham model into its electronic media promotional activities, but it, instead, exploits this known inaccuracy in the point-based scoring system. For example, the Lipitor.com website provides the inaccurate online cardiac risk calculation on its patient and practitioner pages.

259. In 2002, as part of Pfizer's Olympic promotional activities, a CD-based risk calculator for use on desktop computers was distributed. This software, which was distributed

by Pfizer itself, uses the inaccurate 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.

260. None of Pfizer's computerized risk-analysis software carries any warning or advice that the less-accurate scoring system is being used, or that use of the Pfizer-generated system can impact clinical decisions.

261. Pfizer's own clinical sales force was unaware that Pfizer had produced inaccurate risk calculators that were used extensively in community health fairs, at HMOs, and at employer-sponsored health fairs. Several former Pfizer Clinical Education Consultants ("CEC") noted that they were told the software was engineered to produce the most accurate results and were shocked to learn that this was not the case. One former CEC from the New York market, Arlene Lee, Rph noted that the substitution of the Framingham functions with the points system was a "bait and switch".

262. Pfizer also sponsors a free "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.

263. Dr. Jon Lelevier, an internist in San Diego, California, and Dr. Seth Bernard an internist in Flint, Michigan, were both active users of the ePocrates cardiac risk calculators sponsored and branded by Lipitor and used risk calculation as a routine part of their management of patients with high cholesterol. Both clinicians were alarmed to learn that the ePocrates software did not use the accurate Framingham risk functions but had substituted the point

simplification. Both physicians requested and were provided with the links to the NCEP website where pc and pda downloads of the accurate risk calculators designed for computing were located.

264. 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.

265. The 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.

266. A team of physicians and researchers recently compared the accuracy of the point-based risk assessment to the equation based Framingham assessment. This research shows that the use of the point based risk assessment has misclassified millions of Americans into higher risk groups, the result of which is typically more aggressive treatment recommendations. The results of their research is summarized in an article titled "Coronary risk assessment by point-based vs. equation-based Framingham models: Significant implications for clinical care."

267. The study found that for a projected 40 million adults with two risk factors, but no known CHD or risk equivalents, the point based risk assessment would classify 14.3% of adults (5.8 million) into different risk groups than the Framingham assessment would, with 10.8% (4.4 million) being misclassified into higher-risk groups and 3.5% (1.4 million) into lower-risk groups. The projection of 40 million adults was based on 848 subjects whose medical information was collected from the 2005-2006 National Health and Nutrition Examination Survey ("NHANES".)

268. The study found that, on average, the point-based assessment generated risk estimates a mean of .8% higher than the Framingham assessment for men, and .6% higher for women. Importantly, the difference between the two assessments were substantial for many individual patients, and the magnitude of these differences grew as risk increased. Overall, 27% of subjects with risk above 10% (as calculated by the Framingham assessment) had risk estimates that diverged more than 5% from the point-based assessment.

269. By way of an individual example of a misclassification, the study found that:

> [I]f the original Framingham equation estimated a woman as having an 7% risk of a major coronary event over the next 10 years, she would be placed in the < 10% ("moderate risk") risk category. For a patient in this risk category, guidelines recommend initiating drug therapy for LDD >=160 mg/dL and aiming for a target LDL of <130 mg/dL. In contrast, if the point-based system estimated the same woman's risk as 11%, this would place her in the 10-20% ("moderately high risk") risk group. In this risk category, guidelines recommend initiating drug therapy at LDL >=130 mg/DL, with a target LDL of either ,130 ir ,100 mg/dL.

270. The misclassifications generated by the point-based risk assessment typically drive the use of lipid-lowering medications such as Lipitor because over two-thirds of misclassifications moved patients into higher-risk groups.

271. For those patients whose misclassifications result in their placement in high risk categories for which the ATP III Guidelines recommend aggressive treatment through the use of statins, such prescriptions are off-label.

272. Pfizer has, through its promotion and distribution of inaccurate point-based risk assessments in electronic media, caused vast numbers of off-label prescriptions to be written, irrespective of the physician's knowledge that such treatment is off-label.

12. Getting To Goal

273. "Getting to goal" was Pfizer's "mantra" in selling Lipitor, according to Confidential Witness A, a specialty/institution sales representative at Pfizer at nearly 10 years. Indeed, getting to goal "was what everything was ultimately about," said Confidential Witness B,

who worked for Pfizer for almost 30 years as a sales representative, regional sales trainer, district manager and regional account manager.

274. The focus was on the goal, and Confidential Witness B considered the cut-points merely "someone's negotiated number." Likewise, Confidential Witness S, a Pfizer district sales manager for over 15 years, said that "I don't even remember using the terminology 'cut-points.' We never used that terminology. We always used NCEP goals." Similarly, Confidential Witness T, a Pfizer sales representative for several years, recalls targeting only goals and not cut-points.

275. Beyond focusing on goals, Pfizer management pushed sales representatives to ignore cut-points. For example, Confidential Witness R, a Pfizer sales representative for many years, said that "we were told to do that on a number of occasions in what's called POA meetings or field rides with your boss. You were pushed to - it was something I wasn't quite comfortable with, because some patients seemed to be doing well with what they were on."

13. Software vs. Paper NCEP Guidelines

276. According to Confidential Witness C, a Pfizer sales representative for about five years, physicians were not generally aware of software regarding the NCEP Guidelines and Pfizer representatives used the paper model for demonstrations.

277. Indeed, Pfizer apparently neglected to advise salespersons of the software version's very existence, judging from the many who were unaware of it during long periods of employment including Confidential Witness F, a Pfizer sales representative for eight years; Confidential Witness G, a long-time Pfizer sales representative and then district manager; Confidential Witness H, a Pfizer sales representative for 10 years; Confidential Witness I, a Pfizer senior sales representative for eight years; Confidential Witness J, a Pfizer sales

representative for three years; Confidential Witness L, a Pfizer sales representative for ten years; and Confidential Witness P, a Pfizer specialty sales representative for several years.

278. Salespersons who knew of the software version were often unaware it was any different than the paper version, including Confidential Witness E, a Pfizer district sales manager for four years; Confidential Witness M, a Pfizer "master level" sales consultant for almost 30 years; Confidential Witness O, a Pfizer sales representative for eight years; and Confidential Witness V, a Pfizer clinical education consultant for several years.

279. Of course, Pfizer's sales managers and marketing strategists were certainly aware of the difference between the software and paper versions of the NCEP guidelines; they knew the latter cast a broader net and resulted in over-prescription of Lipitor. For example, asked whether Pfizer ever pushed sales representatives to use the paper model rather than the software, Confidential Witness X, a Pfizer district sales manager for more than a dozen years, said "Well, yeah. When you look at points, that's where the market was." Furthermore, "We focused on the points, the patient's LDL level, almost exclusively, and their risk associated with that," because Pfizer advised its sales managers that using the paper version would result in more prescriptions and sales than the software version.

14. Off-Label Promotion

280. Confidential Witness C, a Pfizer sales representative for about five years, "was asked to do a lot of off-label promotion… I was told to make sure the doctor knows [Lipitor] is a class of [statins] and just because there is no clinical data behind it, the other statins on the market have proven X, Y and Z; so therefore, my boss would make me say, 'well, if you throw a rock through a glass window, the glass is going to break - so how many times do you actually have to do a clinical study to prove the same thing?'" Confidential Witness D, a Pfizer sales

representative for approximately ten years, confirmed that Pfizer was "definitely" promoting Lipitor for off-label uses.

281. Sales representatives would routinely "detail" physicians on off-label uses of Lipitor. For example, Confidential Witness M, a Pfizer "master level" sales consultant for almost 30 years, knew that some sales representatives would simply scour the internet for off-label information and pass it on to physicians, such as unknown studies from Europe based on as few as 15 patients. He would personally receive off-label materials from Pfizer management disingenuously labeled "'not for detailing', but why do you think they sent it to you?" Pfizer impliedly knew that "M" and others would use the materials for detailing, because it often instructed them not to leave the materials with physicians.

282. By way of another example, Confidential Witness Q, a Pfizer specialty sales representative for about six years, would receive off-label materials for Pfizer and believed he was "basically kind of free to run with things on your own" and that the "not for detailing" disclaimer was a sham. Similarly, Confidential Witness O, a Pfizer specialty sales representative for eight years, described the "not for detailing" label as another "wink-wink" situation and stated that off-label materials received from management were regularly used to detail physicians. In his case, his supervisor said "Well, it wouldn't be bad if you left [the off-label materials] behind in the office… as you are leaving, leave it on his desk as you are walking out." Confidential Witness Q was instructed by Pfizer management to say, 'Hey, there is some good information in here. I am not really able to discuss it with you, but here's the study."

283. Confidential Witness U, a Pfizer sales representative for several years, was compelled by management to promote Lipitor for patients who had normal cholesterol but also hypertension. "The scheme was to sell the cholesterol pill for patients with normal cholesterol, to use blood-pressure as a marker of risk." Additionally, he and others were encouraged by

Pfizer management to leave materials designated "not for detailing" with physicians regarding Lipitor use for chronic kidney disease. In a nutshell, "it really seemed like [Pfizer] was trying to expand the market outside the realm of what we could justify and what was indicated by the FDA."

284. Confidential Witness W, a Pfizer sales representative for 12 years, attended a meeting where Pfizer management gave sales representatives a detailing piece on off-label use for chronic kidney disease, along with tongue-in-cheek "instructions" about how the piece could and could not be used to detail physicians. He pointed out to this supervisor that he regularly violated those rules, but his comment was ignored.

285. Similarly, Confidential Witness N, a Pfizer sales representative for about four years, was present when physician speakers discussed off-label uses in meetings.

15. Omitting/Downplaying Side Effects

286. Confidential Witness C, a Pfizer sales representative for about five years, was almost fired on several occasions when she directed physicians to the Lipitor package insert on side effects when they raised the subject. Her superiors told her "this was a strict no-no," and not only discouraged her from disclosing side effects but instructed her to downplay any the physician was already aware of. Indeed, when confronted by physicians about side effects in their patients, she was directed to say "Wow, you are really seeing that? You are the only doctor - you're the first physician that is telling me that."

287. Keeping sales representatives in the dark about side-effects was one technique used by Pfizer. For example, Confidential Witness K, a sales representative for three years, would refer side effect issue from physicians to a Pfizer department. However, responsive information would be returned only to the physician and not to sales representatives. Similarly,

Confidential Witness W, a Pfizer sales representative for 12 years, never heard side effects mentioned at any sales meeting and he believed the topic was consciously ignored.

16. "Speaker Fees"

288. Confidential Witness C, a Pfizer sales representative for about five years, freely distributed $1000 "speaker fees" to physicians whether they gave speeches or not. She often targeted physicians who were prolific Lipitor prescribers, or physicians who were thought to be drifting toward competing drugs. Likewise, Confidential Witness O, a Pfizer sales representative for eight years, considered speaking engagements "a wink-wink type deal - get doctor Smith on board and a Lipitor speaker and we'll get some scripts from him" Confidential Witness R, a Pfizer sales representative for many years, said Pfizer would hire speakers "and it would either be people that were high writers for competitive product or someone that we felt we could get to write more." In his experience, the meetings were more for the speakers than the attendees, because the latter would often be "the same people who were coming out over and over again for a free meal."

289. According to Confidential Witness M, a Pfizer "master level" sales consultant for almost 30 years, "all you're doing is paying [speakers] to write scripts" because the fees of $2,000 or $2,500 were disproportionate to the handful of physicians attending the meeting.

17. Pfizer Reveals, And Presents Evidence Of, Its Off-Label Marketing Campaign To The Investment Community

290. Despite the fact that Pfizer's Lipitor label, by incorporating the Guidelines, places a natural limit on the eligible number of new on-label Lipitor patients, 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. At a June 17, 2003, analyst meeting, Karen Katen, Pfizer's Executive Vice President and the 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, Pfizer thereby committed itself to a program of off-label Lipitor marketing.

291. According to the Guidelines, there are approximately 37 million Americans eligible to use statins, far fewer than the 64 million targeted by Pfizer. In fact, Pfizer's own Operating Plan for 2002, discussed *infra*, stated 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 to whom Pfizer unlawfully markets and the 36 million Pfizer believes are eligible for statin use) represents a pool of patients who do *not* meet either Lipitor's label or the Guidelines, and toward whom marketing of Lipitor would be off-label and unlawful.

292. In Pfizer's Second-Quarter 2004 Performance Report, Karen Katen stated,

> 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 well funded and highly organized illegal off-label marketing campaign could this inconceivable number of patients be placed on Lipitor.

293. Pfizer reveals its illegal off-label marketing scheme when it speaks to the investment community, attempting to persuade investors that it can expand the market for

Lipitor, thereby increasing profit and improving stock performance. However, as a result of Pfizer's illegal 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 off-label and medically unnecessary and would not have been written but for Pfizer's illegal marketing scheme.

294. During the Pfizer Annual Report to Investors in May 2005, a physician asked if the company was aware of the high rates of myalgias in patients being treated with Lipitor, and if efforts were underway to modify the drug. Myopathy is a potentially fatal condition and according to Lipitor's FDA label "myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Lipitor should be discontinued if myopathy is diagnosed or suspected." The response from Pfizer's Chairman and CEO, Hank McKinnell, was "he too had aches and pains, and wasn't even taking Lipitor." Joseph Feczko, the company's senior medical director followed with some comments about the rates of side effects of Lipitor versus competitors but did not address the physician's question, or the important safety implications of evaluating and monitoring myalgias.

295. In the First-Quarter 2006 Investor Call and press summary, Pfizer Executive Vice President Karen Katen noted that "new clinical data, educational campaigns on Lipitor that highlight its unique benefit profile are expected to contribute to growth." She later describes how patients on high doses of Lipitor had significantly greater improvements in kidney function than patients on lower doses of Lipitor, and that this data is being communicated through significantly improved physician encounters. This is an improper off-label and off-compendium message. The message also has no basis in established scientific evidence.

296. As a result of Pfizer's illegal 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. (Consumer Reports, *cited supra* n.1, at 10.) Suffice it to say, billions of dollars of potential revenue have been fraudulently taken from the public fisc as a result of Pfizer's illegal off-label marketing campaign.

18. Pfizer's Improper Use Of "Third Party" Organizations And Continuing Medical Education Programs

297. Pfizer has engaged in a widespread, multi-faceted campaign, designed to provide direct and indirect inducements to physicians who participate in Pfizer-funded "medical educational programs" that recommend off-label uses for Lipitor. Pfizer utilizes unrestricted educational grants to fund "third party" organizations to promote this campaign.

298. Pfizer acknowledged in its "Operating Plan" of 2002 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"); the Vascular Biology Working Group ("VBWG"); and the Coalition for the Advancement in Cardiovascular Health ("COACH"). These organizations are an important component of Pfizer's off-label marketing of Lipitor, and provide a more indirect, though no less effective, route for such marketing.

299. 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. These CMEs are little more than sales pitches for off-label uses of Lipitor. Clinicians who participate in these programs are provided free CME credits – a valuable commodity that clinicians must accrue in order to maintain their licenses.

300. The substantial promotional use of continuing medical education[1] through unrestricted educational grants is also a cornerstone of Pfizer's Lipitor off-label marketing 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."

301. As recognized recently by Lewis Morris, Esq., the Chief Counsel of the Office of Inspector General of the Department of Health and Human Services, in the New England Journal of Medicine, in citing the Neurontin case:

> The temptation to promote on an off-label basis is powerful, since off-label sales offer substantial revenue. One study estimated that off-label sales account for 21% of the prescription-drug market. (citation omitted.)
>
> Manufacturers are permitted to sponsor an accredited CME program that, by the independent decision of the CME provider, compensates a physician to favorably discuss a product's off-label use before an audience of targeted prescribers as they enjoy a gourmet meal. … However, when a manufacturer intentionally corrupts CME, prosecution may ensue.

N. Engl. J. Med. 361;25 pp. 2479-82, Dec. 17, 2009.

302. In November 1997, the FDA published guidance on Industry-Supported Scientific and Educational Activities[2] outlining a list of factors to consider in evaluating industry "educational programs" for independence:

1) Control of content and selection of presenters and moderators

2) Disclosures: a) Manufacturer's funding; b) financial relationship between provider, presenters or moderators, and Manufacturer; and c) program includes discussion of unapproved uses of drugs

3) Focus of program (single product, or competing/alternative products discussed; speaker favors one product over another)

4) Relationship between provider and supporting company

[1] 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.

[2] Federal Register/Vol. 62, No. 232, 64093-64100.

5) Provider involvement in sales or marketing

6) Providers demonstrated failure to meet standards

7) Multiple presentations

8) Audience selection

9) Opportunities for discussion

10) Dissemination of product information subsequent to CME session

11) Ancillary promotional activities

12) Complaints

Each of the Pfizer-funded "educational" programs described below fail to meet nearly all of these criteria.

303. Indeed, many of the Pfizer-sponsored CME programs also include dinner, alcoholic beverages, and valet parking at high-end restaurants. As such, the free CME credits (and the accompanying dinners and other perks) are inducements to these physician-attendees in exchange for the physicians' agreement to listen, often unknowingly, to Pfizer's false and misleading off-label sales pitch.

304. 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.)

305. 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 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). The

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 promote off-label prescription of Lipitor.

306. By expanding the pool of patients who were treated with Lipitor to include patients with LDLs below their Guideline treatment threshold, Pfizer increased its Lipitor market by billions of dollars annually. As a direct result of Pfizer's illegal practices, federal government health programs have been caused to reimburse claims for prescriptions that they otherwise would not have.

a. Off-Label Promotion Of Lipitor Through The National Lipid Education Council

307. 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) (the "NLEC").[3]

308. 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.

309. These CME programs, despite purporting 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

[3] NLEC should not be confused with the NIH NCEP.

CME credits in conjunction with the programs, Pfizer induces practicing physicians in the community to prescribe Lipitor off-label and off-compendium.

310. 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.

311. 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.[4] The healthcare division recently accounted for $780 million of Thomson's annual revenues of $7.8 billion.

312. 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."

[4] In addition, Thomson Micromedex is the publisher of the drug compendiums DrugDex and USP-DI (authorized Medicaid and Medicare 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 and Medicare that is not under the editorial control of Thomson is the American Hospital Formulary System compendium.

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

314. As of 2003, there were a total of 14 members of the NCEP. The chairman of NCEP was 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.

315. "In July 2004, the National Cholesterol Education Program conducted a similar revision of the clinical guidelines for diagnosing and treating high cholesterol in adults. With the new guidelines' publication, 8 million Americans became candidates for cholesterol-lowering drugs -- three years after an earlier guideline had added 23 million to the potential roles. Most of the committee members were subsequently found to have had extensive ties to companies that make statins . . .. The guidelines also have made statins -- led by Pfizer's Lipitor -- the world's bestselling prescription medications, despite growing questions about their appropriateness for many users." "From Funding to Findings; When Drug Companies Conduct Research On New Pharmaceuticals, Outcomes May Be Affected -- Greatly," Los Angeles Times, Aug. 6, 2007.

316. "They led influential medical groups, starred at prestigious meetings, published in top journals and were undisputed giants in their field. But when these famous doctors advised the government recently on new cholesterol guidelines for the public, something else they had in common wasn't revealed. Eight of the nine [National Cholesterol Education Program members] were making money from the very companies whose cholesterol-lowering drugs they were urging upon millions of Americans." "Groups Question Industry-Paid Doctors," New York Times, Oct. 16, 2004.

317. The chart below shows the overlap among membership on the NCEP ATP-III publication, the NLEC, and ESLM.[5] The column on the right shows which members are primary authors of Pfizer-funded drug research on hyperlipidemia.

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[6]	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[7]	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		

[5] Attached as Exhibits O and P are a complete list of NLEC council members and ESLM faculty members, respectively.

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

[7] 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
A. Gotto	RFR	Chairman	Chairman	TNT
R. Krauss	RFR	Steering Committee		
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		

318. Many of the NLEC and ESLM faculty receive direct or indirect funding from Pfizer through travel, entertainment, honorarium, speaker fees, and other remuneration. For example, Dr. Donald Hunninghake, who was on the Steering Committee for the National Lipid Education Council—one of Pfizer's supportive "Medical Education Platform" constituents in the 2002 Lipitor marketing plan—was paid $147,000 by Pfizer in 1998.

319. 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.

320. In February 2003, NLEC held its Annual Update Meeting in Half Moon Bay, California. 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.

321. In addition, NLEC convenes meetings and conferences 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.

322. 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." 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. The general "disclaimer"

utterly fails to clarify to its audience which parts of the materials are in compliance with the Guidelines (and Pfizer's FDA-approved Lipitor label) and which constitute off-label marketing.

323. 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."

324. The NLEC Winter 2004/2005 Newsletter (Vol. 9 No. 4 with CME Post-test) provided another example of the off-label promotion and misrepresentation of the Guidelines. The newsletter provided 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, was a paid member of Pfizer's speaker's bureau and was a consultant to Pfizer. She recommended statin therapy, and, as with Pfizer's marketing materials, she misrepresented the Guidelines, suggesting that the 74 year-old female was "not at ATP III guidelines," (*i.e.*, not at goal) when in fact she was in the Low Risk group not in need of statin therapy with an LDL below her cutpoint.

325. Thomson PPS provided a 2004 case study entitled, "Clinical Trial Results Positively Influence a Change in Treatment Regimen in a Hypertensive Male" for free on-line at www.freecme.com. Dr. Ansell, the author of the case, is identified as a NLEC council member, and as a paid lecturer for Pfizer and a recipient of "non-monetary" research support from Pfizer.

Although the sponsor of the free CME is identified as the NLEC, Pfizer's financial support for the NLEC is not readily identifiable. The case study ends with placing the patient on Lipitor after the physician is noted to be successful in overcoming the patients' reluctance. Noteworthy, the patient is also transitioned from his current medication to a combination of atorvastatin/ amlodipine formulation to "minimize the cost and complexity of this regime." The combination product (Lipitor/Norvasc) is an important new Pfizer product. The CME session concludes with the comment: "Our patient is an example of an important at risk population that may not meet ATP III guidelines but nonetheless merits aggressive LDL-C reduction." No identification of the off-label status of this clinical guidance is provided.

326. Pfizer compensates physicians such as Dr. McCann, Dr. Cohen and Dr. Ansell to promote off-label uses at the targeted Moderate Risk group – just as Pfizer set out to do in its Operating Plan for 2002.

b. Off-Label Promotion Of Lipitor Through The ESLM Program

327. As stated above, ESLM (www.eslm.org) is identified by Pfizer as a key component of its 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 Lipitor. ESLM is completely funded by an unrestricted educational grant from Pfizer.

328. According to the ESLM website, ESLM started 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."

329. The ESLM website also states: "Under the guidance of national Co-Chairs Antonio M. Gotto, Jr., M.D., D.Phil., and Peter Libby, M.D., 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.

330. The website notes further:

> 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.

331. ESLM annually assembles "Regional Working Groups" of distinguished clinicians to assist with the program. ELSM's regional working groups were aligned with and were named identically to Pfizer's eight domestic "Primary Care Sales Regions: Western, Southwest, Midwest, Southeast, Great Lakes, Mid-Atlantic, and Northeast." Quite simply, the Regional Working Groups are part of Pfizer's marketing function.

332. ESLM mailed a 2004 invitation to physicians inviting participation in the ESLM national program "New Paradigms in Cardiovascular Risk Reduction: A CME Teleconference," stating that free CME was to be provided. The program's "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. The program contained wide ranging discussions of off-label uses of FDA approved cholesterol-lowering drugs, particularly Lipitor. However, ESLM, a Pfizer-funded organization, provided no clarity as to when discussions of Guidelines-conforming information ended, and discussions of "off-label" information began. The program's slide booklet merely noted "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." No disclosures were made.

333. ESLM, both on its website and on its 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 Pfizer's Lipitor label), the ESLM promoted-tool is programmed to recommend that Moderate Risk patients be given statin even when their LDL levels are below the NCEP drug therapy cutpoints.

334. ESLM's free online CME program 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.

335. Clinical case history 21, entitled "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 contrary to the Guidelines and Pfizer's Lipitor 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.

c. Off-Label Promotion of Lipitor Through VBWG And COACH

336. Conceived in 1994, VBWG's stated mission is "[t]o improve the cardiovascular health of patients by developing a forum for the review, exchange, and assimilation of findings from different aspects of vascular biology research for dissemination to the general clinical medicine community." VBWG is sponsored by the University of Florida College of Medicine.

337. Within 18 months of Lipitor's market entry, Pfizer (then Parke-Davis) began providing unrestricted educational grants to VBWG as an avenue through which it could reach physicians and disseminate its off-label materials. VBWG is listed in Pfizer's 2002 Operating Plan alongside ESLM and NLEC, highlighting the importance of extending the reach of its marketing efforts outside of its traditional sales force by having distinguished physicians deliver its messages. As VBWG's membership has nearly quadrupled over the last decade, to over 17,000 members, Pfizer has increased its intended target audience.

338. Sponsored by the University of Maryland, COACH was formed in 1999. Its stated mission is "[t]o improve the cardiovascular health of patients by raising awareness of the new science underlying cardiovascular disease and speeding the translation of this information into practical clinical medicine." As it did for VBWG, Pfizer was quick to assist COACH to carry out its mission in "speeding the translation" of its off-label messages "into clinical medicine" by providing unrestricted grants for "educational funding" of COACH programs, and getting its paid speakers in front of COACH members.

339. COACH and VBWG have thousands of members in common and are similar in structure, and both have access to the same Pfizer-paid speakers, who, in some instances, give the same presentation for both organizations.[8] Pfizer's purpose in funding these purportedly-independent "education" programs was to promote the off-label use of Lipitor by, *inter alia*, training physicians that failing to give their patients statins outside the NCEP guidelines and the FDA-approved label would put the patients' health, and life, at risk.

340. For example, on or about November 11, 2003, VBWG invited Dr. Peter Cohen of Glenwood Springs, Colorado to "join approximately 50 of [his] colleagues in cardiology as a member of the regional adjunct faculty in a meeting of the Interventions in Cardiology Study

[8] Attached as Exhibits Q and R are lists of VBWG and COACH members, respectively. Attached as Exhibits S and T are representative examples of VBWG and COACH faculty members and lectures presented, respectively.

Group" "sponsored by the University of Florida College of Medicine . . . through an unrestricted educational grant provided by Pfizer Inc."

341. Dr. Cohen was offered food and lodging at the Brown Palace Hotel in Denver, but no money, to attend a four-day meeting on December 6, 2003. He was also offered a collection of "teaching slides that can be used for educational programs" and the opportunity to earn $750 *after* presenting the slides "in any medical education activity."

342. One of the topics at the meeting was "Clinical trials update: Role of early statin use in acute coronary syndromes." Another was "Practical issues for aggressive lipid management in peri-interventional patients: does ATP III go far enough?"

343. One of the speakers at the December 2003 Brown Palace meeting was Dr. Robert A. Vogel. M.D. Dr. Vogel, who is Professor of Medicine and Director of Vascular Biology at the University of Maryland Hospital, has received "significant levels" of consulting fees and honoraria from Pfizer, and has received "significant levels" of Speaker's Bureau fees from Pfizer.

344. In April 2006, Dr. Vogel spoke at another VBWG sponsored presentation in Philadelphia entitled "New Therapies to Improve Outcomes in Patients with Multiple CV Risks."[9] Throughout his presentation when discussing clinical data, particularly data from Pfizer's trials, he voiced one of Pfizer's mantras, "Lower is Better."

345. In discussing the ASCOT-LLA trial, Dr. Vogel advocated that hypertensive patients, should lower their LDL-C by 30% - 40% or more because of the perceived benefit of a percent risk reduction for every percent reduction in LDL -- the logic being, why go 15% if you can do 30%; why do 30% if you can do 40%? At one point, Dr. Vogel equated a lower LDL-C

[9] *See* Ex. S at p. 7. Dr. Vogel also was a lead investigator of the Pfizer-funded REVERSAL Trial, which studied the effect of intensive Lipitor therapy compared with moderate-dose Pravachol on the progression of atherosclerosis in patients with coronary artery disease.

level to a low golf score. All the while, Dr. Vogel gave little regard to the Guidelines, incorrectly treating hypertension as if it was a CHD Risk Equivalent, and downplaying reported adverse events and side effects, such as myalgias in patients on high-dose Lipitor.

346. Also, in discussing the TNT trial, which focused on safety in high vs. low-doses of Lipitor, Dr. Vogel admitted that the data was unpublished at the time. Dr. Vogel again voiced Pfizer's mantra, "Lower is better." He again downplayed reports of myalgias by stating that it was wrong to think that higher doses of statin (Lipitor in particular) cause more myalgias.

347. During his discussion of the CARDS trial, which studied the effect of Lipitor in Type-II diabetic patients with one or more risk factors, Dr. Vogel downplayed all adverse side effects of Lipitor by warning the audience that by taking patients off of statins because of complaints of side effects like myalgias, they are at an increased risk of stroke and myocardial infarctions. Dr. Vogel told the audience that he asks patients about muscle pain before prescribing a statin. Dr. Vogel also said that, unless a patient has real physical issues with statins, he recommends to keep his patients on statins, which he said worked "very, very well". Dr. Vogel also said if a patient complains of muscle pain with Lipitor, he switches the patient from Lipitor to generic atorvastatin, telling him that the generic is a "new" statin which doesn't cause muscle pains, a practice with which he claims to have had tremendous success.

348. Three months prior to his Philadelphia VBWG lecture, in January 2006, Dr. Vogel gave virtually the same presentation to a group that consisted of primary care physicians at a COACH program in Denver.[10] At that program, Dr. Vogel echoed the Pfizer "lower is better" mantra, gave little credence to the authoritative Guidelines, and clearly promoted off-label uses of statins (Lipitor in particular) regardless of LDL-C level, and failed to disclose the off-label nature of his presentation.

[10] *Compare* Ex. T at p. 3 *with* Ex. S at p. 7. The date of the lecture precedes the "Release Date" of the lecture on the VBWG and COACH websites.

349. Several of the slides Dr. Vogel used in his Philadelphia and Denver lectures are found in both VBWG's and COACH's "2006 Core Curriculum" slide decks. In fact, VBWG's "2006 Core Curriculum" slide deck entitled, "New Frontiers in CVD Risk Management: Optimizing Outcomes in Patients with Multiple Cardiovascular Risks" includes many of the same slides and accompanying speaker notes that are also contained in COACH's "2006 Core Curriculum" slide deck entitled, "Challenges and Opportunities in Cardiovascular Risk Reduction." Both slide decks contain the same slides, with the exception of the respective organization's logos, and discuss the same Pfizer-funded trials — ASCOT, ASCOT-LLA, CARDS, PROVE-IT, REVERSAL and TNT.

350. These VBWG and COACH "eduactional" presentations by Dr. Vogel in early 2006 are just two examples of how Pfizer encouraged physicians to ignore the use of the Framingham analysis, while promoting its message that "lower is better" *regardless of patients' cholesterol levels* and downplaying Lipitor's side effects like myalgias. These presentations, and others like it, simply echo what Pfizer itself already told the public in May 2005 as described above.

d. Off-Label Promotion of Lipitor Through Other Organizations

351. 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 Heart Advocacy Network (www.healthadvocacy.org) and the Association for Eradication of Heart Attacks (www.aeha.org). The Association for Eradication of Heart Attacks is noteworthy because it encourages the rapid distribution of unproven diagnostic tests to identify "at risk" patients, who once identified, correctly or incorrectly, are a new pool of patients for Lipitor therapy.

e. Conclusion

352. The purpose of these Pfizer-sponsored "medical educational groups" is to encourage physicians in attendance to directly increase their off-label prescriptions for Lipitor and/or to recommend that other physicians do the same. These Pfizer-sponsored CME providers lack the independence required of CME. Indeed, the Relator has raised, on several occassions, the lack of COACH's independence from Pfizer with the Deans of the University of Maryland Medical School, but to no avail. Pfizer's efforts have resulted in an increase in off-label prescriptions for Lipitor, with a corresponding increase in Pfizer sales and in false claims to government programs.

19. Pfizer's Sampling Program

353. Pfizer acknowledged in its 2002 Operating Plan that increased competition in the statin market required Pfizer to market Lipitor more aggressively to physicians. A centerpiece of that aggressive marketing includes the provision of Lipitor samples to physicians. Pfizer sales representatives bear many gifts, but for practicing physicians none is more valuable than samples of Lipitor. Pfizer headlined its sampling program in its Operating Plan, "Evolving Landscape Requires an Increase in Samples." The free distribution of Lipitor samples to physicians, of course, is not an end in itself. Instead, Pfizer uses a sophisticated tracking system which allows the company to monitor the effects of sampling on each physician's prescription rate, and allows Pfizer, then, to provide Lipitor samples accordingly. Pfizer's sampling marketing involves two parts: (1) increasing the overall level of samples distributed, and, more importantly, (2) strategic sampling to optimize the utility of the samples. The need to increase sampling is explicitly stated in the Pfizer's 2002 Operating Plan – "Additional Sampling Required to Achieve Optimal Level[s]" of "Total Return" to Pfizer. The Plan "recommended" that sampling be increased from $21 million to $42 million annually.

354. Strategic sampling is outlined in Pfizer's Operating Plan as "Ensuring Adequate Sampling Distribution." The supporting slides include a graph illustrating Pfizer's OASIS sampling model. OASIS identifies the specific level of samples per physician needed to "optimize" that physician's rate of new Lipitor prescriptions. It also reinforces the need to avoid "oversampling," *i.e.*, sampling beyond the optimal level. The plan describes oversampled physicians as "unresponsive," that is physicians for whom additional sampling will not generate new Lipitor prescriptions. Oversampled physicians are in contrast to "undersampled" physicians who *are* responsive, and for whom additional sampling is necessitated. Put simply, Pfizer calibrates the precise number of samples it needs to give a particular doctor in order to ensure his or her maximum number of new Lipitor prescriptions – no more, and no less.

355. Pfizer's use of sampling in its marketing was implemented by Local Marketing Teams across the United States. Implementation of Pfizer's national sampling strategy is illustrated in a 2002 program in the Cincinnati Targeted Area Coordination Unit. The stated objective of the sampling program is to "Leverage Samples into Scripts," *i.e.*, prescriptions. The program described "Adequately Sampled" to be "1-2 [samples] for every prescription written"; "Highly Sampled" to be "2+ samples for every prescription written – example: Dr. Samples wrote only 67 Lipitor NRxs but received 512 Lipitor samples" and "Low Sampled" physicians to be physicians who receive less than 1 sample for every prescription written".

356. The Cincinnati sales force was provided with detailed sampling metrics including the physician's name; address; number of sales force visits (or "details"); number of new prescriptions; number of samples; sampling *ratio* for targeted "oversampled" and "undersampled" practitioners and were instructed to increase the number of "Adequately Sampled" physicians in the Cincinnati area. This program also tracked sampling reports for each of the Local Area Teams in the Cincinnati market each quarter. To ensure success, Pfizer

included a performance incentive program that rewarded those members of the sales force who "optimized sampling" and delivered increases in new Lipitor prescriptions.

357. The exhibits hereto contain examples of Cincinnati physicians who were targeted for sampling and detailing based on their prescribing patterns. The identification and targeting of physicians was based on "Quarterly Sampling Reports" produced from Pfizer's sales force data. Pfizer's sampling program induced physicians including those in the Cincinnati market to prescribe off-label Lipitor.

358. Dr. William Ginn, a family physician in West Milton, Ohio, was one such physician identified and targeted. Dr. Ginn was classified as "High (Lipitor) Writing Physician"and targeted by Pfizer in a 2001 "Quarterly Sampling Report" . The report inventoried the number of details (4), the number of new Lipitor prescriptions written by Dr. Ginn (3), the percentage of new prescriptions written by Dr. Ginn for Lipitor (54%), the number of Lipitor samples provided (77), and most importantly the sample ratio (77/3 =3.67).

359. Based on this report, the sales force was directed to reduce the number of samples provided to Dr. Ginn. Additional samples were not inducing Dr. Ginn to write more Lipitor prescriptions. The pool of available on label and off-label patients had been exhausted. Examples of Dr. Ginn's off-label prescriptions caused by Pfizer's marketing scheme including strategic sampling are provided in the attached exhibits.

a. Limiting Supply Of Lower Dosage Samples Increases False Claims

360. According to physicians, it has become increasingly difficult to get 10mg Lipitor samples. According to Pfizer sales representatives, the supply of entry level dosage Lipitor has been limited by Pfizer's headquarters. William Morant, a Pfizer sales representative in Pittsburgh, explained that he had to create elaborate workarounds to secure 10 mg samples,

including obtaining special permission from his sales managers and bartering higher dose Lipitor with colleagues.

361. According to Pfizer's FDA-approved Lipitor label, the entry level dosage of Lipitor is 10mg or 20mg depending on the patient's LDL reduction goals. The label and the NCEP Guidelines identify the target goals of drug therapy. Higher doses of Lipitor can overshoot these target goals and increase both patient risk and cost.

362. Pfizer's motivation in limiting the availability of entry level dosages of Lipitor and promoting higher off-label starting dosages of Lipitor is to maximize its profits. The sale of higher entry level dosages of Lipitor increases Pfizer's profits because the higher dosages are much more expensive. Further, the sale of higher entry level dosages of Lipitor increases sales because the higher dosages are not available in generic alternatives.

363. The off-label high dose Lipitor sampling scheme causes false claims to be submitted to, and to be paid by, public payors. The patient is provided with samples of higher dose Lipitor, the physician writes prescriptions for the higher dose Lipitor when the samples run out, as a result of the higher dose of Lipitor, a comparable generic statin is not available. This increases the cost to the government health care agencies because high dosages of Lipitor are being prescribed despite the fact that the patient needs lower dosages for which a less expensive safe and effective generic drug is available.

364. The annexed exhibits provide examples of Lipitor prescribed in excess of the dosages prescribed by Pfizer's FDA-approved Lipitor label. Included in the appendix are specific prescriptions written by a Cincinnati physician who was targeted by Pfizer for the sampling program described above. These prescriptions are for patients who have LDL levels lower than the goal identified in the label. Lower doses that are safe and effective could have

been prescribed. It is well established that the higher the dose of Lipitor, the higher the likelihood of adverse events and side effects.

b. Samples To Physicians

365. Community-based physicians are running small businesses and customer satisfaction is essential to retain and recruit new patients. Physicians place a premium on samples because samples have substantial impact on patient satisfaction. Although some physicians use samples to assist uninsured and under insured patients, research has established that this is not common.

366. Pfizer's Local Marketing Team Leader for the Boston market, stated that Pfizer is aware of the substantial personal use of samples by physicians and their families. This use has significant cash value to the physician because he does not have to purchase or pay copayments for personal prescriptions. Depending on the dose, retail costs of Lipitor can exceed $100 a month. The view that samples are a subtle form of physician gift giving is echoed in a milestone report by Institute of Medicine.

367. These concerns are echoed in a May 1, 2007 article in the New York Times titled "Free Drug Samples? Bad Idea, Some Say". The article quotes David J. Rothman, president of the Institute of Medicine as a Profession, a research group at Columbia University. Dr. Rothman states that physicians don't realized the extent to which their medical judgement is influenced by their acceptance of the samples. Dr. Ginn agrees and notes the subtle influence sampling has on his Lipitor prescribing. The Institute of Medicine in its 2009 report entitled "Conflict of Interest in Medical Research, Education, and Practice" dedicates a section to sampling. The report states that "Physicians and patients often value drug samples provided as gifts." The report goes on to describe recommendations to limit and report the use of samples by the Medicare Payment

Advisory Commission and the American Association of Medical Colleges. Sampling in general and particularly Pfizer's sampling program is a substantial clinical, economic, and legal concern.

c. Sampling Raises Additional Safety Concerns

368. Sampling also raises patient safety issues. These concerns are noted in a Consumer's Reports August 2007 article named "Free Drug Samples Have Hidden Drawbacks." They summarized that these "gifts" sounded like a great deal but concluded that it was a risky practice. Risks included: 1) Lack of printed instructions; 2) Lack of drug safety and tracking systems; and 3) impact of samples to influence prescription patterns.

d. Sampling Corrupts The Physician-Patient Relationship

369. Pfizer's sampling strategy is a core component of the off-label marketing scheme. It corrupts the physician-patient relationship, because it improperly incentivizes a physician to prescribe drug therapy off label (at off label drug therapy cutpoints or at higher dosages then allowed by the label), or select the "sampled" drug over a less expensive alternative, irrespective of what treatment plan is in the best interest of the patient or the payor. Heavily-sampled physicians prescribe the sampled drug because patients prefer visiting a doctor who provides such samples *gratis*, thereby providing a greater number of patients for the physician to bill. In short, providing Lipitor samples to patients increases physicians' earnings because of the goodwill it engenders with patients.

370. Pfizer's sampling strategy encourages sales representatives to optimize the sampling of every physician in their region, encourages physicians to (i) reciprocate this generosity by allowing Pfizer sales representatives access to promote off-label use of Lipitor and (ii) to place patients on Lipitor – regardless of safety and efficacy. Medical schools such as Stanford, University of Pennsylvania, Yale, and the University of California at Davis have

banned all gifts including samples to reduce the adverse influence of corporate marketing activities on clinical decision making.

E. A Case Study: Pfizer's Aggressive Targeting Of An Ohio Doctor Leads Directly To Off-Label Prescribing Of Lipitor

371. Dr. William N. Ginn is a family practitioner whose practice is located in West Milton, Ohio, a rural village north of Dayton.

372. Many of Dr. Ginn's patients are covered by federal health care programs.

373. Pfizer maintained records on all physicians who were detailed by its sales force. Pfizer also purchased data showing, among other things, how many prescriptions of Lipitor and all of its competitors were written by every physician in whom it was interested.

374. Pfizer evaluated the data by, *inter alia*, comparing the number of samples of Lipitor which were delivered to each physician against that physician's Lipitor prescribing pattern.

375. Pfizer prepared and distributed to its sales force a spreadsheet titled "Category: High Writing physicians with High Sampling Ratios."

376. The "Sampling Ratio" is the number of samples left with a physician, divided by the number of new prescriptions for Lipitor that doctor wrote.

377. Monitoring physician "Sampling Ratios" allowed Pfizer to gauge the extent to which its field forces were achieving the "optimum sampling" goals set out in its US Marketing Plan and elsewhere.

378. The Sampling Ratio spreadsheet was distributed to Pfizer's Lipitor marketing force as part of the "Cincinnati TRIAD project."

379. According to a May 6, 2002, letter from Pfizer marketing executive Jeffrey Spanbauer, the "Cincinnati TRIAD project is to focus the sales representatives on three key areas

that they can control: physician reach/frequency [of detailing], effective sampling and consistent messaging."

380. Dr. Ginn was identified by Pfizer as a "High Writing physician" with a "High Sampling Ratio." Specifically, on the example of this Pfizer-generated marketing spreadsheet available to Relator, which relates to a period prior to May 2002, Dr. Ginn is identified as a "Quintile 4" Lipitor "writer" with a "sampling ratio" of 3.67, based on his having been given 77 Lipitor samples and written 21 new Lipitor prescriptions.

381. In Dr. Ginn's case, the TRIAD goal of "effective" sampling reduced to heavy and frequent sampling.

382. Pfizer also tracked how the "High Writers" prescribing of Lipitor compared to their prescribing of competing statins. In Dr. Ginn's case, 54% of his statin prescriptions were for Lipitor.

383. Dr. Ginn was heavily detailed, and heavily sampled, by Pfizer sales representatives. For example, for a period of approximately six months in or around 2005, he was visited once a week by two Pfizer marketing representatives, Marilyn Parks and Patty (last name unknown).

384. These two sales representatives frequently brought lunch for Dr. Ginn and his staff, and left pens, clocks, and other items behind.

385. The sales representatives routinely ensured that Dr. Ginn's "High Sampling Ratio" was preserved, by leaving large numbers of samples in his office. Indeed, Dr. Ginn maintains eight sample cabinets, and he recalls that at one point, six of them contained Lipitor.

386. Dr. Ginn received many more samples of Lipitor than of any other statin drug.

387. During most of their visits, the Lipitor sales representatives talked to Dr. Ginn about his prescribing of Lipitor. However, the NCEP guidelines and the differences between goals and cutoff points were never discussed.

388. Instead, Dr. Ginn was repeatedly told that his patients needed to "get to goal." The overall (off-label) message Dr. Ginn received from the representatives was that achieving an LDL of 120 was a benchmark for most patients. In particular, Dr. Ginn understood the "goal" to mean lowering cholesterol for patients with total cholesterol at or above 200 and LDL at or above 120. Dr. Ginn was told that the "goal" for patients with cardiac risk factors was an LDL of 100 or less.

389. Dr. Ginn was also consistently told by the Pfizer sale representatives that "lower [cholesterol] is better."

390. The Pfizer sales representatives left Dr. Ginn a large volume of Lipitor samples on a weekly basis. Typically, the representatives would leave two or three "sleeves" of Lipitor, each containing 8-12 weeks worth of Lipitor. These were typically in 20mg doses, but he was also provided with 10mg and 40 mg doses.

391. Although the frequency of visits by Pfizer's sales representatives slowed after the period in which two representatives visited weekly, Dr. Ginn continued to receive regular visits from Lipitor sales representatives, and to receive more samples of Lipitor than of any other drug, until in or about in early to mid-2009.

392. Dr. Ginn is the only physician in the township in which West Milton is located, and there is no other medical office for six to eight miles. The frequency of visits to his office by Pfizer's Lipitor sales force was directly driven by the fact that he was a "High Writing physician" whose frequency of prescribing Lipitor correlated directly to his being given a high volume of samples.

393. Prescription-drug samples are important to Dr. Ginn because he can start a patient's drug therapy and evaluate progress without the patient having to pay for a prescription.

394. Pfizer's heavy sampling led directly to Dr. Ginn's "High Sampling Ratio," and his status as a "High Writing physician." Pfizer influenced Dr. Ginn to write a greater numbers of Lipitor prescriptions than he would have written if those samples were not available.

395. The frequent presence of Lipitor sales representatives in Dr. Ginn's office influenced his prescribing habits. The sales representatives acted as though they were Dr. Ginn's friends and he wanted to help them succeed.

396. Dr. Ginn also came to believe that Lipitor was a better statin than most of the competing drugs, but attributes this belief to the assiduous attention of Pfizer's marketing representatives.

397. Dr. Ginn prescribed Lipitor in accordance with the "get to goal" and "lower is better" philosophies espoused by Pfizer's marketing representatives.

398. As a direct and proximate result of those efforts, Dr. Ginn prescribed Lipitor based on clinical intuition, rather than through the use of risk calculation.

399. As a direct and proximate result of the misleading and incorrect information provided to Dr. Ginn by Pfizer marketing representatives, many, if not most, of Dr. Ginn's Lipitor prescriptions commencing in 2002 were off-label.

400. Many of Dr. Ginn's patients to whom he prescribed Lipitor reported experiencing muscular myalgias as a side effect of the drug. When Dr. Ginn reported this to the Pfizer sales representatives, they told him that a small percentage of people would experience this side effect. However, at least 20% of Dr. Ginn's patients reported it. More recently, approximately one-third of Dr. Ginn's patients have reported muscular myalgia associated with Lipitor use.

VI. FALSE CLAIMS FOR OFF-LABEL USE SUBMITTED TO GOVERNMENT HEALTHCARE PROGRAMS

A. NHANES

401. The National Health and Nutrition Examination Survey ("NHANES") is an ongoing program to assess the health of adults and children in the United States. It is conducted by the National Center for Health Statistics ("NCHS"), which is part of the Centers for Disease Control and Prevention ("CDC"). Each year, NHANES performs interviews, physical examinations, and laboratory tests on a nationally representative sample of 5,000 Americans to determine the prevalence of, and risk factors for, major diseases. This information is also used to develop public health policy, guide health program development and generate knowledge about the health of Americans. (http://www.cdc.gov/nchs/nhanes/about_nhanes.htm) NHANES is particularly useful in studying heart disease and is used in analyses and publications produced by the National Cholesterol Education Program ("NCEP," part of the National Institutes of Health[11]) and the Centers for Disease Control.[12]

1. Off-Guideline Prescription of Lipitor

402. When a search of the medical literature failed to reveal any studies of the off-label/off-guideline prescribing of Lipitor, Dr. Polansky's counsel retained the Research Triangle Institute ("RTI")[13] to examine the frequency and pattern of off-guideline prescribing of statins

[11] *See* ATP-III Final Report at VI-3 and -15.

[12] *See* Trends in High Levels of Low-Density Lipoprotein Cholesterol in the United States, 1999-2006, *Journal of the American Medical Ass'n* (Nov. 18, 2009).

[13] Founded in 1958 as part of a larger effort to harness the intellectual capital of the area's three major universities – the University of North Carolina at Chapel Hill, North Carolina State University, and Duke University – RTI is the second largest independent nonprofit research organization in the United States, "an independent nonprofit research institute dedicated to improving the human condition by turning knowledge into practice," and has completed major scientific research projects in the public and private sectors globally.

between 2001 and 2006.[14] During this period there was explosive year over year growth of the statin market in general, and in which Pfizer remained the market leader.

403. RTI's statistical analysis of NHANES data documents the significant - more than 150% - increase in the proportion of Lipitor prescriptions that were filled by people who did not qualify for statin therapy by the standards of the 2004 update to the NCEP guidelines during the study period. In comparison, there was no increase in the proportion of off-guideline prescriptions for non-Lipitor statins during the same time period. This dramatic increase in off-guideline prescribing of Lipitor began contemporaneously with the implementation of Pfizer's marketing schemes identified in this complaint.

404. This analysis supports Dr. Polansky's allegations, as set forth in this complaint, that Pfizer's illegal marketing campaign was responsible for the writing of millions of off-label prescriptions for Lipitor, which were then filled and improperly paid by Medicaid and other federal healthcare programs.

405. For the entire period between 2001 and 2006, 20.9% of Lipitor prescriptions were off-guideline compared to 12.8% of prescriptions for non-Lipitor statins. Thus, the proportion of Lipitor that was prescribed off-guideline was 63% greater than the proportion for non-Lipitor statins. In statistical terms, the relative risk for off-guideline prescribing of Lipitor compared to non-Lipitor statins (which was not directly increased by Pfizer's off-label marketing campaign for Lipitor) was 1.63. The chance of this imbalance happening purely at random was less than 5 out of 100. The term "statistically significant" is applied to imbalances that have less than 5 chances out of 100 of occurring at random ("$p<0.05$"). Thus, the probability of the difference in proportions of people treated with Lipitor or a non-Lipitor statin who did not qualify for statin therapy by the criteria of the 2004 update to the NCEP guidelines was statistically significant.

[14] RTI was compensated for the time expended by its experts at their usual hourly rates. No part of that compensation was dependent upon the content of their analysis.

406. To examine the overall effect of Pfizer's campaign to increase off-guideline prescribing of Lipitor, the rates of off-guideline prescribing of Lipitor and non-Lipitor statins were compared for two time periods: 2001-2002 (the early years of the Pfizer's off-label marketing campaign) and 2003 and 2006 (the middle years of the Pfizer's off-label marketing campaign). This comparison reveals that the proportion of Lipitor prescriptions for people who did not qualify for statin therapy by the criteria of the 2004 update to the NCEP guidelines increased from 9.4% of total Lipitor prescriptions during 2001-2002 to 25.2% between 2003 and 2006. This 268% increase – well more than doubling – in the proportion of off-guideline prescribing of Lipitor was statistically significant (relative risk 2.8, $p<0.05$). In contrast to this significant increase in off-guideline prescribing of Lipitor, the proportion of off-guideline prescriptions non-Lipitor statins during the same time periods remained virtually constant: 12.5% of total non-Lipitor prescriptions during 2001-2002 compared to 13.0% between 2003 and 2006. Thus, the proportion of off-guideline prescriptions for Lipitor increased by 268% during the time that Pfizer conducted its off-label marketing campaign for Lipitor, while at the same time there was no statistically significant increase in the proportion of off-guideline prescriptions for non-Lipitor statins.

407. In the next several months NHANES will release data for the 2007-2008 which will enable measurement of off-label use in this later period of the illegal marketing scheme. The NHANES data show that the proportion of off-guideline prescribing for Lipitor was not equally distributed among risk groups. During the entire period from 2001 to 2006, by far the greatest proportion of off-guideline prescribing of Lipitor occurred in the moderate risk group, 62.4% compared to 39.7% for the low risk group, 6.2% for the moderate high risk group, and 1.1% for the high risk group. The proportions of off-guideline Lipitor prescriptions for the low

and moderate risk groups were both statistically significantly higher than for the moderate high and high risk groups.

408. The imbalance in proportion of off-guideline prescribing of statins was not equally distributed by gender. For the period from 2001 to 2006, the proportion of off-guideline prescribing of Lipitor was significantly more than three-fold higher for women compared to men, 31.2% vs. 9.9%, respectively, relative risk 3.15, $p<0.05$.

409. Finally, the proportion of off-guideline prescriptions for Lipitor was approximately equal between government payers (18%) and private payers (23%). In stark contrast, the proportion of off-guideline prescriptions for non-Lipitor statins was significantly lower for Medicaid (2%) than for other government or private payers. The data clearly supports the proposition that Pfizer's illegal marketing scheme was causing significant numbers of off-label prescriptions to be written by physicians for patients with public and private insurance. The off-label campaign did not differentiate who was paying for Lipitor.

410. The bottom line is that by 2005-06, more than one out of four Lipitor prescriptions were off-guideline/off-label. In 2005, Pfizer's revenues from sales of Lipitor approximated $12 billion, meaning that Pfizer received over $3 billion in revenue in 2005 from off-label sales of Lipitor – a stunning return on investment for Lipitor's 2002 marketing expenses of $190 million. *See* Pfizer 2002 Lipitor Marketing Presentation, Slide No. 88.

411. The NHANES data show that the enormous increase in the absolute amount and proportion of off-guideline/off-label Lipitor prescriptions directly coincided with Lipitor's off-label marketing campaigns, including Pfizer's "Get to Goal" and "Lower is Better" campaigns. Prior to the inception of Pfizer's off-label campaigns, Pfizer's off-label Lipitor prescriptions were actually slightly lower than other non-Lipitor statins, 9.3% vs. 12.5%, respectively.

412. If the enormous growth in Pfizer's off guideline/off-label Lipitor prescriptions had been the result of anything other than Pfizer's off-label marketing campaign – such as doctors reading exploratory scientific papers and studies or articles in the popular press about the benefits of statins in patients with existing heart disease – the off-label sales of all other statins would have experienced similar growth. However, as stated above, that did **not** happen. Instead, the off-guideline/off-label sales of only one statin – Lipitor – grew significantly both in terms of relative and absolute growth. The only plausible explanation for this unprecendented volume and growth is Pfizer's off-label marketing campaign for Lipitor.

413. Furthermore, the growth of off-guideline/off-label Lipitor sales occurred primarily in only one risk group: moderate risk, which was a primary target of the "Get to Goal" campaign. Off-guideline/off-label sales of Lipitor to the moderate risk group averaged 62.4% of all Lipitor sales to that group over the three NHANES cycles examined – meaning that for the moderate risk group, there were more off-guideline/off-label sales of Lipitor than on-label sales of Lipitor.

2. Individual Claims

414. NHANES data includes specific patient identifiers. These data include, for each individual patient: the patient's insurance carrier (eg. Medicaid), whether the patient is taking Lipitor or another statin, what the patient's Total Cholesterol and LDL-C level is, and whether the patient has various risk factors, such as being a smoker or having a previous diagnosis of CHD, which enable calculation of that patient's Framingham risk assessment of the chance of a coronary event over the next decade (a "Framingham risk assessment"). As a result, individual off-label patients whose prescriptions were paid for by government healthcare programs can be determined from the NHANES data. Accordingly, Plaintiff presents the following patients as illustrative examples of individual off-label claims whose prescriptions were caused by Pfizer's

off-label marketing campaign and that were submitted and paid for by government health care programs. The full inventory of off-label patients paid for by government health care programs can be found below.

415. For example, Patient 21685 (from NHANES 2003-04) was a 49 year old woman without coronary health disease or a risk equivalent. She was taking Lipitor, was on Medicaid, had a LDL-C of 72 mg/dL, had two or more risk factors, and a Framingham risk assessment of less than 10%. The absolute lowest LDL-C level at which Lipitor was approved for use with such a patient during the relevant period was 160 mg/dL. This patient according to NCEP and the RTI analysis is in the Moderate Risk Group and was prescribed Lipitor off-label.

416. Another example is Patient 40881 (from NHANES 2005-06), who was a 41 year old man without coronary health disease or a risk equivalent. He was taking Lipitor, was on Medicaid, had a LDL-C of 72 mg/dL, had two or more risk factors, and a Framingham risk assessment of less than 10%. The absolute lowest LDL-C level at which Lipitor was approved for use with such a patient during the relevant period was 160 mg/dL. This patient according to NCEP and the RTI analysis is in the Moderate Risk Group and was prescribed Lipitor off-label.

B. Pfizer's Own Analysis of the Effects of Its False and Misleading NCEP-Based Programs

417. In October 2002, Pfizer's Field Force Effectiveness Team produced the "Pull Through Resources Guide." Pull-through was defined as an "integrated process to move market share and increase sales for a specific product in a defined timeframe," usually in response to a specific challenge or opportunity. This guide provided guidance to the sales organization on how to identify and maximize business opportunities. It was created after extensive interviews with the company's marketing and sales team. Nine "proven" programs were identified as "Impact Practices" and examined in detail.

418. Three of the nine "impact programs" identified the new NCEP ATP-III guidelines as a market opportunity for increasing Lipitor prescriptions The programs all used the false and misleading Pfizer-produced slide decks as program foundations. Programs with patient outreach leveraged inaccurate point based risk calculators to produce off-label Lipitor prescriptions.

419. The first program was called "Treating CVD (cardiovascular disease) to New Targets". The goal of the program was to develop consensus among cardiologists and primary care physicians around the need to "treat to goal" and to influence pcp practice patterns towards earlier and more aggressive treatment of CVD. The program was developed in conjunction with Atlanta Cardiovascular Research Institute. As part of this program in a local market, a set of "opinion leaders" were trained to take the message of "treatment-to-goal parameters" to primary care physicians and cardiologists in the Atlanta market.

420. The educational materials that were used were developed and approved by the Lipitor marketing team including the false and misleading ATP-III slide deck described above. As described previously this purported ATP-III educational tool includes false statements that statins should be considered for all patients with ldl levels above goal, despite the fact that the drug treatment threshold ("cutpoint") for the "moderate" risk group (10-20 % Framingham risk) is 160 mg/dL, which different from the LDL-C goal for that group: 130 mg/dL. This marketing message is based on whether the patient has achieved his LDL-C goal, than whether the patient is above the cutpoint, and thus caused off-label prescriptions for moderate-risk patients whose LDL-C levels are between goal and cutpoint. For patients in government healthcare programs whose prescriptions were paid for in whole or in part by the government, those prescriptions constituted false claims because they would not have been written, and thus would not have been paid for by the government, were it not for this illegal marketing campaign by Pfizer.

421. This model program was hailed as a success within Pfizer as it reached a large number of key physicians. The program convened several "Opinion Leader Council" meetings and 10 CME dinner meetings for 250 primary care physicians ("PCP's") and cardiologists.. The field representatives and their managers identified influential and high prescribing primary care physicians to participate in the dinner meetings. Field representatives were "motivated to increase sales of Liptor by bringing the "treat to goal" message to physicians. CME credits and elegant dining were provided to attendees. The clinical faculty were required to follow the slides and talking points and induced to participate with speaker fees.

422. The second program, "Rhythm of the Heart" ("TACU 2002 Resource Guide page 37") , "was designed to leverage local partners and 'cultural compentency' around CVD" among a large African-American population in the northeast. Program partners included Keystone Mercy Health Plan (a large Pennsylvania Medicaid plan), State Representatives, and community leaders. Implemenation included community, payor, and media events. Pfizer field representatives targeted local churches and their ministers as sources of participants for the "Health Fair in the Box." Local healthcare professionals and community leaders were induced to participate based on speaking fees. The health care professionals were recruited based on having large Afican American patient panels.

423. The off-label program was tracked by Pfizer and the results were substantial. The program increased total Lipitor prescriptions in three key metrics: (1) a 9.2% increase among African American providers compared to district norms; (2) a 29% increase in Mercy Keystone Health Plan compared to comparitor health /plans; and (3) a 4.5% increase in predominantly African-American sales territories compared to district/national norms.

424. The third impact program was called the "Lipitor Messaging Program." This program was implemented in an underperforming Midwestern local market. It also used the

Pfizer false and misleading APT-III materials in educational symposia to accelerate sales. Once again the sales organization was tasked with identifying a recruiting PCP's "targeted" for their prescribing potential. In particular physicians were identified who were high prescribers of statins but low prescribers of Lipitor.

425. This model program reached over 2,000 physicians with the new ATP-III messages and 197 physicians were induced to attend ATP-III symposium. Most importantly, Pfizer recognized the program as the driver for a greater than 20% market increase in new Lipitor prescriptions. The illegal off-label ATP-III-centred marketing programs and messages were delivering impressive Lipitor sales results.

C. Individual Claims

426. The following off-label[15] claims have been identified from the practices of Dr. Mohammad Rana and Dr. Gold, both located in Baltimore, MD; Dr. W. of Easton, MD; Dr. JL of San Diego, California; Dr. DL of Albuquerque, NM; Dr. William Chenitz of Newark, NJ; and Dr. William Ginn of West Milton, OH.:

Patient	Age	Sex	Risk Group*	Practice	Payor	Pharmacy	City	State
Margaret Alexander	71	F	2	Dr. Mohammad Rana	Medicare Part D		Baltimore	MD
Roy Johnson	66	M	3	Dr. Gold	FEHBP (postal)	Rite Aid	Baltimore	MD
John Leonardo	75	M	4	Dr. Gold	FEHBP		Baltimore	MD

[15] The claims were off-label either because the patients' LDL levels were below the NCEP cut-points for drug thereapy even after adjusting for Lipitor's cholesterol-lowering effect or because a 20 mg or greater dose was prescribed when a 10 mg dose was all that was needed for the patient to meet his or her cholesterol goal.

Patient ID	Age	Sex	Risk Group*	CKD-ESRD	Practice	Payor	Pharmacy	City	State
0282	86	F	3	yes	Dr. W	Medicare Part D	Hills Pharmacy	Easton	MD
0020	86	F	4	yes	Dr. W	Medicare Part D	Hills Pharmacy	Easton	MD
1681	69	F	1	yes	Dr. W	Medicare Part D	Hills Pharmacy	Easton	MD
1676	73	M	4	yes	Dr. W	Medicare Part D	Walgreens	Chestertown	MD
0614	49	F	1	yes	Dr. W	Medicaid		Easton	MD
0176	78	F	4	yes	Dr. W	Medicare Part D	Edwards Pharmacy	Centreville	MD
0194	78	F	3	yes	Dr. W	Medicare Part D	Eastern Shore Pharmacy	Salisbury	MD
1331	71	M	3	yes	Dr. W	Medicare Part D	Kent Drugs	Easton	MD
1471	49	F	1	yes	Dr. W	Medicare Part D	Edwards Pharmacy	Centreville	MD
1237	75	F	1	yes	Dr. W	Medicare Part D		Easton	MD
2235	79	F	1	yes	Dr. W	Medicare Part D		Easton	MD
0614	49	F	2	yes	Dr. W	Medicaid		Easton	MD
0555	40	M	1	yes	Dr. W	Medicare Part D		Cambridge	MD
1471	49	F	1	yes	Dr. W	Medicaid		Centreville	MD
1237	75	F	2	yes	Dr. W	Medicare Part D		Easton	MD
2235	79	F	2	yes	Dr. W	Medicare Part D		Easton	MD
38711	83	F	1	no	Dr. JL	Tricare	Rite Aid	San Diego	CA
37525	74	M		no	Dr. JL	Tricare	Express Scritps	San Diego	CA
38886	52	M	1	no	Dr. JL	Tricare	Rx Solutions	San Diego	CA
35700	66	M	3	no	Dr. JL	Tricare	Camp Pentleton	San Diego	CA
41311	77	F	1	no	Dr. JL	Tricare	CVS	San Diego	CA
DL005	75	F	2	no	Dr. DL	Medicare Part D		Albuquerque	NM
DL010	83	F	2	no	Dr. DL	Tricare		Albuquerque	NM
DL003	83	F	2		Dr. DL			Albuquerque	NM
DL006	70	M	2		Dr. DL			Albuquerque	NM

Patient ID	Age	Sex	Risk Group*	CKD-ESRD	Practice	Payor	Pharmacy	City	State
DL008	69	F	1		Dr. DL			Albuquerque	NM
DL010	83	F	1		Dr. DL			Albuquerque	NM
NJ002			1		Dr. Cheniz	MCD Horizon		Newark	NJ
G0011			3		Dr. Ginn			West Milton	OH
G0015			3		Dr. Ginn			West Milton	OH
G0016			3		Dr. Ginn			West Milton	OH

* 1 = lower risk 2 = moderate risk 3 = moderately high risk 4 = high risk

VII. PFIZER VIOLATED THE ANTI-RETALIATION PROVISIONS OF THE FALSE CLAIMS ACT

427. 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.

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

429. 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 Pfizer's "national" marketing materials for Lipitor.

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

431. Specifically, Dr. Polansky became concerned that Pfizer's use and communication of NCEP/ATP III information in marketing materials, messages and programs was potentially misleading and inaccurate. He was concerned, among other things, that Pfizer's 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.

432. 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.

433. 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.

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

435. Beginning in the Fall of 2002, Dr. Polansky requested and compiled a more comprehensive inventory of Pfizer's corporately developed and approved Lipitor marketing materials.

436. As part of his investigation, Dr. Polansky attended Plan of Action (POA) meetings at which sales representatives are trained on company marketing plans.

437. Dr. Polansky's assessment of the POA and the associated materials added to his concerns that Lipitor was being marketed too aggressively.

438. Beginning in the fall of 2002, Dr. Polansky sought to alleviate his concerns about Pfizer's Lipitor marketing programs by meeting with physicians who worked in conjunction with Pfizer's Corporate Lipitor Review Committee. Dr. Polansky met at least twice with Connie Newman, M.D. from Pfizer's Regulatory Affairs. At one of the meetings, they were joined by a physician colleague of Dr. Newman.

439. 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.

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

441. 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).

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

443. In early 2003, Dr. Polansky spoke to Pat Andrews, the Senior Director for Local Marketing, and advised her of some of his concerns regarding Pfizer's marketing materials. Dr. Polansky advised Ms. Andrews of his difficulty in getting his questions answered by Dr. Newman.

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

445. 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.

446. Dr. Polansky had identified that 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.

447. 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.

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

449. Dr. Polansky also advised the Pfizer Compliance Unit that the Pfizer Local Marketing Team Review Committee had been told that Lipitor local marketing programs would no longer be reviewed by it and that these programs would only be reviewed by Pfizer's "national" Lipitor Review Committee.

450. This change in Pfizer's procedures followed a critical initial review of the Cardiovascular Leadership program in Atlanta by the Pfizer's Atlanta Local Marketing Team Review Committee.

451. Dr. Polansky also advised Pfizer's Compliance Unit 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.

452. 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 Pfizer's aggressive and potentially illegal marketing of Lipitor, and that Dr. Polansky's investigation concerned potentially false or fraudulent claims against the federal government which could be asserted in a False Claims Act action.

453. At the time of Dr. Polansky's investigation of Pfizer's 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 Pfizer's off-label promotion of the Pfizer drug Neurontin.

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

B. 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

455. 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, M.D. Baker and Eng provided feedback on Dr. Polansky's performance and the performance of the OMS team, telling Dr. Polansky that he "was an outstanding performer, highly valued by Pfizer, and had a bright future." In addition, Dr. Eng advised Dr. Polansky that the OMS Team was "undergoing routine

challenges faced by a newly formed team," and that Dr. Polansky "had no reason to be concerned." Dr. Eng also told Dr. Polansky that this was Baker's first management assignment and his inexperience would contribute to difficulties the team was experiencing.

456. 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 not to engage human resources in a discussion about the team's performance.

457. 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 Dr. Polansky was hired and confirmed Dr. Eng's and Baker's verbal communications with Dr. Polansky concerning Dr. Polansky's outstanding performance. During 2001, Dr. Polansky had also achieved the maximum amount of Pfizer awards for exceptional behavior in "innovation, leadership, performance, and respect." These awards, which are 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.

458. On March 20, 2002, Dr. Polansky met with Maile Dooley, Pfizer's Manager, Human Resources, Worldwide Medical and Regulatory. During this meeting, Dr. Polansky complained, providing specific examples demonstrating 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 Dr. Polansky 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.

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

460. 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 FDCA.

461. In addition, the promotional CD, including the PCRA, has been actively used by Pfizer in marketing and sales activities directed at the public through health education activities at Pfizer's large segment clients such as employers and managed care organizations. 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.

462. This promotional CD, Pfizer's Lipitor health education compact disc, includes the flawed and hazardous PCRA, which is an inaccurate reproduction of a cardiac risk assessment produced by the NCEP/ATP III. The PCRA was approved for use, according to Pfizer policy, by Pfizer's Lipitor Review Committee in 2001 and by 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.

463. As summarized above, 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, such as diabetics, 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).

464. 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 is derived 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 two-thirds to three fourths of those for heart disease.

465. 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 label 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.

466. 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.

467. 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. Therefore, at a minimum, more than 10% of adult Americans should be undergoing risk assessment, according to the guidance of ATP III.

468. 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."

469. 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.

470. The impact of the two errors Dr. Polansky identified during his tenure at Pfizer results in underestimations of 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.

471. 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.

472. 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.

473. 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.

474. 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 to cease the ongoing distribution of the misleading, dangerous and illegal PCRA contents described above.

475. 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 Pfizer's 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 Pfizer's 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 Pfizer's Outcomes Research senior management team, told Dr. Polansky that his "problem" was that he "was looking into issues that [were] none of [his] business."

476. Dr. Polansky also served, independently of his work in Outcomes Research, as the Medical Director for Pfizer's Local Marketing Team Review Committee. As part of this

responsibility, Dr. Polansky 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 Dr. Polansky 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 taken.

477. 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, Pfizer took no appropriate remedial action.

478. 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 Dr. Polansky's performance. They threatened Dr. Polansky with disciplinary action and told him that he had sixty days to make the necessary corrections.

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

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

481. Dr. Polansky's 2002 annual evaluation was discussed and provided to him in December 2002. As part of the evaluation process, Pfizer 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 concerning Dr. Polansky provided him, as a courtesy, copies of 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."

482. 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.

483. 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 Dr. Polansky's 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 demonstrated, and, in further retaliation, concluded that Dr. Polansky's dismissal was not improper.

484. 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.

485. 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 subsequently asserted 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.

486. Pfizer's foregoing retaliatory acts were performed willfully, intentionally, and with reckless indifference to Dr. Polansky's protected rights.

COUNT I

Federal False Claims Act
31 U.S.C. §§ 3729(a)(1) And (a)(2)

487. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

489. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

490. By 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.

491. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

492. 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.

493. Efforts by Dr. Polansky to assist the Government in learning about this fraudulent scheme include requests made by Dr. Polansky 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. Dr. Polansky has been informed by the Office of Inspector General, as recently as June, 2007, that Pfizer is objecting to the release of various documents.

494. By reason of Pfizer'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)

495. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1-475 of this Complaint.

496. 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 an employee because of lawful acts undertaken by that employee in furtherance of investigating False Claims Act violations.

497. 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)

498. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

500. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

501. By 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.

502. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

505. 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)

506. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

508. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

509. By 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.

510. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

513. 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)

514. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

516. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

517. By 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.

518. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

521. 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)

522. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

524. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

525. By 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.

526. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

529. 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)

530. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

532. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

533. By 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.

534. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

537. 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)

538. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

540. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

541. By 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.

542. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

545. 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*.

546. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

548. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

549. By 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.

550. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

553. 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)

554. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

556. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Government of the Commonwealth of Massachusetts for payment or approval.

557. By 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 of the Commonwealth of Massachusetts to approve and pay such false and fraudulent claims.

558. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

560. By reason of Pfizer's acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

561. The Commonwealth 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*.

562. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

564. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

565. By 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.

566. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

569. 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)

570. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

572. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

573. By 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.

574. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

577. 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)

578. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

580. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

581. By 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.

582. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

585. 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)

586. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

588. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

589. By 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.

590. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

591. 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 Pfizer,

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

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

593. 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)

594. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

596. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

597. By 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.

598. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

601. 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*.

602. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

604. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

605. By 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.

606. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

609. 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

610. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

612. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

613. By 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.

614. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

617. 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)

618. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

620. By the acts described above, Pfizer knowingly presented or caused to be presented, false or fraudulent claims to the Government of the Commonwealth of Virginia for payment or approval.

621. By 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 of the Commonwealth of Virginia to approve and pay such false and fraudulent claims.

622. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

624. By reason of Pfizer's acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

625. The Commonwealth 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)

626. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1 through 414 of this Complaint.

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

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

629. By 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.

630. Dr. Polansky 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. Dr. Polansky has no control over or dealings with such entities and has no access to the records in their possession.

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

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

633. 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. §2000 *Et Seq*.

634. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 415-475 of this complaint.

635. Pfizer has violated Title VII by discriminating against Dr. Polansky 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.

636. Pfizer acted intentionally and with malice and/or reckless indifference to Dr. Polansky's rights protected by Title VII.

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

COUNT XXI

New York Human Rights Law ("HRL")
New York Executive Law § 290

638. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 415-475 of this complaint.

639. Pfizer has violated the HRL by discriminating against Dr. Polansky 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.

640. Dr. Polansky has suffered, is now suffering, and will continue to suffer irreparable injury and monetary damages as a result of Pfizer'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.*

641. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 415-475 of this complaint.

642. Pfizer has violated the NYCHRL by discriminating against Dr. Polansky 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.

643. Dr. Polansky 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

644. Dr. Polansky realleges and incorporates by reference the allegations contained in paragraphs 1-465 of this Complaint.

645. Pfizer has violated the Whistleblower Statute by retaliating against Dr. Polansky because Dr. Polansky 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 and other components of the illegal marketing scheme for Lipitor 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.

646. Pfizer acted intentionally and with malice and/or reckless indifference to Dr. Polansky's rights protected by the Whistleblower Statute.

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

PRAYER FOR RELIEF

WHEREFORE, Dr. Polansky prays for judgment against Pfizer as follows:

A. That Pfizer 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 Pfizer in an amount equal to three times the amount of damages the United States has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of California has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Delaware has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Florida has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Illinois has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Indiana has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Michigan has sustained because of Pfizer's actions, plus civil penalties for each violation of Mich. Comp. Laws. § 400.601 *et seq*.;

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

P. That this Court enter judgment against Pfizer in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the State of Texas has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Pfizer'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 Pfizer in an amount equal to three times the amount of damages the District of Columbia has sustained because of Pfizer'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 Dr. Polansky 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 Dr. Polansky 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 Pfizer on Dr. Polansky's Title VII, HRL, and NYCHRL claims enjoining continued violation of those laws and any further retaliation against Dr. Polansky; awarding Dr. Polansky reinstatement; awarding Dr. Polansky compensation for lost salary, wages, benefits and other forms of compensation or remuneration, including front pay; awarding Dr. Polansky compensatory damages for the emotional distress Pfizer's unlawful conduct has caused Dr. Polansky; and awarding punitive damages in sufficient amount to punish Pfizer for its conduct;

W. That this Court enter judgment against Pfizer on Dr. Polansky's Whistleblower Statute claim, enjoining continued violation of the Whistleblower Statute and retaliation against

Dr. Polansky; awarding Dr. Polansky reinstatement; awarding Dr. Polansky compensation for lost salary, wages, benefits and other forms of compensation or remuneration, including front pay, as a result of Pfizer's violation of the Whistleblower Statute; and directing Pfizer to pay Dr. Polansky compensatory damages for the emotional distress Pfizer's unlawful conduct has caused Dr. Polansky;

X. That Dr. Polansky 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 Dr. Polansky be granted all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

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

DATED: February 10, 2010

Respectfully submitted,

MILBERG LLP

By: /s/ Kirk E. Chapman

Kirk E. Chapman (KC7371)
One Pennsylvania Plaza
New York, New York 10119-0165
Tel: 212.594.5300
Fax: 212.868.1229
kchapman@milberg.com

MORGAN VERKAMP LLC

Frederick M. Morgan, Jr.
Jennifer M. Verkamp

700 Walnut Street, Suite 400
Cincinnati, OH 45202-2015
Tel: (513) 651-4400
Fax: (513) 651-4405

(As to Counts I, and III through XIX)

BANTLE & LEVY LLP

Lee F. Bantle
817 Broadway, 6th Floor
New York, NY 10003
Tel: (212) 228-9666
Fax: (212) 228-7654

(As to Counts II, and XX through XXIII)

Attorneys for Plaintiff-Relator
Dr. Jesse Polansky

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ET AL., EX REL. DR. JESSE POLANSKY, Plaintiff, vs. PFIZER, INC., Defendant.	No. 04 CV 0704 (ERK) (ALC) ORIGINAL FILED BY ECF

CERTIFICATE OF SERVICE

I, Kirk E. Chapman, hereby certify that on February 10, 2010, I electronically filed the foregoing ***FIFTH AMENDED COMPLAINT*** with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all registered ECF users in this action.

By: */s/ Kirk E. Chapman*

Kirk E. Chapman
MILBERG LLP
One Pennsylvania Plaza
New York, NY 10119-0165
Tel: (212) 594-5300
Fax: (212) 868-1229