UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Case No.: _____

UNITED STATES OF AMERICA ex rel.
HEALTH SUPPORT AWARENESS, INC.,

Plaintiffs/Relator,

v.

PFIZER INC,

Defendant.

**Filed Under Seal Pursuant to 31 U.S.C. §3730(b)(2)**

_____/

**COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE FALSE CLAIMS ACT (31 U.S.C. §3730)**

On behalf of the UNITED STATES OF AMERICA, Plaintiff, Plaintiff/Relator HEALTH SUPPORT AWARENESS INC. (hereinafter "HSA" or "Relator"), files this qui tam complaint against Defendant, PFIZER INC. (hereinafter "PFIZER" or Defendant), pursuant to 31 U.S.C. §3729, *et seq.*, as amended, to recover all damages, penalties, and other remedies available under the False Claims Act.

## I. INTRODUCTION

### A. Federal Law

1. This is an action based upon federal law to recover treble damages and civil penalties on behalf of the United States of America in connection with the systematic misbranding and illegal marketing by PFIZER.

2. Pursuant to the False Claims Act (FCA), Relator seeks to recover, on behalf of the United States of America, treble damages, civil penalties and attorney's fees arising from false or fraudulent claims that Defendant submitted or caused to be submitted to government

funded health insurance programs based upon Defendant's practices as more fully described herein.

3. Relator alleges that as the direct, proximate, and foreseeable result of PFIZER's misbranding and deceptive promotion of Lipitor, PFIZER knowingly caused individuals to submit false claims for reimbursement or payment to Medicare, Medicaid, the federal Employees Health Benefits Program ("FEHBP"), the managed care component of the United States Department of Military Health Systems (TRICARE), the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), and the Civilian Health and Medical Program of the Uniformed Service (CHAMPUS), as well as other government funded insurance programs.

4. The end result of PFIZER's actions is the submission of numerous false claims for the unjustified and illegal enrichment of Defendant and the corresponding loss of millions of dollars of taxpayer's funds.

5. On behalf of the United States of America, Relator seeks to recover these damages as well as civil penalties arising from the false claims that Defendant caused to be submitted to the United States.

## II. PARTIES

### The Relator

6. Under the federal FCA, a person with knowledge of false or fraudulent claims against the government (a "Relator') may bring an action on behalf of the government and himself.

7. Relator, Health Support Awareness, Inc. is a not-for-profit organized and run by Louis H. Mueller since 1999. Mr. Mueller is a citizen and resident of Palm Harbor, Florida. Mr.

Mueller was most recently employed as a pharmacist at an outpatient clinic affiliated with the James A. Haley Veterans' Hospital in New Port Richey, Florida. Mr. Mueller graduated from the University of Florida, College of Pharmacy and is a registered pharmacist in Florida.

8. Mr. Mueller currently serves on the National Advisory Board for the College of Pharmacy at the University of Florida where he has served for the past 18 years. During Mr. Mueller's career he has owned a pharmacy and a durable medical equipment store in Clearwater, Florida. He also owned a not-for-profit pharmacy in Palm Harbor, Florida to serve the uninsured in the Tampa Bay area.

9. Relator's primary goal was to help inform and provide the public with relevant Pharmacy issues and to help people obtain their medications, especially when they were uninsured or underinsured. Through Relator, Mr. Mueller has conducted numerous seminars and in-service programs for Pharmacists and Nurses regarding drug utilization, dispensing errors and patient counseling.

10. Under the FCA, a person with knowledge of false or fraudulent claims against the government, known as a "relator," may bring an action on behalf of the United States of America.

11. None of the allegations set forth in this Complaint are based on a public disclosure of information in a criminal, civil, or administrative hearing; in a Congressional, administrative, or General Accounting Office report, hearing, audit, or investigation; or from news media. Rather, they are the independent declaration of the Relator.

12. Relator is an original source of information within the meaning of the False Claims Act, 31 U.S.C. §3730(e)(4)(B).

**The Defendant**

13. Pfizer, Inc. (NYSE: PFE) is an American multinational pharmaceutical corporation headquartered in New York City with its research headquarters in Groton, Connecticut. It is the world's largest pharmaceutical company by revenue. Lipitor was created in 1997 by Warner-Lambert. Warner-Lambert partnered with Pfizer to assist in the late stage testing of the drug as well as eventual marketing. In 2000, Pfizer purchased Warner-Lambert. It is estimated that more than 29 million people have been prescribed Lipitor. Lipitor is distributed by Parke-Davis, a division of Pfizer, Inc.

## III. JURISDICTION AND VENUE

14. Jurisdiction is proper in this Court because Relator seeks remedies on behalf of the United States for multiple violations of 31 U.S.C. §3729.

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345.

16. Relator has made voluntary disclosures to the government prior to the filing of this lawsuit as required by 31 U.S.C.§3730(b)(2).

17. This Court has personal jurisdiction over Defendant because it transacts business in the District of Massachusetts, and because some of the acts complained of herein occurred in the District of Massachusetts.

18. Venue is proper in the District of Massachusetts pursuant to 31 U.S.C.§3732(a) because Defendant transacts business in the District of Massachusetts, and because the acts alleged herein to be in violation of 31 U.S.C.§3729 occurred in the District of Massachusetts.

## IV. NATURE OF THE CASE

19. Atorvastatin calcium was originally created by Warner-Lambert and named Lipitor. As the original patent holder, Warner-Lambert, faced serious challenges in bringing Lipitor to market as it was the fifth statin to come to market. One of the biggest challenges was to overcome the perception that Lipitor was merely another "me-too" product. Merck and Bristol-Myers Squibb, the primary incumbents, already had proven products in the market. Warner-Lambert decided to employ a 'saturation' approach to sell Lipitor. The intent of the 'saturation' strategy was to have as many sales representatives as possible contacting physicians.

20. Warner-Lambert chose Pfizer to help market Lipitor. Warner-Lambert and Pfizer effectively outgunned the competition by using the largest statin sales force in history. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were believed to be selling Lipitor at the time of its launch in the United States.

21. The Lipitor promotion team visited family doctors as well as cardiologists, and blanketed patients and doctors with data showing that Lipitor was best in class at lowering cholesterol. Lipitor sales representatives stressed to doctors nervous about safety that Lipitor's lowest dose worked as well as rivals' highest doses.

22. After launching in January 1997, Lipitor reached $1 billion in domestic sales within its first twelve months on the market. Pfizer benefited from some fortuitous timing in entering the market in 1997, as that was the year the Food and Drug Administration first allowed pharmaceutical ads targeting consumers, known as direct to consumer or DTC ads.

23. Pfizer spent tens of millions of dollars on television ads, including on the popular medical drama "ER". The ad campaign urged patients to "Know Your Numbers" and then showed patients discussing how Lipitor helped them get their cholesterol numbers below

guideline goals. Health groups, many of whom were supported in part by Pfizer, kept lowering the cholesterol targets in national guidelines, thereby causing millions more patients to believe they were good candidates for statin treatment.

24. In addition, clinical researchers, many of whom were supported financially by Pfizer, established a link between cholesterol levels and health consequences such as heart attacks.

25. Pfizer eventually utilized Dr. Robert Jarvik as its main spokesperson to promote Lipitor. International ad campaigns were designed around Dr. Jarvik's credibility as the co-inventor of the Jarvik artificial heart coupled with his personal health success taking Lipitor. Images which purported to show Dr. Jarvik rowing across the water were used to demonstrate how healthy he had become after taking Lipitor. However, after public and Congressional scrutiny claimed the ad campaign was misleading for, among other things, misrepresenting Dr. Jarvik's credentials and using body doubles, the company withdrew Dr. Jarvik as its spokesman in 2008.

26. As Pfizer was approaching the expiration point for the patent on Lipitor, also known as the 'patent cliff' or 'end of the product's life cycle', Pfizer undertook additional efforts to maximize its profits.

27. Pfizer negotiated what is known as a "Pay to Delay" deal with generic drug manufacturer Ranbaxy to keep generic competition from entering the marketplace. These agreements have recently been found by the United States Supreme Court to be subject to antitrust regulatory scrutiny. *See* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (June 17, 2013). Litigation related to this agreement was recently remanded to state court in West Virginia.

28. Pfizer entered into an exclusive agreement with Watson Pharmaceuticals that allowed Watson to market and distribute an authorized generic version of Lipitor that launched at the same time as Ranbaxy's generic version of atorvastatin. In return, Watson allegedly gave approximately 70 percent of its atorvastatin-related profits to Pfizer, allowing Pfizer to protect some of the revenue it would have lost to Ranbaxy.

29. In 2011, Pfizer began heavily promoting a new discount program called "Lipitor For You" through advertisements, pamphlets distributed at doctors' offices, and a "Lipitor For You" website. The program offered privately insured patients a coupon card that let them purchase Lipitor for a $4 copayment, well below the average copayment for preferred brand-name drugs and even below the average copayment for generics. The program also provided options like direct delivery of the prescription at no additional cost and automatic reminders to refill Lipitor prescriptions.

30. Initially, Pfizer paid patients taking Lipitor up to $50 of the difference between the patient's new $4 copayment and their normal brand name copayment, up to an annual limit of $600. The program was set to end on June 30, 2012, when other generic versions were expected to enter the market. However, Pfizer has since extended and enhanced "Lipitor for You," now paying up to $75 of the difference between the patient's new $4 copayment and their normal brand-name copayment, with an annual limit of $1,000.

31. The "Lipitor for You" website also states that the coupon card and program will now expire on December 29, 2014, although "Pfizer reserves the right to rescind, revoke, or amend the program without notice at any time." Pfizer reported that more than 750,000 people have signed up for "Lipitor for You."

32. Pfizer was able to support programs like "Lipitor For You" because they raised prices for Lipitor after patent protection expired. In 2011, the year that Lipitor's patent expired, the average annual retail price change for Lipitor 20 mg tablets was 17.5 percent more than four times the average annual price increase from 2006 through 2009, and almost twice the average annual price increase from 2010. The 2012 retail price increase for Lipitor 20 mg tablets added an additional $201 to the average annual cost of therapy.

33. Pfizer's spending on direct-to-consumer advertising for Lipitor made it the prescription medicine most promoted to consumers in 2009 and 2010, with annual spending totals of $237 million and $250 million, respectively.

34. In contrast to the substantial drop in overall marketing spending that typically takes place during a drug's final year under patent, Pfizer kept its total marketing spending for Lipitor nearly level in the 12 months prior to patent expiration, spending $659 million.

35. Pfizer's worldwide Lipitor sales dropped from $9.6 billion in 2011 to $3.9 billion in 2012, and it has been estimated that Lipitor sales volumes will continue to decline over the next few years, dropping to just above $3 billion in 2015.

36. Despite the drop in volume, Pfizer's strategies have allowed Lipitor to become the bestselling drug by dollar volume in pharmaceutical history with an estimated $125 billion in sales since entering the market in 1997.

37. Notably, Pfizer has faced dozens of government investigations, private lawsuits, and regulatory oversight related to its promotional and pricing practices.

38. With regard to Lipitor, the FDA's Division of Drug Marketing, Advertising and Communication (DDMAC) sent Pfizer a warning or Notice of Violation letter on November 23, 1998. The letter informed Pfizer that DDMAC found the direct-to-consumer television

commercials for Lipitor were misleading in overstating effects and failing to use consumer friendly language. The letter also points out that DDMAC instructed Pfizer to discontinue the television ad on a conference call on November 21, 1998.

39. DDMAC sent another letter to Pfizer on July 12, 2001. The letter cited three specific violations of a journal ad placed by Pfizer for Lipitor. DDMAC found the ad promoted Lipitor for an unapproved use, lacked fair balance, and broadened indications.

40. A little more than one year later, on August 12, 2002, DDMAC issued another violation notice to Pfizer for certain direct-to-consumer ads which appeared in nationally distributed magazines like Time, Reader's Digest, and Good Housekeeping. DDMAC found that Pfizer's ad materially understated and misrepresented safety risks.

41. On August 31, 2011, DDMAC sent another notice to Pfizer for violative activity relating to Lipitor. DDMAC found that Pfizer's website which promoted Lipitor was misleading for failing to provide risk information about other products featured on the site.

42. In addition to the above warning letters, Pfizer has faced other regulatory scrutiny. Pfizer ultimately entered into a Corporate Integrity Agreement with the Office of Inspector General for Department of Health and Human services (OIJ-HHS) in 2002 relating to Lipitor. Pfizer entered into similar agreements in 2004 and 2009 for unlawful conduct relating to other products.

**Pill Splitting**

43. As early as 2002, articles and research began questioning why certain medications could not be physically split in order to save money on rapidly escalating health care expenses. In a November/December 2002 article in the Journal of Managed Care Pharmacy,[1] researchers found that "tablet splitting of HMGs had no short-term negative effects on laboratory outcomes

[1] www.amcp.org Vol. 8, No. 6 November/December 2002 JMCP Journal of Managed Care Pharmacy

and favorable effects on humanistic outcomes as measured by patient satisfaction and compliance. Tablet splitting of HMGs is an effective way to reduce costs and nearly double the number of patients who can be treated for the same expense."[2]

44. Atorvastatin calcium was specifically reviewed in the study and found to be a good candidate for splitting. Statin drugs are good candidates for splitting because the drug levels linger in the body for a relatively long time; therefore small dosage fluctuations as a result of the pill splitting do not make a major difference in reaching therapeutic levels. In addition, statins like Lipitor are not controlled release or delayed release formulations.

45. As part of its comprehensive marketing strategy, Pfizer indicated in its patient information and in numerous advertisements for Lipitor, "[d]on't break Lipitor tablets before taking." As an example, the May 2011 addition of Readers Digest magazine contained an advertisement for Lipitor. Under the heading "how to take Lipitor," it states "[d]o not break the tablet." It should be noted that Pfizer has continually pushed back when confronted with evidence that patients could split the Lipitor pills.

46. Pfizer provides patient information on Lipitor that states in part that patients should not split or break the tablet. However, this warning or direction is not based upon reliable scientific evidence.

47. The Pfizer Lipitor web site currently provides the following warning:

***"Take LIPITOR each day at any time of day at about the same time each day.***

***LIPITOR can be taken with or without food. Don't break LIPITOR tablets before taking."***

48. A Consumer Reports Shopper's guide to Prescription drugs[3] entitled "Pill Splitting" discussed the types of drugs that can be split and states, "most notably, all the

[2] HMGs or HMG-CoA is defined as 3 hydroxy-3 methylglutaryl-coenzyme A. HMG-CoA inhibitors are also known as statin drugs.

cholesterol-lowering drugs known as statins can be split as can many of the drugs used to treat high blood pressure and depression." The article on pill splitting listed several statins that could be safely split, including Lipitor (Atorvastatin), Pravachol (Pravastatin), Crestor (Rosuvastatin) and Zocor (Simvastatin).

49. Pfizer used a "flat pricing" strategy for Lipitor. This type of pricing keeps the higher doses at the same price or relatively close in cost. Flat pricing is used by drug manufacturers to better predict expenditures since the bulk of costs come from packaging, advertising, research and development. Pfizer knew that flat pricing would minimize price jumps if patients were changed to a higher dose while lessoning the chance they would switch to a competitor's less expensive brand.

50. Pfizer was also aware that the disadvantage of flat pricing is the tendency for the pills to be split since a higher dose can be purchased for relatively the same cost of the lower doses. The patient can get twice the amount of medicine by splitting a higher dose pill in half and providing as much as a 50% savings. For example, a Medicare patient prescribed a 20 mg dose of Lipitor daily can purchase a 30-day supply of 40 mg tablets and split them in half giving them a 60-day supply of medication for relatively half the cost.

51. Pill splitting results in reduced costs not only to consumers but to hospitals and other health care providers trying to manage increasing drug costs. Large managed-care companies like Kaiser Permanente and United Healthcare encourage pill-splitting programs for drugs like Lipitor. The Henry J. Kaiser Foundation estimated that someone who halves their dose of Lipitor could save close to $600 a year. United Healthcare members who split pills are only required to pay half the usual out-of-pocket co-payment for their medications; a typical $25 co-payment drops to $12.50.

[3] Consumer Reports Best Buy Drugs www.CRBestBuyDrugs.org

52. Pfizer knew that pill splitting was common for flat priced drugs and employed tactics to counteract this trend. Pfizer developed a strong warning in the consumer package insert and in their ads stating, among their other warnings, "[d]on't break Lipitor tablets before taking" implying that there was some adverse effect or serious consequence if this was done.

53. Pfizer knew the tablets could be safely split without any adverse effect. The "do not split" warning was not provided in the physician and health care prescribing information.[4] If there had been a potential health or safety threat advising against splitting the tablets, this warning statement would have been carried over to the medical community.

54. Pfizer's decision to advertise the warning only in their consumer literature reinforces their concern that patients would be more apt to split the pills as a way to cut costs, especially when Lipitor would become one of the most expensive statins on the market.

55. Pfizer persuaded doctors to prescribe higher and more expensive doses of Lipitor. Pfizer funded two studies on the use of maximum strength (80 mg) Lipitor. These studies showed that by increasing a patient's dose from the standard 10 mg to the maximum 80 mg it reduced the number of deaths associated with heart attacks and strokes. This information was treated by Pfizer as a medical breakthrough. They aggressively marketed physicians to prescribe the maximum and most expensive dose of Lipitor.

56. The effect of this campaign increased Pfizer's 2006-second quarter revenue by 2% to $3.1 billion and by June the number of patients taking the highest doses of Lipitor increased by more than 10% compared with the previous month of May.[5]

57. While Pfizer capitalized on the favorable reports and profits over some of the study findings, they failed to proceed with caution in pushing the larger doses knowing that these

[4] http://labeling.pfizer.com/ShowLabeling.aspx?id=587

[5] *Bloomberg*. "Pfizer Lifts Lipitor Revenue by Promoting Larger, Pricier Doses." Pettypiece, Sharon. August 23, 2006. www.bloomberg.com/apps/news?pid=20601086&sid=aU0FKY3RaHIM&refer=news.

studies also showed that those patients on the higher doses were at increased risk for serious side effects and at an increased risk of death due to other causes when compared to those patients on the lower dose. Pfizer decided to focus on the part of the study that was favorable for their profits despite concerns in the medical community over its safety and efficacy.

58. The actual motive to move patients to the highest available dose was an intent to prevent or offset pill splitting. Patients who are prescribed 80mg per day have no higher dose pill available to split.

59. Through the deceptive marketing practices of Defendant, healthcare consumers were intentionally subjected to misleading advertising campaigns and patient safety warnings which scared them into not breaking their pills or taking a dose which could not be split.

**Relator's Experience**

60. Acting through Mr. Mueller's experience as a pharmacist, Relator has provided assistance and counseling to the neediest members of society. HSA became the voice of the people in pharmacy matters and continually strived to reduce the cost of medications so that he could improve people's lives.

61. During the past 14 years, HSA provided contract services to multiple federal, county and city agencies. HSA entered into several contracts to provide pharmacist services on Indian reservations in Nevada, to include the Pyramid Lake Indian Reservation, the Fallon Indian Reservation, the Walker River Indian Reservation, the Yerington Indian Reservation and the Washoe Indian Reservation.

62. HSA's work on the Indian Reservations included processing and filling prescriptions, patient counseling and order and inventory control. Lipitor was not usually carried

by the various pharmacies on the Indian Reservations due to the high costs and price structuring of Lipitor.

63. Pfizer's pricing and mandate of "do not break pills" eliminated any chance that a customer on the Indian Reservation could use Lipitor. Relator found that similar statins on the market such as Mevacor (Lovastatin) and Zocor (Simvastatin) were being utilized due to their pricing structure and the ability to break the tablet in two, thereby reducing the cost by half for the customer.

64. Relator contracted with the Pinellas County Health Department to provide pharmacist services in clinics in St. Petersburg and Clearwater, Florida. These services included dispensing medication, patient counseling, inventory control and purchasing. Relator's goal was to provide affordable prescription medication, including discounted generic medicines as well as providing brand name (and usually expensive) drugs to needy persons for a minimal monthly fee.

65. In 2005, Relator established a non-profit pharmacy called Rx Meds Support (Rx Meds). Rx Meds was set up to serve the indigent population as well as the uninsured and underinsured. Relator was aware that many insurance plans offered a $5.00 co-pay for a one month supply of most generic medications.

66. Relator wanted to provide uninsured customers the same deal on generic medications at approximately the same cost. Rx Meds was able to provide more than 120 generic medications for chronic diseases such as high blood pressure, diabetes, cholesterol and lipid control, arthritis and chronic pain, depression and anxiety, glaucoma, eczema and psoriasis and breast cancer. Rx Meds was able to offer these drugs at a cost from $12.60 to $14.60 for up

to a three month supply. Relator's main goal in establishing the pharmacy and pricing structure was to inform the consumer that these drugs could be purchased at reduced costs.

67. In 2007, Relator contracted with Seaborn, a private government staffing company, to provide pharmacist services to a Veterans Administration clinic in New Port Richey, Florida. Relator operated in conjunction with the clinic for nearly six years. During this time they processed, checked and verified hundreds of thousands of prescriptions to include narcotics and other maintenance drugs for Veterans. Lipitor was not frequently used by the Veterans Administration due to its high cost even though Lipitor was fast becoming the most popular drug in America.

68. HSA was frequently asked by Patients why they could not split or break Lipitor. The patients would read the patient literature handout that comes with Lipitor and also see it in advertising. Relator had difficulty answering the patient's questions because the professional literature that was provided to doctors and pharmacists did not speak to not breaking the Lipitor tablet.

69. HSA did its own independent research by comparing different statins that were on the market. HSA looked especially at Zocor by Merck, since its dosing, tablet size and shape and mechanism of action were similar to Lipitor. Merck did not mention any instructions to patients or medical professional about breaking or splitting the tablets. HSA found this to be confusing to its President, Mr. Mueller, and to other professionals as well since Pfizer was so emphatic about it in their Lipitor Patient Information but not in their professional information. HSA could find no research related to the "do not break" policy.

70. Relator found that the Veterans Administration had a nationwide policy and procedure to split or break pills whenever possible and in fact, had a policy to give patients a

tablet cutter whenever requested. Relator found that patients were afraid to split their Lipitor pills due to the warnings and directions from Pfizer.

71. Pfizer's insistence on requiring patients to not break or split Lipitor pills went against everything Relator was trying to achieve. Relator and Mr. Mueller have spent more than a dozen years attempting to reduce the costs of prescription medication, both generic and brand name.

**Government Purchases**

72. Medicare Part D[6] beneficiaries filled approximately 870 million prescriptions in 2010 and Medicaid prescriptions increased to approximately 337 million in 2010. Patients with Medicare Part D or Medicaid coverage filled approximately 30% of all prescriptions in 2010 compared to approximately 22% in 2006, the first year of the Part D program.[7]

73. Between 2007 and 2010 approximately 43% of Medicare beneficiaries in the Part D program have been prescribed statin drugs. This has amounted to Medicare spending $6.7 billion on statins in 2010 alone.

74. The damage caused by Pfizer's misleading marketing campaign and its manipulation of patient information for Lipitor has cost government sponsored health care programs and consumers billions of dollars over the last decade. Pfizer's aggressive attitude to increase sales and market share resulted in unprecedented profits at the expense of the entire health care system. The Centers for Disease Control (CDC) reported in 2011 that Medicare prescriptions for statin drugs totaled 113 million in 2008, 126 million in 2009 and 136 million in 2010. Estimated losses to Medicare due to not splitting Lipitor were nearly $1.4 billion for each year.

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[6] Medicare Part D is a federal prescription drug program offered to Medicare eligible beneficiaries enacted 1 January 2006 as part of the Medicare Modernization Act of 2003 (MMA).

[7] Source is IMS Institute for Healthcare Informatics.

**Regulatory Framework**

75. After a drug like Lipitor is approved, the FDA continues to exercise control over the product labeling and marketing. FDA regulations restrict how drug companies may market and promote approved drugs. FDA regulations prohibit manufacturers from making false and misleading statements about a drug's use. See 21 U.S.C. §§ 331, 352; and 21 C.F.R. § 314.81.

76. Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. See 21 U.S.C. §§ 331, 352.

77. The same requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. Promotional materials may only make claims that are supported by "substantial" scientific evidence and they may not be false or misleading. federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as to the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

78. The law prohibits drug manufacturers from marketing or promoting a drug for a use or patient group that 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. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a), prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to

include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product." Id.

79. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below. Id. Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See* 21 C.F.R. 202.1(e)(6)(xi); *see also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); Id. §331(a) (prohibiting distribution of a misbranded drug); Id. § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

80. FDA regulations ban advertisements that are false, lacking in fair balance, or otherwise misleading. The use of unsubstantiated comparative claims is also prohibited by law. See 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Pfizer may not promote, or as in the instant matter discourage, use of their approved drugs through unsubstantiated methods of delivery or consumption. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by federal Programs, including Medicaid.

81. Regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications, and effectiveness of the drug use. See 21 C.F.R. 202.1(e)(5), et seq. A Company violates this regulation if it presents "false or misleading"

information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. Id. Section 202.1(1)-(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer, or distributor of the drug. 21 C.F.R. 202.1(1)-(2)

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

83. FDA approved drugs are "misbranded" if their labeling does not bear "adequate directions for use." Specifically, 21 U.S.C. §352(f)(1) provides that a drug is misbranded "[u]nless its labeling bears: (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

84. "Adequate directions for use" of drugs are defined in 21 CFR § 201.5 as:

> "directions under which the layman can use a drug safely and for the purposes for which it is intended. Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

> **(a)** Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.
>
> **(b)** Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.
>
> **(c)** Frequency of administration or application.
>
> **(d)** Duration of administration or application.
>
> **(e)** Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).
>
> **(f)** Route or method of administration or application.
>
> **(g)** Preparation for use, i.e., shaking, dilution, adjustment of temperature, or, other manipulation or process.

85. "Intended use" "may change" if "the article is offered and used for a purpose for which it is n[ot] labeled." Id. Intended use is defined in 21 CFR § 201.128 as:

> Meaning of "intended uses":
> The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those

> intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

**Pfizer's Internal Compliance**

86. Pfizer has a set of healthcare law compliance codes it calls the White Guide[8]. The White Guide contains standards or requirements for the company to meet in promoting its products. Among their requirements for promotion of their drugs are the below five core principles:

- All claims must be consistent with product labeling;
- All claims must be supported by substantial evidence;
- All claims must be truthful and not misleading;
- All claims must appropriately balance the benefits of the product with its risks;
- All promotional materials must be approved through Review Committee (RC).

87. In addition to the five core principles contained in the White Guide, Pfizer also specifically promises to abide by PhRMA's[9] Guiding DTC Principles. The PhRMA principles seek to ensure that DTC communications educate patients and consumers and encourage them to seek guidance from their healthcare professionals. All Pfizer DTC materials must be consistent with this guidance. In the event of any inconsistency, the Pfizer guidance takes priority over the PhRMA Principles.

[8] Pfizer's White Guide is available at http://www.pfizer.com/files/corporate_citizenship/whiteguide.pdf

[9] PhRMA stands for the Pharmaceutical Research & Manufacturers of America whose mission is among things, to ensure transparent, effective regulation and a free flow of information to patients.

88. Pfizer's labeling and marketing is in violation of their own core principles as well as PhRMA's principles and FDA regulations. See 21 U.S.C. 352.

89. Pfizer has a long history of using misleading tactics and false claims requiring government intervention. As discussed above, the FDA has sent numerous warning letters to Pfizer regarding their false claims and overly aggressive marketing campaigns. HHS has requested they stop running ads misleading consumers regarding off label promotions, such as advertising that Lipitor will reduce the risk of developing coronary heart disease (CHD) when this has never been proven, claiming that Lipitor is safer than other statins and minimizing the known serious side effects of taking Lipitor.

## I. Medicare

90. Medicare is a federally funded program, 42 U.S.C. §1395 et seq., which provides medical care based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426A.

91. Overall responsibility for the administration of Medicare, as authorized by 42 U.S.C. §1395, et seq., (hereafter "Social Security Act or SSA"), resides with the Secretary of the Department of Health and Human Services (hereafter "HHS").

92. Within HHS, the responsibility for administration of the Medicare program has been delegated to the Centers for Medicare and Medicaid Services (hereafter "CMS"). Medicare provides prescription drug coverage through a program known as Medicare Part D. The pharmacies where Lipitor prescriptions get filled agree to provide pharmaceuticals to Medicare Part D Plans ("PDPs") for Medicare patients that they serve, and the PDPs in turn reimburse these pharmacies for the cost of the Pfizer drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicare patients. PDPs are administered

under contract with CMS by private entities such as Blue Cross Blue Shield plans, large commercial insurers such as Humana, and pharmacy benefit managers.

93. Every time a beneficiary fills a prescription covered under Part D, PDPs must submit a summary called the prescription drug event, or PDE record. The PDE record contains drug cost and payment data that enable CMS to administer the Part D benefit. CMS uses the PDE record to calculate reimbursement to PDPs for the cost of the Pfizer drugs, plus an amount meant to provide the PDPs with a profit for administering the PDP.

94. CMS reimbursement to PDPs pursuant to the PDE overstated the amount of federal funds to which PDPs were entitled by the amount fraudulently paid as a result of off-label prescriptions for Lipitor. They were, therefore, false records or statements caused to be made or used to get false claims paid and approved by the United States. The claims for reimbursement submitted by the pharmacies to PDPs, which in turn caused the PDPs to submit these claims for reimbursement to the federal government, constituted false claims as a result of the claims for reimbursement for prescriptions tainted by false and misleading promotional claims.

95. Government programs including Medicare and Medicaid require that pharmaceutical manufacturers comply with the relevant laws and regulations in promoting their drugs in order for those drugs to be eligible for reimbursement. The Medicare CMS Form 855, which providers must sign to be eligible to bill Medicare, states that: "I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions...."

96. Pfizer's false, misleading, and unsubstantiated promotions caused health care professionals to prescribe Lipitor, and in turn pharmacies to submit claims to Government

Programs for payment of those misbranded drugs. Because claims for payment of Pfizer's misbranded drugs were ineligible for reimbursement by Government Programs, these claims were false within the meaning the federal False Claims Act and State analogues, and Government Programs would not have reimbursed for these claims if they knew that they had resulted from Pfizer's false, misleading, and unsubstantiated promotions.

97. Pfizer's false, misleading, and unsubstantiated promotions therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs. Pfizer engaged in this illegal promotion knowingly and with the intent to cause the submission of false claims to Government Programs. Government Programs paid reimbursements for the resulting false claims, and as a result have incurred and continue to incur significant damages due to Pfizer's illegal promotion of its drugs. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Pfizer also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims.

## II. Medicaid

98. In 1965, Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program for the needy and the medically needy aged, blind, disabled, and families with dependent children. 42 U.S.C. §§ 1396-1396v. This became known as the "Medicaid Program." The Medicaid Program is funded by both federal and State monies, collectively referred to as "Medicaid Funds," with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b).

99. Each State is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the Department of Health and Human Services ("HHS").

Among other forms of medical assistance, the States are permitted to provide medical assistance from the Medicaid Funds to eligible persons for outpatient prescription drugs. 42 U.S.C. §1396a(10) (A); 1396d(a) (12). HHS is an agency of the United States and is responsible for the administration, supervision and funding of the federal Medicaid Program. The Centers for Medicare & Medicaid Services ("CMS") is the division of HHS that is directly responsible for administering the federal Medicaid Program. Prior to 2001, CMS was known as the Health Care Finance Administration, or "HCFA."

100. The pharmacies where the Pfizer drugs are filled agree to provide pharmaceuticals to the patients served by the States' Medicaid programs, and the States in turn reimburse these pharmacies for the cost of the Pfizer drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicaid patients.

101. The pharmacies submit their Medicaid claims for reimbursement by "batching them" daily, and submitting them electronically to the States. As part of each electronic claim, the pharmacies affix their unique Medicaid provider identification numbers, which serve as electronic stamps indicating that (as Medicaid providers) they are in compliance with all applicable federal and state laws.

102. The pharmacies are reimbursed on a monthly basis by the States for all approved claims. The States are not financially responsible for paying 100% of the pharmacies' claims for reimbursement. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups, primarily low-income and disabled persons.

103. The federal government provides matching funds and ensures that the states comply with minimum standards in the administration of the program. The federal share of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is

based on each individual state's per capita income compared to the national average. Among the states, the FMAP is at least 50%, and in some instances, as high as 77%. Through the FMAP process, State Medicaid administrators obtain the federal government's share of the pharmacies' reimbursements by submitting a quarterly Form 64 to CMS. For this reason, claims submitted to state Medicaid agencies are presented to the federal government within the meaning of the FCA.

104. The federal government in turn pays Medicaid claims through a continuing line of credit certified by the Secretary of the Treasury in favor of the state payee. 42 C.F.R. § 430.30(d)(3), (4).

105. The federal government authorizes the state payee "to draw federal funds as needed to pay the federal share of disbursements." 42 C.F.R. § 430.30(d)(3). The states can draw down on those funds only to pay the Medicaid claims of healthcare providers. 42 C.F.R. § 430.30(d).

106. The funds made available to the state thus remain federal funds, in a Federal Reserve account, until they are drawn by the state and used to pay the pharmacies' claims. The federal government also "approves" within the meaning of the FCA the claims submitted and paid through the Medicaid program.

107. When a state presents its Form 64 to CMS, the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were appropriate. If CMS determines that certain claims paid by the state were improper, CMS may recoup the amount of the erroneously expended funds by reducing the amount of money provided to the state during the next quarter.

108. Because the Form 64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state, these reports overstated the amount of federal funds to which the state was entitled by the amount fraudulently paid as a result of the deceptive marketing campaign undertaken by Pfizer to keep patients from splitting their pills. They were, therefore, false records or statements caused to be made or used to get false claims paid and approved by the United States.

109. The claims for reimbursement submitted by the pharmacies to the States, which in turn caused the States to submit these claims for reimbursement to the federal government pursuant to FMAP, constituted false claims as a result of the claims for reimbursement for prescriptions and tainted by false and misleading promotions.

110. Any provider who submits claims to Medicaid must sign a provider agreement with each Medicaid program to which it submits claims. For example, Massachusetts regulation 130 CMR 450.261 provides: "All members and providers must comply with all federal and state laws and regulations prohibiting fraudulent acts and false reporting...."

111. Pfizer used false, misleading, and unsubstantiated promotions to deter patients from splitting their Lipitor pills and in doing so it misbranded those drugs under 21 U.S.C. 352, making them ineligible for reimbursement by Government Programs.

## III. Other Federally-Funded Health Care Programs

112. Although false claims to Medicare are the primary FCA violations at issue in this case, the patients who were misled and overspent on their medications were actually beneficiaries of one of four federally-funded health care benefit programs – Medicare, Medicaid (discussed above), TRICARE/CHAMPUS, and the FEHBP.

## IV. TRICARE, formerly known as CHAMPUS

113. Tricare is a federal program established by 10 U.S.C. §§ 1071-1110 that provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents. Although TRICARE is administered by the Secretary of Defense, the regulatory authority establishing the TRICARE program provides reimbursement to individual health care providers applying the same reimbursement requirements and coding parameters that the Medicare program applies. 10 U.S.C. §§ 1079(j)(2) (institutional providers), (h)(1) (individual health care professionals) (citing 42 U.S.C. § 1395, et seq.). Like Medicare and Medicaid, TRICARE will pay only for "medically necessary services and supplies required in the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1)(i).

114. Participants in TRICARE were subject to the deceptive messaging and promotion by Pfizer as more fully described herein. The patients who received and filled and later sought reimbursement for or coverage from TRICARE for Lipitor prescriptions relied upon the misrepresentations made by Pfizer.

## V. CHAMPVA

115. CHAMPVA is another federal program which provides health care benefits to eligible beneficiaries, which include, among others, the children, spouses and widow(er)s of service members who are otherwise not eligible for TRICARE.

116. False claims submitted to CHAMPVA are subject to the federal False Claims Act.

117. Participants in CHAMPVA were subject to the deceptive messaging and promotion by Pfizer as more fully described herein. The patients who received and filled and

later sought reimbursement for or coverage from CHAMPVA for Lipitor prescriptions relied upon the misrepresentations made by Pfizer.

## VI. Federal Employees Health Benefit Program (FEHBP)

118. The federal Employees Health Benefit Program is a government administered health care insurance program for employees of the federal government. It contains numerous coverage options similar to private health insurance.

119. False claims submitted to the agents or third party contractors of the FEHBP are subject to the False Claims Act.

120. Participants in the FEHBP were subject to the deceptive messaging and promotion by Pfizer as more fully described herein. The patients who received and filled and later sought reimbursement for or coverage from the FEHBP for Lipitor prescriptions relied upon the misrepresentations made by Pfizer.

## V. THE FALSE CLAIMS ACT

121. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, inter alia, knowingly submitting or causing the submission of false or fraudulent claims for payment to the United States Government and for making or using false statements material to false or fraudulent claims paid by the United States. 31 U.S.C. §§ 3729(a)(1)(B) (West 2012). The FCA provides, in pertinent part, that:

> (a)(1) any person who – (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

> (b) For purposes of this section, (1) the terms "knowing" and "knowingly" mean – (A) that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud . . . .31 U.S.C. §3729 (West 2012).

122. The standard of proof under the FCA is preponderance of the evidence. 31 U.S.C. §3731(d).

## VI. CLAIMS FOR RELIEF

### FIRST CAUSE OF ACTION
### (False Claims Act: Presentation of False Claims)
### (31 U.S.C. §3729(a)(1)(a))

123. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 122 of this Complaint as if fully set forth herein.

124. This Count is brought by Plaintiffs-Relator in the name of the United States against the Defendants for Defendants' violation of 31 U.S.C. § 3729(a)(1).

125. Defendant knowingly presented, or caused to be presented, the false or fraudulent claims for payment or approval that have been set forth in the Complaint herein.

126. Plaintiff United States, unaware of the falsity of the claims and/or statements which Defendant caused doctors, pharmacists, other health care providers and consumers to make to the United States, and in reliance on the accuracy thereof, paid claims that would otherwise not have been allowed.

127. The amounts of the false or fraudulent claims to the United States were material.

128. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy thereof, paid and may continue to pay Defendant for the prescription drug Lipitor that otherwise should not have been paid under

the Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the federal Health Benefit Program, and other federal health care programs.

129. The United States directly and vis-à-vis the state Medicaid programs, has been damaged by the payment of false or fraudulent claims.

130. Pfizer knowingly presented physicians, pharmacists and consumers with false information regarding the safety and efficacy of splitting Lipitor. Pfizer's actions rendered Lipitor misbranded.

131. As a result, Pfizer knowingly caused the submission of false claims for payment by Government payors. Pfizer's actions were in violation of the False Claims Act, 31 U.S.C. ¶¶ 3729-3733.

132. The United States made payment on these false or fraudulent claims. Had the United States known that Pfizer was knowingly causing physicians, pharmacists and consumers to submit such false claims for payment, the United States would not have provided reimbursement for such prescriptions under Government payor programs.

133. As a result, the United States has suffered and continues to suffer substantial damage.

**SECOND CAUSE OF ACTION**
(False Claims Act: Making or Using False
Record Statement to Cause Claim to be Paid)
(31 .S.C. §3729(a)(1)(B))

134. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 122 of this Complaint as if fully set forth herein.

135. As particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendant PFIZER knowingly made or used false records or statements (a) to get false or fraudulent claims paid or approved by the Government, or (b) material to false or fraudulent

claims, in violation of 31 U.S.C. §3729(a). The false records or statements included, but were not limited to, Pfizer's deceptive promotional practices and misbranding of products which caused healthcare providers, pharmacists and consumers to submit false claims to federal and state healthcare programs for payment or approval.

136. By virtue of the false records or statements Defendant made or caused to be made, the United States Government has suffered substantial monetary damages.

**TRIAL BY JURY**

Relator hereby demands a trial by jury as to all issues.

Dated this 9th day of August, 2013.

Respectfully submitted,

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